FEDERAL REGISTER

Vol. 82 Tuesday,

No. 1 January 3, 2017

Book 1 of 2 Books

Pages 1–178

OFFICE OF THE FEDERAL REGISTER

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402 is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

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Contents

Federal Register

Vol. 82, No. 1

Tuesday, January 3, 2017

Agency for Toxic Substances and Disease Registry
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 124–128

Centers for Medicare & Medicaid Services
RULES
Medicaid and Children's Health Insurance Programs:
Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability; Correction, 37–40
Medicare Program:
Advancing Care Coordination through Episode Payment Models; Cardiac Rehabilitation Incentive Payment Model; Changes to the Comprehensive Care for Joint Replacement Model, 180–651
Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; etc., 24–37

Coast Guard
RULES
Safety Zones:
Lower Mississippi River, Natchez, MS, 20–22

Commerce Department
See International Trade Administration
See National Institute of Standards and Technology
See National Oceanic and Atmospheric Administration
PROPOSED RULES
Public Information, Freedom of Information Act and Privacy Act Regulations, 56–59

Consumer Product Safety Commission
PROPOSED RULES
Procedures for Disclosure or Production of Information under the Freedom of Information Act; Amendments, 59–67

Copyright Royalty Board
NOTICES
Rates and Terms; Determinations:
Making Ephemeral Copies of Sound Recordings for Transmission to Business Establishments (Business Establishments III), 143–144

Education Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Lender's Request for Payment of Interest and Special Allowance, 106
Student Assistance General Provisions—Satisfactory Academic Progress Policy, 107–108
Applications for New Awards:
Personnel Development to Improve Services and Results for Children with Disabilities—Interdisciplinary Preparation in Special Education, Early Intervention, and Related Services for Personnel Serving Children with Disabilities who have High-Intensity Needs, 95–106
National Advisory Committee on Institutional Quality and Integrity Membership, 106–107

Energy Department
See Federal Energy Regulatory Commission
NOTICES
Meetings:
Environmental Management Site-Specific Advisory Board, Nevada, 109
Environmental Management Site-Specific Advisory Board, Northern New Mexico, 110
Environmental Management Site-Specific Advisory Board, Oak Ridge Reservation, 108–109
Environmental Management Site-Specific Advisory Board, Paducah, 111
Environmental Management Site-Specific Advisory Board, Portsmouth, 109–110
Environmental Management Site-Specific Advisory Board, Savannah River Site, 110–111
Fusion Energy Sciences Advisory Committee, 108

Environmental Protection Agency
RULES
Air Quality State Implementation Plans; Approvals and Promulgations:
Extension of Deadline for Action on the November 2016 Section 126 Petition From Maryland, 22–24
PROPOSED RULES
Significant New Use Rule on Certain Chemical Substances; Reopening of Comment Period, 80–81
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 115–116
Human Health Mitigation Decision:
Paraquat Dichloride, 118
Meetings:
Board of Scientific Counselors Executive Committee, 118–119
Pesticide Product Registrations:
Applications for New Active Ingredients, 113–114
Applications for New Uses, 114–115
Proposed Consent Decrees, Clean Air Act Citizen Suits, 116–118

Equal Employment Opportunity Commission
RULES
Affirmative Action for Individuals with Disabilities in Federal Employment, 654–681

Federal Aviation Administration
RULES
Airworthiness Directives:
Airbus Airplanes, 12–15
BAE Systems (Operations) Limited Airplanes, 7–10
Bombardier, Inc. Airplanes, 10–12
The Boeing Co. Airplanes, 5–7
PROPOSED RULES
Airworthiness Directives:
Airbus Airplanes, 50–52
CFE Company Turbofan Engines, 52–54
Piper Aircraft, Inc. Airplanes, 48–50
The Boeing Company Airplanes, 54–56

Federal Emergency Management Agency
RULES
Updated Public Assistance and Fire Management Assistance Grant Regulations—Terminology of Uniform Administrative Requirements, Cost Principles, and Audit Requirements, 40–44

Federal Energy Regulatory Commission
NOTICES
Combined Filings, 111–113

Federal Maritime Commission
RULES
Rules of Practice and Procedure; Presentation of Evidence in Commission Proceedings; Correction, 46

Federal Mine Safety and Health Review Commission
NOTICES
Meetings; Sunshine Act, 119–120

Federal Trade Commission
NOTICES
Proposed Consent Agreements:
Abbott Laboratories and St. Jude Medical, Inc., 120–122

Food and Drug Administration
NOTICES
Guidance for Industry:
Labeling of Red Blood Cell Units with Historical Antigen Typing Results, 130–132
Guidance:
Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act, 129–130
Premarket Notification Submissions for Bone Anchors, 128–129

Foreign Assets Control Office
NOTICES
Blocking or Unblocking of Persons and Properties, 176–177

General Services Administration
RULES
General Services Administration Acquisition Regulations:
Update Contract Reporting Responsibilities, 46–47
NOTICES
Federal Management Regulations:
Transportation Prepayment Audit Requirements, 122

Government Ethics Office
NOTICES
Application of the Criminal Conflict of Interest Prohibition to Certain Beneficial Interests in Discretionary Trusts; Request for Public Input, 122–124

Health and Human Services Department
See Agency for Toxic Substances and Disease Registry
See Centers for Medicare & Medicaid Services
See Food and Drug Administration
See National Institutes of Health
See Substance Abuse and Mental Health Services Administration

Homeland Security Department
See Coast Guard
See Federal Emergency Management Agency

Housing and Urban Development Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Public Housing Capital Fund Program, 135–136

Interior Department
See Reclamation Bureau

International Trade Administration
NOTICES
Antidumping or Countervailing Duty Investigations, Orders, or Reviews:
Calcium Hypochlorite from the People's Republic of China, 83–84
Fresh Garlic from the People's Republic of China, 82–83
Initiation of Five-Year (Sunset) Reviews, 84–85

International Trade Commission
NOTICES
Antidumping or Countervailing Duty Investigations, Orders, or Reviews:
Furfuryl Alcohol from China; Institution of a Five-Year Review, 140–143
Light-Walled Rectangular Pipe and Tube from Taiwan; Institution of a Five-Year Review, 137–140
Investigations; Determinations, Modifications, and Rulings, etc.:
Stainless Steel Plate from Belgium, South Africa, and Taiwan, 140

Judicial Conference of the United States
NOTICES
Meetings:
Hearings of the Judicial Conference Advisory Committee on the Federal Rules of Bankruptcy Procedure; Cancellation, 143

Library of Congress
See Copyright Royalty Board

National Endowment for the Humanities
RULES
Regulations Implementing the FOIA Improvement Act of 2016, 44–46

National Foundation on the Arts and the Humanities
See National Endowment for the Humanities

National Highway Traffic Safety Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 175–176

National Institute of Standards and Technology
NOTICES
Meetings:
Visiting Committee on Advanced Technology, 92–93
Requests for Nominations:
National Institute of Standards and Technology Federal Advisory Committees, 85–92

National Institutes of Health
NOTICES
Meetings:
National Cancer Institute, 133
National Heart, Lung, and Blood Institute, 133
National Institute on Aging, 134

Prospective Grants of Exclusive Patent Licenses:
Development, Manufacture and Commercialization of Gene Therapy Products for Human Gene Therapy Use to Treat and/or Prevent Methylmalonic Acidemia, 132–133

National Oceanic and Atmospheric Administration
PROPOSED RULES
Takes of Marine Mammals Incidental to Waterfront Construction:
Naval Submarine Base Kings Bay, GA,, 684–709
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
West Coast Region U.S.-Canada Albacore Treaty Reporting System, 93
Meetings:
Mid-Atlantic Fishery Management Council, 94
New England Fishery Management Council, 95
North Pacific Fishery Management Council, 94–95
Permit Applications:
Marine Mammals; File No. 20666, 93–94

Nuclear Regulatory Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Licensee Event Report; Correction, 153
Applications and Amendments Involving Proposed No Significant Hazards Considerations, etc., 145–151
Combined Licenses:
Duke Energy Carolinas, LLC, William States Lee III Nuclear Station Units 1 and 2, 144–145
Facility Operating and Combined Licenses:
Applications and Amendments Involving No Significant Hazards Considerations; Biweekly Notice, 154–164
Indemnity Agreements:
Duke Energy Carolinas, LLC, William States Lee III Nuclear Station Units 1 and 2, 154
License Applications; Renewals:
University of Maryland; Maryland University Training Reactor, 151–153

Postal Regulatory Commission
NOTICES
New Postal Products, 165–166
Rate Adjustments, 164–165

Postal Service
NOTICES
International Product Changes:
Inbound PRIME Tracked Service Agreement, 166

Presidential Documents
EXECUTIVE ORDERS
Defense and National Security:
Cyber-Enabled Activities; Taking Additional Steps to Address the National Emergency (EO 13757), 1–3

Reclamation Bureau
NOTICES
Environmental Impact Statements; Availability, etc.:
Columbia River System Operations; Extension of Public Comment Period, 137

Securities and Exchange Commission
NOTICES
Self-Regulatory Organizations; Proposed Rule Changes:
Chicago Board Options Exchange, Inc., 167–175

State Department
RULES
International Traffic in Arms:
International Trade Data System, Reporting, 15–19
NOTICES
Global Terrorist Designations:
Lashkar-e-Tayyiba, et al., 175

Substance Abuse and Mental Health Services Administration

NOTICES
Certified Laboratories and Instrumented Initial Testing Facilities:
List of Facilities that meet Minimum Standards to Engage in Urine Drug Testing for Federal Agencies, 134–135

Transportation Department
See Federal Aviation Administration
See National Highway Traffic Safety Administration

Treasury Department
See Foreign Assets Control Office
PROPOSED RULES
Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance, 67–80
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 177

Separate Parts In This Issue

Part II
Health and Human Services Department, Centers for Medicare & Medicaid Services, 180–651

Part III
Equal Employment Opportunity Commission, 654–681

Part IV
Commerce Department, National Oceanic and Atmospheric Administration, 684–709

Reader Aids
Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

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CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

3 CFR

Executive Orders:

13694 (amended by 13757) 1

13757 1

14 CFR

39 (4 documents) 5, 7, 10, 12

Proposed Rules:

39 (4 documents) 48, 50, 52, 54

15 CFR

Proposed Rules:

4 56

16 CFR

Proposed Rules:

1015 59

22 CFR

120 15

123 15

126 15

29 CFR

1614 654

31 CFR

Proposed Rules:

40 67

33 CFR

165 20

40 CFR

52 22

Proposed Rules:

721 80

42 CFR

414 24

416 24

419 24

431 37

433 37

438 37

440 37

457 37

482 24

486 24

488 24

495 (2 documents) 24, 37

510 180

512 180

44 CFR

204 40

206 40

207 40

45 CFR

1171 44

46 CFR

502 46

48 CFR

504 46

50 CFR

Proposed Rules:

217 684

Federal Register
Vol. 82, No. 1
Tuesday, January 3, 2017

Presidential Documents

Title 3—

The President

Executive Order 13757 of December 28, 2016

Taking Additional Steps to Address the National Emergency With Respect to Significant Malicious Cyber-Enabled Activities

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA), the National Emergencies Act (50 U.S.C. 1601 *et seq.*) (NEA), and section 301 of title 3, United States Code,

I, BARACK OBAMA, President of the United States of America, in order to take additional steps to deal with the national emergency with respect to significant malicious cyber-enabled activities declared in Executive Order 13694 of April 1, 2015, and in view of the increasing use of such activities to undermine democratic processes or institutions, hereby order:

Section 1. Section 1(a) of Executive Order 13694 is hereby amended to read as follows:

''Section 1. (a) All property and interests in property that are in the United States, that hereafter come within the United States, or that are or hereafter come within the possession or control of any United States person of the following persons are blocked and may not be transferred, paid, exported, withdrawn, or otherwise dealt in:

(i) the persons listed in the Annex to this order;

(ii) any person determined by the Secretary of the Treasury, in consultation with the Attorney General and the Secretary of State, to be responsible for or complicit in, or to have engaged in, directly or indirectly, cyber-enabled activities originating from, or directed by persons located, in whole or in substantial part, outside the United States that are reasonably likely to result in, or have materially contributed to, a significant threat to the national security, foreign policy, or economic health or financial stability of the United States and that have the purpose or effect of:

(A) harming, or otherwise significantly compromising the provision of services by, a computer or network of computers that support one or more entities in a critical infrastructure sector;

(B) significantly compromising the provision of services by one or more entities in a critical infrastructure sector;

(C) causing a significant disruption to the availability of a computer or network of computers;

(D) causing a significant misappropriation of funds or economic resources, trade secrets, personal identifiers, or financial information for commercial or competitive advantage or private financial gain; or

(E) tampering with, altering, or causing a misappropriation of information with the purpose or effect of interfering with or undermining election processes or institutions; and

(iii) any person determined by the Secretary of the Treasury, in consultation with the Attorney General and the Secretary of State:

(A) to be responsible for or complicit in, or to have engaged in, the receipt or use for commercial or competitive advantage or private financial gain, or by a commercial entity, outside the United States of trade secrets

misappropriated through cyber-enabled means, knowing they have been misappropriated, where the misappropriation of such trade secrets is reasonably likely to result in, or has materially contributed to, a significant threat to the national security, foreign policy, or economy of the United States;

(B) to have materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, any activity described in subsections (a)(ii) or (a)(iii)(A) of this section or any person whose property and interests in property are blocked pursuant to this order;

(C) to be owned or controlled by, or to have acted or purported to act for or on behalf of, directly or indirectly, any person whose property and interests in property are blocked pursuant to this order; or

(D) to have attempted to engage in any of the activities described in subsections (a)(ii) and (a)(iii)(A)–(C) of this section.''

Sec. 2. Executive Order 13694 is further amended by adding as an Annex to Executive Order 13694 the Annex to this order.

Sec. 3. Executive Order 13694 is further amended by redesignating section 10 as section 11 and adding a new section 10 to read as follows:

''Sec. 10. The Secretary of the Treasury, in consultation with the Attorney General and the Secretary of State, is hereby authorized to determine that circumstances no longer warrant the blocking of the property and interests in property of a person listed in the Annex to this order, and to take necessary action to give effect to that determination.''

Sec. 4. This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

Sec. 5. This order is effective at 12:01 a.m. eastern standard time on December 29, 2016.

THE WHITE HOUSE,

December 28, 2016.

Billing code 3295–F7–P

Annex

Entities

1. Main Intelligence Directorate (a.k.a. Glavnoe Razvedyvatel'noe Upravlenie) (a.k.a. GRU); Moscow, Russia
2. Federal Security Service (a.k.a. Federalnaya Sluzhba Bezopasnosti) (a.k.a FSB); Moscow, Russia
3. Special Technology Center (a.k.a. STLC, Ltd. Special Technology Center St. Petersburg); St. Petersburg, Russia
4. Zorsecurity (a.k.a. Esage Lab); Moscow, Russia
5. Autonomous Noncommercial Organization "Professional Association of Designers of Data Processing Systems" (a.k.a. ANO PO KSI); Moscow, Russia

Individuals

1. Igor Valentinovich Korobov; DOB Aug 3, 1956; nationality, Russian
2. Sergey Aleksandrovich Gizunov; DOB Oct 18, 1956; nationality, Russian
3. Igor Olegovich Kostyukov; DOB Feb 21, 1961; nationality, Russian
4. Vladimir Stepanovich Alexseyev; DOB Apr 24, 1961; nationality, Russian

[FR Doc. 2016–31922

Filed 12–30–16; 8:45 am]

Billing code 4811–33–C

Rules and Regulations

Federal Register

Vol. 82, No. 1

Tuesday, January 3, 2017

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–3698; Directorate Identifier 2015–NM–138–AD; Amendment 39–18733; AD 2016–25–07]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain The Boeing Company Model 767–200 and –300 series airplanes. This AD was prompted by an evaluation by the design approval holder (DAH) indicating that the aft pressure bulkhead is subject to widespread fatigue damage (WFD). This AD requires replacing the aft pressure bulkhead with a new, improved aft pressure bulkhead, and doing related investigative and corrective actions if necessary. We are issuing this AD to prevent the unsafe condition on these products.

DATES: This AD is effective February 7, 2017.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of February 7, 2017.

ADDRESSES: For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740; telephone 562–797–1717; Internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–3698.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–3698; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Wayne Lockett, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6447; fax: 425–917–6590; email: *wayne.lockett@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model 767–200 and –300 series airplanes. The NPRM published in the **Federal Register** on February 22, 2016 (81 FR 8668) (''the NPRM''). The NPRM was prompted by an evaluation by the DAH indicating that the aft pressure bulkhead at Station 1582 is subject to WFD. The NPRM proposed to require replacing the aft pressure bulkhead with a new, improved aft pressure bulkhead, and doing related investigative and corrective actions if necessary. We are issuing this AD to prevent fatigue cracking in the radial web lap splices of the aft pressure bulkhead. Such cracking could result in rapid decompression and consequent reduced structural integrity of the airplane.

Comments

We gave the public the opportunity to participate in developing this AD. We have considered the comments received. Boeing and United Airlines supported the NPRM.

Effect of Winglets on Accomplishment of the Proposed Actions

Aviation Partners Boeing stated that accomplishing the supplemental type certificate (STC) ST01920SE does not affect compliance with the actions specified in the NPRM.

We agree with the commenter. We have redesignated paragraph (c) of the proposed AD as (c)(1) and added paragraph (c)(2) to this AD to state that installation of STC ST01920SE does not affect the ability to accomplish the actions required by this final rule. Therefore, for airplanes on which STC ST01920SE is installed, a ''change in product'' alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

Changes To This AD

We have reviewed Boeing Alert Service Bulletin 767–53A0267, Revision 1, dated August 4, 2016, and there are no substantial changes. Therefore, we have included Boeing Alert Service Bulletin 767–53A0267, Revision 1, dated August 4, 2016, in paragraphs (c), (g), (h), and (i) of this AD. We have also provided credit in paragraph (j) of this AD for actions done prior to the effective date of this AD using Boeing Alert Service Bulletin 767–53A0267, dated August 13, 2015.

We have also revised paragraph (g) of this AD to clarify certain terminating actions.

Conclusion

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

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

We also determined that these changes will not increase the economic

burden on any operator or increase the scope of this AD.

Related Service Information Under 1 CFR part 51

We reviewed Boeing Alert Service Bulletin 767–53A0267, Revision 1, dated August 4, 2016. The service information describes procedures for replacing the aft pressure bulkhead at Station 1582 of Section 48 with a new, improved aft pressure bulkhead, including all applicable related investigative and corrective actions. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects 86 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replacement	1,541 work-hours × $85 per hour = $130,985	$646,889	$777,874	$66,897,164

We have received no definitive data that enables us to provide cost estimates for the on-condition investigative and corrective actions specified in this AD.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

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

(3) Will not affect intrastate aviation in Alaska, and

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2016–25–07 The Boeing Company: Amendment 39–18733; Docket No. FAA–2016–3698; Directorate Identifier 2015–NM–138–AD.

(a) Effective Date

This AD is effective February 7, 2017.

(b) Affected ADs

This AD affects the ADs specified in paragraphs (b)(1), (b)(2), and (b)(3) of this AD.

(1) AD 2004–05–16, Amendment 39–13511 (69 FR 10917, March 9, 2004).

(2) AD 2004–14–19, Amendment 39–13728 (69 FR 42549, July 16, 2004).

(3) AD 2009–06–19, Amendment 39–15856 (74 FR 12243, March 24, 2009).

(c) Applicability

(1) This AD applies to The Boeing Company Model 767–200 and –300 series airplanes, certificated in any category, as identified in Boeing Alert Service Bulletin 767–53A0267, Revision 1, dated August 4, 2016.

(2) Installation of Supplemental Type Certificate (STC) ST01920SE (*http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgSTC.nsf/0/38B606833BBD98B386257FAA00602538?OpenDocument&Highlight=st01920se*) does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST01920SE is installed, a ''change in product'' alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by an evaluation by the design approval holder (DAH) indicating that the aft pressure bulkhead at Station 1582 is subject to widespread fatigue damage (WFD). We are issuing this AD to prevent fatigue cracking in the radial web lap splices of the aft pressure bulkhead. Such cracking could result in rapid decompression and consequent reduced structural integrity of the airplane.

(f) Compliance

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

(g) Replacement, Related Investigative and Corrective Actions, and Terminating Actions

Before the accumulation of 60,000 total flight cycles, or within 36 months after the effective date of this AD, whichever occurs later, but not earlier than 37,500 total accumulated flight cycles: Replace the aft pressure bulkhead at Station 1582 of Section 48 with a new, improved aft pressure bulkhead, and perform all applicable related investigative and corrective actions, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 767–53A0267, Revision 1, dated August 4, 2016; except as required by paragraph (h) of this AD. Do all applicable related investigative and corrective actions before further flight. Accomplishing the replacement in this paragraph terminates all requirements of the ADs identified in paragraphs (g)(1), (g)(2), and (g)(3) of this AD.

(1) AD 2004–05–16, Amendment 39–13511 (69 FR 10917, March 9, 2004).

(2) AD 2004–14–19, Amendment 39–13728 (69 FR 42549, July 16, 2004).

(3) AD 2009–06–19, Amendment 39–15856 (74 FR 12243, March 24, 2009).

(h) Corrective Actions

If any defect (*e.g.,* rifling, gouging, nicks, or burrs, or excessive surface roughness) is found in any fastener hole (other than normally produced during a typical reaming operation), during accomplishment of any inspection (related investigative actions) required by this AD, and Boeing Alert Service Bulletin 767–53A0267, Revision 1, dated August 4, 2016, specifies to contact Boeing for repair instructions: Before further flight, repair in accordance with the procedures specified in paragraph (k) of this AD.

(i) Exception to the Service Information

Where Boeing Alert Service Bulletin 767–53A0267, Revision 1, dated August 4, 2016, specifies a compliance time ''after the original issue date of this service bulletin,'' this AD requires compliance within the specified time after the effective date of this AD.

(j) Credit for Previous Actions

This paragraph provides credit for the actions required by paragraphs (g) and (h) of this AD, if those actions were performed before the effective date of this AD using Boeing Alert Service Bulletin 767–53A0267, dated August 13, 2015; which is not incorporated by reference in this AD.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (l) of this AD. Information may be emailed to: *9–ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) Except as required by paragraph (h) of this AD: For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (k)(4)(i) and (k)(4)(ii) apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or sub-step is labeled ''RC Exempt,'' then the RC requirement is removed from that step or sub-step. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(l) Related Information

For more information about this AD, contact Wayne Lockett, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle ACO, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6447; fax: 425–917–6590; email: *wayne.lockett@faa.gov.*

(m) Material Incorporated by Reference

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

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

(i) Boeing Alert Service Bulletin 767–53A0267, Revision 1, dated August 4, 2016.

(ii) Reserved.

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740; telephone 562–797–1717; Internet *https://www.myboeingfleet.com.*

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

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

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

John P. Piccola, Jr.,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–29678 Filed 12–30–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–0457; Directorate Identifier 2015–NM–084–AD; Amendment 39–18751; AD 2016–25–25]

RIN 2120–AA64

Airworthiness Directives; BAE Systems (Operations) Limited Airplanes

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

ACTION: Final rule.

SUMMARY: We are superseding Airworthiness Directive (AD) 2012–11–15 for all BAE Systems (Operations) Limited Model 4101 airplanes. AD 2012–11–15 required a one-time detailed inspection for cracks, corrosion, and other defects of the rear face of the wing rear spar, and repair if necessary. This new AD requires repetitive detailed inspections, and repair if necessary. This AD was prompted by new reports of cracking found in the wing rear spar and technical analysis results, which confirmed that the crack initiation and propagation are due to fatigue, with no indication of any other crack initiation mechanism (*e.g.,* stress corrosion). We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective February 7, 2017.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of February 7, 2017.

ADDRESSES: For service information identified in this final rule, contact BAE Systems (Operations) Limited, Customer Information Department, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; telephone +44 1292 675207; fax +44 1292 675704; email *RApublications@baesystems.com;* Internet *http://www.baesystems.com/Businesses/RegionalAircraft/index.htm.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–0457.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–0457; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (telephone 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT:

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

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2012–11–15, Amendment 39–17079 (77 FR 36127, June 18, 2012) (''AD 2012–11–15''). AD 2012–11–15 applied to all BAE Systems (Operations) Limited Model 4101 airplanes. The NPRM published in the **Federal Register** on January 21, 2016 (81 FR 3350) (''the NPRM''). The NPRM was prompted by new reports of cracking found in the wing rear spar and technical analysis results, which confirmed that the crack initiation and propagation are due to fatigue, with no indication of any other crack initiation mechanism (*e.g.,* stress corrosion). The NPRM proposed to require a one-time detailed inspection for cracks, corrosion, and other defects of the rear face of the wing rear spar, and repair if necessary. The NPRM also proposed to require repetitive detailed inspections, and repair if necessary. We are issuing this AD to detect and correct cracking in the wing rear spar, which could propagate to a critical length, possibly affecting the structural integrity of the area and resulting in a fuel tank rupture, with consequent damage to the airplane and possible injury to its occupants.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2015–0100, dated June 3, 2015 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all BAE Systems (Operations) Limited Model 4101 airplanes. The MCAI states:

> During an investigation of a fuel leak on the rear spar of a Jetstream 4100 aeroplane, 4 cracks were found between Ribs 6 and 7 (immediately inboard of the inboard engine rib). The cracks initiated at adjacent fastener bores in the rear spar upper boom, and progressed downwards, diagonally, into the rear spar web.
>
> These cracks, if not detected and corrected, could propagate to a critical length, affecting the structural integrity of the area, possibly resulting in a fuel tank rupture with consequent damage to the aeroplane and injury to occupants.
>
> Prompted by these findings, EASA issued AD 2011–0096 [which corresponds to FAA AD 2012–11–15, Amendment 39–17079 (77 FR 36127, June 18, 2012)] to require a one-time [detailed] inspection [for cracks, corrosion, and other defects] of the rear face of the wing rear spar and the accomplishment of applicable corrective actions [*i.e.,* repair], depending on findings. Initial analysis of the event did not lead to the conclusion that the cracking was fatigue related, therefore [EASA] AD 2011–0096 did not require repetitive inspections.
>
> Since that [EASA] AD [2011–0096] was issued, the results of the technical analysis confirmed that the cracks were due to fatigue, with no indication of any other crack initiation mechanism (*e.g.* stress corrosion). In addition, further similar in-service events have been reported. During investigation of those events, further metallurgical analysis indicated that the crack initiation and propagation are indeed fatigue driven and occur at the same location.
>
> To address this unsafe condition, a review of the inspection interval was undertaken based on the cracks from both aeroplanes and BAE Systems (Operations) Ltd issued Service Bulletin (SB) J41–A57–029 Revision 3 in order to reduce the inspection interval of the wing rear spar from 2 000 flight cycles (FC) to 1 600 FC.
>
> For the reasons described above, this [EASA] AD supersedes [EASA] AD 2011–0096, without retaining its requirements, introduces repetitive inspections and, depending on findings, requires the accomplishments of applicable corrective action(s) [*i.e.,* repair].

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–0457.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM or on the determination of the cost to the public.

Explanation of Change in This AD

The NPRM incorrectly referred to Subject 57–00–00, Wings General, of Chapter 57, Wings, of the BAE Systems (Operations) Limited Jetstream Series 4100 Structural Repair Manual (SRM), Volume 1, Revision 32, dated October 15, 2014, for damage criteria and repair instructions. We have revised this final rule to refer to Chapter 57 of the SRM instead of Subject 57–00–00.

Conclusion

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

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

BAE Systems (Operations) Limited has issued Alert Service Bulletin J41–A57–029, Revision 3, dated April 8, 2014. The service information describes detailed inspections for cracks, corrosion, and other defects of the rear face of the wing rear spars.

BAE Systems (Operations) Limited also has issued Chapter 57, Wings, of the Jetstream Series 4100 SRM, Volume 1, Publication Ref. No. (Transmittal No.) SA 4–4100/SRM/400, Revision 32, dated October 15, 2014. Among other actions, Chapter 57 describes damage criteria and procedures for repairing the wing structure.

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

Costs of Compliance

We estimate that this AD affects 15 airplanes of U.S. registry.

We also estimate that it takes up to 25 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this AD on U.S. operators to be up to $31,875, or up to $2,125 per product.

We have received no definitive data that enables us to provide a cost estimate for the on-condition actions (repairing cracks, corrosion, and defects) specified in this AD.

Authority for This Rulemaking

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

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

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

Regulatory Findings

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2012–11–15, Amendment 39–17079 (77 FR 36127, June 18, 2012), and adding the following new AD:

2016–25–25 Bombardier: Amendment 39–18751; Docket No. FAA–2016–0457; Directorate Identifier 2015–NM–084–AD.

(a) Effective Date

This AD is effective February 7, 2017.

(b) Affected ADs

This AD replaces AD 2012–11–15, Amendment 39–17079 (77 FR 36127, June 18, 2012) (''AD 2012–11–15'').

(c) Applicability

This AD applies to BAE (Operations) Limited Model 4101 airplanes, certificated in any category, all models and all serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Reason

This AD was prompted by new reports of cracking found in the wing rear spar and technical analysis results, which confirmed that the crack initiation and propagation are due to fatigue, with no indication of any other crack initiation mechanism (*e.g.,* stress corrosion). We are issuing this AD to detect and correct cracking in the wing rear spar, which could propagate to a critical length, possibly affecting the structural integrity of the area and resulting in a fuel tank rupture, with consequent damage to the airplane and possible injury to its occupants.

(f) Compliance

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

(g) Repetitive Inspections and Repair

Within 30 days after the effective date of this AD, or within 1,600 flight cycles since the most recent detailed inspection was done as specified in BAE Systems Alert Service Bulletin J41–A57–029, whichever occurs later: Do a detailed inspection for cracks, corrosion, and other defects (defects include scratches, dents, holes, damage to fastener holes, or damage to surface protection and finish) of the rear face of the wing rear spars, in accordance with the Accomplishment Instructions of BAE Systems Alert Service Bulletin J41–A57–029, Revision 3, dated April 8, 2014. Repeat the inspection thereafter at intervals not to exceed 1,600 flight cycles.

(1) If any cracking, corrosion, or other defect is found within the criteria defined in Chapter 57, Wings, of the Jetstream Series 4100 Structural Repair Manual (SRM), Volume 1, Publication Ref. No. (Transmittal No.) SA 4–4100/SRM/400, Revision 32, dated October 15, 2014 (''Chapter 57 of the SRM''): Before further flight, repair the affected area, in accordance with the repair instructions of Chapter 57 of the SRM.

(2) If any cracking, corrosion, or other defect is found exceeding the criteria defined in Chapter 57 of the SRM: Before further flight, repair using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or BAE Systems (Operations) Limited's EASA Design Organization Approval (DOA).

(h) Repair Does Not Constitute Terminating Action Except for Certain Repairs

Accomplishment of a repair as required by paragraphs (g)(1) and (g)(2) of this AD, does not constitute terminating action for the repetitive inspections required by paragraph (g) of this AD, unless the approved repair required by paragraph (g)(2) of this AD states otherwise (*e.g.,* the approved repair states the repair terminates the inspections for the repaired area only).

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

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

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

(j) Related Information

Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2015–0100, dated June 3, 2015, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–0457.

(k) Material Incorporated by Reference

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

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

(i) BAE Systems Alert Service Bulletin J41–A57–029, Revision 3, dated April 8, 2014.

(ii) Chapter 57, Wings, of the BAE Systems (Operations) Limited Jetstream Series 4100 Structural Repair Manual, Volume 1, Publication Ref. No. (Transmittal No.) SA 4–

4100/SRM/400, Revision 32, dated October 15, 2014.

(3) For service information identified in this AD, contact BAE Systems (Operations) Limited, Customer Information Department, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; telephone +44 1292 675207; fax +44 1292 675704; email *RApublications@baesystems.com;* Internet *http://www.baesystems.com/Businesses/RegionalAircraft/index.htm.*

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

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

Issued in Renton, Washington, on December 6, 2016.

Dionne Palermo,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–30412 Filed 12–30–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–8180; Directorate Identifier 2016–NM–083–AD; Amendment 39–18760; AD 2016–26–02]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc. Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Bombardier, Inc. Model CL–600–2C10 (Regional Jet Series 700, 701, & 702) airplanes, Model CL–600–2D15 (Regional Jet Series 705) airplanes, Model CL–600–2D24 (Regional Jet Series 900) airplanes, and Model CL–600–2E25 (Regional Jet Series 1000) airplanes. This AD was prompted by a determination that the protective polyurethane tapes applied to the upper surfaces of the aluminum and titanium floor structural members may overhang the profiles of the floor structural parts and may allow fire propagation below the floor structure. This AD requires an inspection of the polyurethane protective tapes installed on the floor structure for excess tape or incorrect tape installation, and corrective actions if necessary. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective February 7, 2017.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of February 7, 2017.

ADDRESSES: For service information identified in this final rule, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; Widebody Customer Response Center North America toll-free telephone 1–866–538–1247 or direct-dial telephone: 1–514–855–2999; fax: 514–855–7401; email: *ac.yul@aero.bombardier.com;* Internet: *http://www.bombardier.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8180.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8180; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone: 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Fabio Buttitta, Aerospace Engineer, Airframe and Mechanical Systems Branch, ANE–171, FAA, New York Aircraft Certification Office (ACO), 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7303; fax: 516–794–5531.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Bombardier, Inc. Model CL–600–2C10 (Regional Jet Series 700, 701, & 702) airplanes, Model CL–600–2D15 (Regional Jet Series 705) airplanes, Model CL–600–2D24 (Regional Jet Series 900) airplanes, and Model CL–600–2E25 (Regional Jet Series 1000) airplanes. The NPRM published in the **Federal Register** on July 28, 2016 (81 FR 49577) (''the NPRM''). The NPRM was prompted by a determination that the protective polyurethane tapes applied to the upper surfaces of the aluminum and titanium floor structural members may not be trimmed properly, and on some places may overhang the profiles of the floor structural parts. Subsequent tests revealed that the overhanging pieces of tapes that are not bonded to the structure do not meet the flammability requirements and may allow fire propagation below the floor structure. The NPRM proposed to require an inspection of the polyurethane protective tapes installed on the floor structure for excess tape or incorrect tape installation, and corrective actions if necessary. We are issuing this AD to detect and correct overhanging pieces of protective polyurethane tapes, which are not bonded to the structure and do not meet the flammability requirements; this condition may allow fire propagation below the floor structure.

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian AD CF–2016–14, dated May 18, 2016 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Bombardier, Inc. Model CL–600–2C10 (Regional Jet Series 700, 701, & 702) airplanes, Model CL–600–2D15 (Regional Jet Series 705) airplanes, Model CL–600–2D24 (Regional Jet Series 900) airplanes, and Model CL–600–2E25 (Regional Jet Series 1000) airplanes. The MCAI states:

> An inspection revealed that the protective polyurethane tapes applied to the upper surfaces of the aluminum and titanium floor structural members installed on CRJ 700/900/1000 aeroplanes may not be trimmed properly and on some places may overhang the profiles of the floor structural parts. Subsequent tests revealed that the overhanging pieces of tapes which are not bonded to the structure, do not meet the flammability requirements. If not corrected, this condition may allow fire propagation below the floor structure.
>
> This [Canadian] AD was issued to mandate the [detailed] inspection and removal of any excessive pieces of overhanging tape [or replacing incorrectly installed tape] found on the floor structure.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8180.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comment received on the NPRM and the FAA's response.

Request To Revise Compliance Time

Endeavor Air requested that we revise the compliance time from 12,600 flight hours after the effective date of this AD to 16,000 flight hours after the effective date of this AD. Endeavor Air explained that it understands that the 12,600-flight-hour threshold was established to coincide with 12,000-flight-hour 2C check tasks, when removal of all the floor boards over the entire length of the airplane is scheduled, and not due to other calculations. Endeavor Air stated that Bombardier is in the process of escalating the intervals for a C-check (which includes removing the floor boards to expose the polyurethane tapes) from 12,000 flight hours to 16,000 flight hours. Endeavor Air explained that this increase will prevent an undue financial burden by allowing operators to accomplish this inspection during scheduled floor removal. Endeavor Air also stated that it has received written support from Bombardier for escalating this corrective action to 16,000 flight hours.

We do not agree with the commenter's request to extend the compliance time. Escalation of the C-check interval has not been approved yet and is a separate issue from the safety concern being addressed in this AD. We have determined that the compliance time, as proposed, represents the maximum interval of time allowable for the affected airplanes to continue to safely operate before the inspection is done. However, according to the provisions of paragraph (i) of this AD, we might approve requests to adjust the compliance time if the request includes data that substantiates that the new compliance time would provide an acceptable level of safety. We have not changed this AD in this regard.

Conclusion

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

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

Bombardier has issued Service Bulletin 670BA–53–055, dated December 3, 2015. The service information describes procedures for inspecting the polyurethane protective tapes for any excess tape or incorrect tape installation on the floor structure, and doing corrective actions, which include removing any excess tape and replacing any incorrectly installed tape. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects 569 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection and repair	190 work-hours × $85 per hour = $16,150	$0	$16,150	$9,189,350

Bombardier provided a single cost only. It did not separate out costs for inspection and corrective actions. Therefore, we have not specified separate on-condition repair costs.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

3. Will not affect intrastate aviation in Alaska; and

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2016–26–02 Bombardier, Inc.: Amendment 39–18760; Docket No. FAA–2016–8180; Directorate Identifier 2016–NM–083–AD.

(a) Effective Date

This AD is effective February 7, 2017.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the Bombardier, Inc. airplanes identified in paragraphs (c)(1), (c)(2), and (c)(3) of this AD, certificated in any category.

(1) Model CL–600–2C10 (Regional Jet Series 700, 701, & 702) airplanes, serial numbers 10002 through 10342 inclusive.

(2) Model CL–600–2D15 (Regional Jet Series 705) airplanes and Model CL–600–2D24 (Regional Jet Series 900) airplanes, serial numbers 15001 through 15347 inclusive.

(3) Model CL–600–2E25 (Regional Jet Series 1000) airplanes, serial numbers 19001 through 19040 inclusive.

(d) Subject

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

(e) Reason

This AD was prompted by a determination that the protective polyurethane tapes applied to the upper surfaces of the aluminum and titanium floor structural members may not be trimmed properly, and on some places may overhang the profiles of the floor structural parts. Subsequent tests revealed that the overhanging pieces of tapes that are not bonded to the structure do not meet the flammability requirements and may allow fire propagation below the floor structure. We are issuing this AD to detect and correct overhanging pieces of protective polyurethane tapes, which are not bonded to the structure and do not meet the flammability requirements; this condition may allow fire propagation below the floor structure.

(f) Compliance

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

(g) Inspection and Corrective Actions

Within 12,600 flight hours after the effective date of this AD: Do a detailed inspection for excess tape or incorrect tape installation of the polyurethane protective tapes installed between floor panels and floor structure between fuselage station (FS) 280.00 and FS969.00; and do all applicable corrective actions; in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 670BA–53–055, dated December 3, 2015, except as specified in paragraph (h) of this AD. Do all applicable corrective actions before further flight.

(h) Exception to Service Information

Where Bombardier Service Bulletin 670BA–53–055, dated December 3, 2015, specifies to contact Bombardier, Inc., to ''get an approved disposition to complete this service bulletin,'' before further flight, repair using a method approved by the Manager, New York Aircraft Certification Office (ACO), ANE–170, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO).

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

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

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

(j) Related Information

Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian AD CF–2016–14, dated May 18, 2016, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8180.

(k) Material Incorporated by Reference

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

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

(i) Bombardier Service Bulletin 670BA–53–055, dated December 3, 2015.

(ii) Reserved.

(3) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; Widebody Customer Response Center North America toll-free telephone 1–866–538–1247 or direct-dial telephone: 1–514–855–2999; fax: 514–855–7401; email: *ac.yul@aero.bombardier.com;* Internet: *http://www.bombardier.com.*

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

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

Issued in Renton, Washington, on December 9, 2016.

Dionne Palermo,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–30418 Filed 12–30–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–3631; Directorate Identifier 2015–NM–060–AD; Amendment 39–18757; AD 2016–25–31]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Airbus Model A330–200 and –300 series airplanes; Model A330–200 Freighter series airplanes; and Model A340–200, –300, –500, and –600 series airplanes. This AD was prompted by reports of chafed wiring at the upper left corner of the cockpit door. The affected wire bundle was not grounded on the cockpit door frame. This AD requires modifying the cockpit door frame structure, installing bonding-leads to the upper cockpit door frame, and modifying the upper cockpit door plate cover. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective February 7, 2017.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of February 7, 2017.

ADDRESSES: For service information identified in this final rule, contact Airbus SAS, Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone: +33 5 61 93 36 96; fax: +33 5 61 93 45 80; email: *airworthiness.A330-A340@airbus.com;* Internet: *http://www.airbus.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–3631.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–3631; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone: 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT:

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

SUPPLEMENTARY INFORMATION:

Discussion

We issued a supplemental notice of proposed rulemaking (SNPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Airbus Model A330–200 and –300 series airplanes; Model A330–200 Freighter series airplanes; and Model A340–200, –300, –500, and –600 series airplanes. The SNPRM published in the **Federal Register** on June 6, 2016 (81 FR 36211) (''the SNPRM''). We preceded the SNPRM with a notice of proposed rulemaking (NPRM) that was published in the **Federal Register** on September 18, 2015 (80 FR 56405) (''the NPRM''). The NPRM proposed to require modifying the cockpit door frame structure, installing bonding-leads to the upper cockpit door frame, and modifying the upper cockpit door plate cover. The NPRM was prompted by reports of chafed wiring at the upper left corner of the cockpit door. The SNPRM proposed to also require, for certain airplanes, installing a noise-reduced cockpit door locking system (CDLS). We are issuing this AD to prevent electrical shock injury to persons contacting the cockpit door.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2015–0037, dated March 2, 2015 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Airbus Model A330–200 and –300 series airplanes; Model A330–200 Freighter series airplanes; and Model A340–200, –300, –500, and –600 series airplanes. The MCAI states:

> An operator has reported chafed wiring at the upper left corner of the cockpit door. The investigation concluded that the affected wire bundle, which supplies a voltage of 115V [volt] AC [alternating current], was not grounded on the cockpit door frame as part of the design of A330 and A340 aeroplanes.
>
> This condition, if not corrected, could result in injury [electrical shock], in case any person gets in contact with the door frame.
>
> Prompted by these findings, Airbus issued SB [service bulletin] A330–25–3534, SB A340–25–4349 and SB A340–25–5212 to provide instructions to modify the electrical bonding of the cockpit door.
>
> For the reasons described above, this [EASA] AD requires modification of the cockpit door frame structure, installation of bonding-leads to the upper cockpit door frame and modification of the upper cockpit door plate cover.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–3631.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the SNPRM and the FAA's response to each comment.

Requests To Remove Requirement for Additional Concurrent Actions

Delta Airlines (DAL) requested that we remove the proposed requirement to install the CDLS as specified in Airbus Service Bulletin A330–25–3254, Revision 02, dated December 13, 2004. American Airlines (AAL) requested that we clarify the airplanes affected by that proposed requirement. Both commenters stated that Airbus has confirmed that installation of the noise-reduced CDLS specified in Airbus Service Bulletin A330–25–3254, Revision 02, dated December 13, 2004, is optional and applies only to certain Qantas Airways Limited airplanes. Airbus stated that modification of the airplane as specified in Airbus Service Bulletin A330–25–3213, Revision 02, dated August 12, 2016, has the same impact on the airplane as the modification specified in Airbus Service Bulletin A330–25–3254, Revision 02, dated December 13, 2004. Airbus explained that the airplanes affected by proposed requirement are defined as configuration 01 in Airbus Service Bulletin A330–25–3534, Revision 02, dated May 18, 2015, which will be corrected at its next revision to remove the reference to optional Airbus Service Bulletin A330–25–3254, Revision 02, dated December 13, 2004.

We agree with the commenters' requests. We have confirmed that modification of the airplane as specified in Airbus Service Bulletin A330–25–3254, Revision 02, dated December 13, 2004, is optional and applies only to certain Qantas Airways Limited airplanes. We have removed paragraphs (i) and (j)(3) from the proposed AD (in the SNPRM) and redesignated subsequent paragraphs accordingly.

Changes to Final Rule

Airbus has released Service Bulletin A330–25–3213, Revision 02, dated August 12, 2016. This service information revision specifies minor additional work to replace the fasteners of the cover of the cockpit door frame. We have determined that this minor change will not increase the overall cost estimates specified in the SNPRM or otherwise impose an additional burden on any operator. We have revised paragraph (h) of this AD to specify A330–25–3213, Revision 02, dated August 12, 2016, as an appropriate source of service information for accomplishing the required actions. We have removed Airbus Service Bulletin A330–25–3213, dated October 12, 2004, from paragraph (j)(2)(i) of the proposed AD (in the SNPRM) and redesignated subsequent paragraphs accordingly.

Conclusion

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

- Are consistent with the intent that was proposed in the SNPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the SNPRM.

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

Related Service Information Under 1 CFR Part 51

Airbus has issued the following service information.

- Airbus Service Bulletin A330–25–3213, Revision 02, dated August 12, 2016. This service information describes procedures for modification of the upper cockpit door plate cover.
- Airbus Service Bulletin A330–25–3534, Revision 02, dated May 18, 2015. This service information describes procedures for modifying the cockpit

door frame structure and installing bonding-leads to the upper cockpit door frame.

• Airbus Service Bulletin A340–25–4217, Revision 01, dated April 25, 2005. This service information describes procedures for modification of the upper cockpit door plate cover.

• Airbus Service Bulletin A340–25–4349, Revision 02, dated September 4, 2015. This service information describes procedures for modifying the cockpit door frame structure and installing bonding-leads to the upper cockpit door frame.

• Airbus Service Bulletin A340–25–5046, Revision 02, dated February 5, 2007. This service information describes procedures for modification of the upper cockpit door plate cover.

• Airbus Service Bulletin A340–25–5212, Revision 01, dated October 27, 2014. This service information describes procedures for modifying the cockpit door frame structure and installing bonding-leads to the upper cockpit door frame.

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

Costs of Compliance

We estimate that this AD affects 70 airplanes of U.S. registry.

We estimate that it would take about 53 work-hours per product to comply with the new basic requirements of this AD. The average labor rate is $85 per work-hour. Required parts would cost about $2,430 per product. Based on these figures, we estimate the cost of this AD on U.S. operators to be $485,450, or $6,935 per product.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

3. Will not affect intrastate aviation in Alaska; and

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2016–25–31 Airbus: Amendment 39–18757; Docket No. FAA–2015–3631; Directorate Identifier 2015–NM–060–AD.

(a) Effective Date

This AD is effective February 7, 2017.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus airplanes, certificated in any category, identified in paragraphs (c)(1), (c)(2), and (c)(3) of this AD, except airplanes on which Airbus Modification 203066, Modification 203074, or Modification 203372 has been embodied in production.

(1) Model A330–201, –202, –203, –223, –223F, –243, –243F, –301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes; all manufacturer serial numbers (MSNs); if modified in-service as specified in Airbus Service Bulletin A330–25–3161, or in production with Airbus Modification 50014.

(2) Model A340–211, –212, –213, –311, –312, and –313 airplanes; all MSNs, if modified in-service as specified in Airbus Service Bulletin A340–25–4181, or in production with Airbus Modification 50014.

(3) Model A340–541 airplanes and Model A340–642 airplanes; all MSNs.

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/furnishings.

(e) Reason

This AD was prompted by reports of chafed wiring at the upper left corner of the cockpit door. The affected wire bundle was not grounded on the cockpit door frame. We are issuing this AD to prevent electrical shock injury to persons contacting the cockpit door.

(f) Compliance

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

(g) Door Modification and Installation

Within 24 months after the effective date of this AD, modify the cockpit door frame structure and install bonding-leads to the upper cockpit door frame, in accordance with the Accomplishment Instructions of the applicable service information identified in paragraphs (g)(1), (g)(2), and (g)(3) of this AD.

(1) Airbus Service Bulletin A330–25–3534, Revision 02, dated May 18, 2015.

(2) Airbus Service Bulletin A340–25–4349, Revision 02, dated September 4, 2015.

(3) Airbus Service Bulletin A340–25–5212, Revision 01, dated October 27, 2014.

(h) Cover Plate Modification of the Upper Flight Deck Door

Except for airplanes on which Airbus Modification 52869 or Modification 53292 has been embodied in production: Prior to or concurrently with accomplishing the actions required by paragraph (g) of this AD, modify the upper cockpit door plate cover, in accordance with the Accomplishment Instructions of the applicable service information identified in paragraphs (h)(1), (h)(2), and (h)(3) of this AD.

(1) For configuration 1 airplanes identified in Airbus Service Bulletin A330–25–3534, Revision 02, dated May 18, 2015: Airbus Service Bulletin A330–25–3213, Revision 02, dated August 12, 2016.

(2) For airplanes identified in Airbus Service Bulletin A340–25–4349, Revision 02, dated September 4, 2015: Airbus Service Bulletin A340–25–4217, Revision 01, dated April 25, 2005.

(3) For airplanes identified in Airbus Service Bulletin A340–25–5212, Revision 01,

dated October 27, 2014: Airbus Service Bulletin A340–25–5046, Revision 02, dated February 5, 2007.

(i) Credit for Previous Actions

(1) This paragraph provides credit for the actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Airbus Service Bulletin A330–25–3534, Revision 01, dated October 23, 2014; or Airbus Service Bulletin A340–25–4349, Revision 01, dated October 27, 2014, as applicable. These service bulletins are not incorporated by reference in this AD.

(2) This paragraph provides credit for the actions required by paragraph (h) of this AD, if those actions were performed before the effective date of this AD using the applicable service information specified in paragraphs (i)(2)(i), (i)(2)(ii), and (i)(2)(iii) of this AD. This service information is not incorporated by reference in this AD.

(i) Airbus Service Bulletin A340–25–4217, dated October 12, 2004.

(ii) Airbus Service Bulletin A340–25–5046, dated October 12, 2004.

(iii) Airbus Service Bulletin A340–25–5046, Revision 01, dated May 11, 2005.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

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

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

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

(k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2015–0037, dated March 2, 2015, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–3631.

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

(l) Material Incorporated by Reference

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

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

(i) Airbus Service Bulletin A330–25–3213, Revision 02, dated August 12, 2016.

(ii) Airbus Service Bulletin A330–25–3534, Revision 02, dated May 18, 2015.

(iii) Airbus Service Bulletin A340–25–4217, Revision 01, dated April 25, 2005.

(iv) Airbus Service Bulletin A340–25–4349, Revision 02, dated September 4, 2015.

(v) Airbus Service Bulletin A340–25–5046, Revision 02, dated February 5, 2007.

(vi) Airbus Service Bulletin A340–25–5212, Revision 01, dated October 27, 2014.

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

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

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

Issued in Renton, Washington, on December 6, 2016.

Dionne Palermo,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–30280 Filed 12–30–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF STATE

22 CFR Parts 120, 123, and 126

[Public Notice: 9811]

RIN 1400–AE07

International Traffic in Arms Regulations: International Trade Data System, Reporting

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State amends the International Traffic in Arms Regulations (ITAR) to enable U.S. Customs and Border Protection (CBP) to implement the International Trade Data System (ITDS), which will allow businesses to electronically submit the data required to import or export cargo, as provided by Executive Order 13659 and the Security and Accountability for Every Port Act of 2006 (SAFE Port Act).

DATES: This final rule is effective on December 31, 2016.

FOR FURTHER INFORMATION CONTACT: Mr. C. Edward Peartree, Director, Office of Defense Trade Controls Policy, Department of State, telephone (202) 663–2792; email *DDTCResponseTeam@state.gov.* ATTN: International Trade Data System, reporting.

SUPPLEMENTARY INFORMATION: The Directorate of Defense Trade Controls (DDTC) of the Department of State regulates the export and temporary import of defense-related goods and defense services under the Arms Export Control Act (AECA) and its implementing regulations, the International Traffic in Arms Regulations (ITAR). This rule is being issued to conform DDTC's regulations to ITDS, ''an electronic information exchange capability, or 'single window', through which businesses will transmit data required by participating agencies for the importation or exportation of cargo'' (Executive Order 13659, Sec. 3, Feb. 19, 2014). Executive Order 13659 requires government-wide implementation of ITDS by December 31, 2016. Additionally, Section 405 of the Security and Accountability for Every Port Act of 2006 (SAFE Port Act) mandates agency participation in ITDS for all Federal agencies that have oversight of imports and exports. A consortium of 47 Federal agencies led by CBP are implementing ITDS.

ITDS represents a shift in the way that imports and exports are declared to CBP by importers and exporters engaged in international commerce. Traders will only need to create and submit a single set of data for each import or export, thus significantly reducing the

paperwork and reporting burden currently experienced by importers and exporters. Beginning on December 31, 2016, traders will access the ITDS system via an integrated web portal hosted by CBP. Users may visit *https://www.cbp.gov/trade/automated* for more information on the single portal.

Through the CBP Partner Government Agency (PGA) program, DDTC promulgated a PGA Message Set that requires traders to enter data relevant to DDTC's jurisdiction. Beginning December 31, 2016, when declaring permanent or temporary exports and/or temporary imports of defense articles controlled by the U.S. Munitions List (USML), traders will input data relevant to DDTC in CBP's electronic system(s). CBP will transmit the relevant shipment details to DDTC via an electronic data exchange, eliminating the need for traders to notify DDTC separately.

This rule amends pertinent provisions throughout the ITAR to reflect this new submission mechanism and allow for successor systems to be put in place.

This rule will make the following changes to the ITAR (22 CFR parts 120–130):

Section 120.28—Listing of Forms Referred to in This Subchapter

Section 120.28 is revised to strike the reference to the Automated Export System and add, in its place, ''U.S. Customs and Border Protection's electronic system(s)''.

Section 120.30—The Automated Export System (AES)

Section 120.30 is removed and reserved.

Section 123.4—Temporary Import License Exemptions

Section 123.4(d)(2) is revised to strike the reference to the Automated Export System (AES) and add, in its place, instructions to electronically file information with CBP.

Section 123.5—Temporary Export Licenses

Section 123.5(b) is revised to update certain reporting procedures and to clarify that license information will be submitted to CBP electronically.

Section 123.16—Exemptions of General Applicability

Sections 123.16(b)(4) and (5) are revised to clarify that certifications will be sent to CBP electronically and not via hard copy.

Section 123.17—Exports of Firearms, Ammunition, and Personal Protective Gear

All references to AES in § 123.17 are struck and, in their place, instructions to electronically file with CBP are inserted. Additionally, § 123.17(g)(2) and (h) are revised to update certain documentation procedures.

Section 123.22—Filing, Retention, and Return of Export Licenses and Filing of Export Information

Section 123.22 of the ITAR is revised by making certain grammatical changes and to clarify procedures for the electronic reporting of exports and temporary imports of defense articles, services, and technical data pursuant to a license or other approval. All references to AES in § 123.22 are struck and, in their place, instructions to electronically file with CBP are inserted.

Section 123.22(a) is revised to clarify electronic reporting procedures for exports. Paragraphs (a)(1) and (a)(2) are also revised for clarification of certain procedures.

Section 123.22(b)(2) is revised to clarify that emergency shipment data shall no longer be required to be sent directly to DDTC, but rather be electronically declared to CBP, which will make the data available to DDTC via an electronic data exchange.

Section 123.22(b)(3)(iii) is revised to update electronic reporting procedures for technical data and defense service exemptions.

Section 123.22(c) is revised to strike a provision relating to the return of licenses and to reorder the sub-paragraphs.

Section 123.24—Shipments by U.S. Postal Service

Section 123.24 is revised to strike references to AES and insert, in their place, instructions to electronically file with CBP. The underlying content of this section is not affected by this change.

Section 126.4—Shipments by or for United States Government Agencies

Section 126.4(d) is amended by revising the first sentence to account for electronic reporting, and by striking the second sentence.

Section 126.6—Foreign-Owned Military Aircraft and Naval Vessels, and the Foreign Military Sales Program

Section 126.6(c) is revised to clarify certain procedures relating to the declaration of information to CBP, and to remove references to form DSP–94. Section 126.6(c)(5)(iii) is revised to require that the exporter provide CBP with a copy of the transportation plan under the Department of Defense National Industrial Security Program Operating Manual for shipments of classified defense articles exported pursuant to a Foreign Military Sale Letter of Offer and Acceptance. Section 126.6(c)(6)(iii) is revised to correct a punctuation error made in a previous rulemaking.

Section 126.16—Exemption Pursuant to the Defense Trade Cooperation Treaty Between the United States and Australia

Section 126.16(l) is revised to strike references to the Automated Export System and insert, in their place, instructions to electronically file with CBP. The underlying content of this section will not be affected by this change.

Section 126.17—Exemption Pursuant to the Defense Trade Cooperation Treaty Between the United States and the United Kingdom

Section 126.17(l) is revised to strike references to the Automated Export System and insert, in their place, instructions to electronically file with CBP. The underlying content of this section will not be affected by this change.

Regulatory Analysis

Administrative Procedure Act

The Department of State is of the opinion that controlling the import and export of defense articles and services is a foreign affairs function of the United States Government and that rules implementing this function are exempt from sections 553 (rulemaking) and 554 (adjudications) of the Administrative Procedure Act. As this rule serves to implement the requirements of the Security and Accountability for Every Port Act of 2006 (Pub. L. 109–347), the Department of State is publishing this final rule using the ''good cause'' exception to the Administrative Procedure Act, as this rule is being published to fulfill the requirements outlined in Executive Order 13659. The Department has determined that public comment on this rulemaking would be impractical, unnecessary, and contrary to the public interest.

Regulatory Flexibility Act

Because this rulemaking is exempt from Section 553 of the Administrative Procedures Act, a Regulatory Flexibility Analysis is not required and has not been prepared.

Unfunded Mandates Reform Act of 1995

This rule does not involve a mandate that will result in the expenditure by

State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

The Department does not believe this rulemaking is a major rule within the definition of 5 U.S.C. 804.

Executive Orders 12372 and 13132

This rulemaking will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, the Department has determined that this rulemaking does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this rulemaking.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess 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, distributed impacts, and equity). These executive orders stress the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The Department has determined that the benefits of this rulemaking outweigh any cost to the public, which the Department believes will be minimal. OMB has designated this rule non-significant.

Executive Order 12988

The Department of State has reviewed the proposed amendment in light of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13175

The Department of State has determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not preempt tribal law. Accordingly, Executive Order 13175 does not apply to this rulemaking.

Paperwork Reduction Act

This rulemaking does not impose or revise any information collections subject to 44 U.S.C. Chapter 35.

List of Subjects

22 CFR Part 120

Approvals, Arms and munitions, Definitions, Forms.

22 CFR Part 123

Arms and munitions, Exemptions, Licenses, Reporting, Shipments.

22 CFR Part 126

Arms and munitions, General policies and provisions.

For the reasons set forth above, title 22, chapter I, subchapter M, parts 120, 123 and 126 are amended as follows:

PART 120—PURPOSE AND DEFINITIONS

■ 1. The authority citation for part 120 continues to read as follows:

Authority: Secs. 2, 38, and 71, Public Law 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); 22 U.S.C. 2794; 22 U.S.C. 2651a; Public Law 105–261, 112 Stat. 1920; Public Law 111–266; Section 1261, Public Law 112–239; E.O. 13637, 78 FR 16129.

■ 2. Amend § 120.28 (b)(2) to read as follows:

§ 120.28 Listing of forms referred to in this subchapter.

* * * * *

(b) * * *

(2) Electronic Export Information submitted using U.S. Customs and Border Protection's electronic system(s).

* * * * *

§ 120.30 [Removed and Reserved]

■ 3. Remove and reserve § 120.30.

PART 123—LICENSES FOR THE EXPORT AND TEMPORARY IMPORT OF DEFENSE ARTICLES

■ 4. The authority citation for part 123 continues to read as follows:

Authority: Secs. 2, 38, and 71, Public Law 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); 22 U.S.C. 2753; 22 U.S.C. 2651a; 22 U.S.C. 2776; Public Law 105–261, 112 Stat.1920; Sec. 1205(a), Public Law 107–228; Sec 520, Public Law 112–55; Section 1261, Public Law 112–239; E.O. 13637, 78 FR 16129.

■ 5. Section 123.4 is amended by revising paragraph (d)(2) to read as follows:

§ 123.4 Temporary import license exemptions.

* * * * *

(d) * * *

(2) At the time of export, in accordance with the U.S. Customs and Border Protection (CBP) procedures, the Directorate of Defense Trade Controls (DDTC) registered and eligible exporter, or an agent acting on the filer's behalf, must electronically file the export information with CBP, identify 22 CFR 123.4 as the authority for the export, and provide, as requested by CBP, the entry document number or a copy of the CBP document under which the article was imported.

■ 6. Section 123.5 is amended by revising the last three sentences of paragraph (b) to read as follows:

§ 123.5 Temporary export licenses.

* * * * *

(b) * * * The license for temporary export must be electronically submitted to U.S. Customs and Border Protection, unless electronic reporting of such information is unavailable, in which case U.S. Customs and Border Protection will issue instructions. In the event a physical license is required by U.S. Customs and Border Protection, the licensee is to retain the duly endorsed license for temporary export in accordance with § 123.22(b) of this subchapter. In the case of a military aircraft or vessel temporarily exported under its own power, evidence that the Department of State has duly authorized it to leave the United States must be readily available on board the aircraft or vessel.

* * * * *

■ 7. Section 123.16 is amended by revising the penultimate sentence of paragraph (b)(4), and the last sentence of paragraph (b)(5), to read as follows:

§ 123.16 Exemptions of general applicability.

* * * * *

(b) * * *

(4) * * * U.S. persons who avail themselves of this exemption must electronically submit a certification to U.S. Customs and Border Protection that these conditions are met, unless directed by U.S. Customs and Border Protection to provide such a certification in another manner. * * *

(5) * * * U.S. persons who avail themselves of this exemption must electronically submit a certification to U.S. Customs and Border Protection that these conditions are met, unless directed by U.S. Customs and Border Protection to provide such a certification in another manner.

* * * * *

■ 8. Section 123.17 is amended by revising paragraphs (a)(2)(iii), (a)(3)(iii), (c)(1), (f)(1), the second sentence of paragraph (g)(2), and the penultimate sentence of paragraph (h) to read as follows:

§ 123.17 Exports of firearms, ammunition, and personal protective gear.

(a) * * *

(2) * * *

(iii) The exporter makes an electronic declaration to U.S. Customs and Border Protection pursuant to § 123.22(a), and the exporter is eligible to export under this exemption pursuant to § 120.1(c) of this subchapter, unless the electronic submission of such declaration is unavailable, in which case U.S. Customs and Border Protection will issue instructions; or

(3) * * *

(iii) The exporter makes an electronic declaration to U.S. Customs and Border Protection pursuant to § 123.22(a), and the exporter is eligible to export under this exemption pursuant to § 120.1(c) of this subchapter, unless the electronic submission of such declaration is unavailable, in which case U.S. Customs and Border Protection will issue instructions.

* * * * *

(c) * * *

(1) The person declares the articles to a CBP officer upon each departure from the United States, presents the Internal Transaction Number from submission of the export information through CBP's electronic system(s) per § 123.22 (unless electronic reporting of such information is unavailable, in which case U.S. Customs and Border Protection will issue instructions), and the articles are presented to the CBP officer for inspection;

* * * * *

(f) * * *

(1) The person declares the articles to a CBP officer upon each departure from the United States, presents the Internal Transaction Number from submission of the export information through CBP's electronic system(s) per § 123.22 (unless electronic reporting of such information is unavailable, in which case U.S. Customs and Border Protection will issue instructions), and the articles are presented to the CBP officer for inspection;

* * * * *

(g) * * *

* * * * *

(2) * * * The person shall electronically submit documentation to this effect, along with the Internal Transaction Number from U.S. Customs and Border Protection's electronic system(s), unless electronic reporting of such information is unavailable, in which case U.S. Customs and Border Protection will issue instructions.

(h) * * * The person shall electronically submit documentation to this effect, along with the Internal Transaction Number using U.S. Customs and Border Protection's electronic system(s), unless electronic reporting of such information is unavailable, in which case U.S. Customs and Border Protection will issue instructions. * * *

* * * * *

■ 9. Section 123.22 is amended by:

■ a. Revising paragraph (a);

■ b. Revising paragraphs (b)(1) introductory text, (b)(2) introductory text, (b)(2)(ii), and (b)(3)(iii); and

■ c. Revising paragraph (c).

The revisions read as follows:

§ 123.22 Filing, retention, and return of export licenses and filing of export information.

(a) Any export, as defined in this subchapter, of a defense article controlled by this subchapter, to include defense articles transiting the United States, requires the electronic reporting of export information. The reporting of the export information shall be to the U.S. Customs and Border Protection using its electronic system(s), or directly to the Directorate of Defense Trade Controls (DDTC), as appropriate. Before the export of any hardware, via a license or other authorization, the DDTC registered applicant/exporter, or an agent acting on the filer's behalf, must electronically submit export information to U.S. Customs and Border Protection, unless electronic reporting is unavailable, in which case U.S. Customs and Border Protection will issue instructions (*see* paragraph (b) of this section). In addition to electronically providing the export information to U.S. Customs and Border Protection before export, all mandatory supporting documentation (*e.g.* attachments, certifications, proof of filing in U.S. Customs and Border Protection's system(s) such as the Internal Transaction Number (ITN)) must be submitted electronically, unless electronic reporting of such information is unavailable, in which case U.S. Customs and Border Protection will issue instructions.

(1) If necessary, an export may be made through a port other than the one designated on the license if the exporter complies with the procedures established by U.S. Customs and Border Protection.

(2) When a defense article is temporarily exported from the United States and subsequently moved from one destination authorized on a license to another destination authorized on the same or another temporary license, the applicant, or an agent acting on the applicant's behalf, must ensure that U.S. Customs and Border Protection decrements both temporary licenses to show the exit and entry of the hardware.

(b) * * *

(1) *Filing of export information with the U.S. Customs and Border Protection.* Before exporting any hardware controlled by this subchapter using a license or exemption, the DDTC registered applicant/exporter, or an agent acting on the filer's behalf, must electronically file the export information with U.S. Customs and Border Protection in accordance with the following timelines:

* * * * *

(2) *Emergency shipments of hardware that cannot meet the pre-departure filing requirements.* U.S. Customs and Border Protection may permit an emergency export of hardware by truck or air by a U.S. registered person when the exporter is unable to comply with the Electronic Export Information (EEI) filing timeline in paragraph (b)(1)(i) of this section. The applicant, or an agent acting on the applicant's behalf, must provide documentation required by the U.S. Customs and Border Protection and this subchapter. The documentation provided to U.S. Customs and Border Protection must include the Internal Transaction Number (ITN) for the shipment and must be accompanied by an explanation for urgency. The export filing via U.S. Customs and Border Protection's electronic system(s) must be made at least two hours prior to any departure by air from the United States. When shipping via ground, the filing in U.S. Customs and Border Protection's electronic system(s) must be made when the exporter provides the articles to the carrier or at least one hour prior to departure from the United States, when the permanent export of the hardware has been authorized for export:

* * * * *

(ii) On a valid license, and the ultimate recipient and ultimate end-user identified on the license is a foreign government.

(3) * * *

(iii) *Technical data and defense service exemptions.* In any instance when technical data is exported using an exemption in this subchapter (*e.g.,* §§ 125.4(b)(2), 125.4(b)(4), 126.5) from a U.S. port, the exporter must provide the export data electronically to DDTC. A copy of the electronic notification to DDTC must accompany the technical data shipment and be made available to

the U.S. Customs and Border Protection upon request.

* * * * *

(c) *Return of licenses.* Licenses issued by the Directorate of Defense Trade Controls are subject to return requirements as follows:

(1) A license issued electronically by DDTC and electronically decremented by U.S. Customs and Border Protection through its electronic system(s) is not required to be returned to DDTC. A copy of the license must be maintained by the applicant in accordance with § 122.5 of this subchapter.

(2) Licenses issued by DDTC but not decremented by U.S. Customs and Border Protection through its electronic system(s) (*e.g.* oral or visual technical data releases) must be returned by the applicant, or the government agency with which the license was filed, to DDTC upon expiration, to include when the total authorized value or quantity has been shipped. A copy of the license must be maintained by the applicant in accordance with § 122.5 of this subchapter.

(3) A license issued by DDTC but not used by the applicant does not need to be returned to DDTC, even when expired.

(4) A license revoked by DDTC is considered expired and must be handled in accordance with paragraphs (c)(1) and (c)(2) of this section.

■ 10. Amend § 123.24 by revising paragraph (a) as follows:

§ 123.24 Shipments by U.S. Postal Service

(a) The export of any defense hardware using a license or exemption in this subchapter by the U.S. Postal Service must be filed with U.S. Customs and Border Protection using its electronic system(s) and the license must be filed with U.S. Customs and Border Protection before any hardware is actually sent abroad by mail. The exporter must certify the defense hardware being exported in accordance with this subchapter by clearly marking on the package:

''This export is subject to the controls of the ITAR, 22 CFR (identify section for an exemption) or (state license number) and the export has been electronically filed with U.S. Customs and Border Protection.''

* * * * *

PART 126—GENERAL POLICIES AND PROVISIONS

■ 11. The authority citation for part 126 continues to read as follows:

Authority: Secs. 2, 38, 40, 42, and 71, Public Law 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2780, 2791, and 2797); 22 U.S.C. 2651a; 22 U.S.C. 287c; E.O. 12918; 59 FR 28205; 3 CFR, 1994 Comp., p. 899; Sec. 1225, Public Law 108–375; Sec. 7089, Public Law 111–117, Public Law 111–266; Section 7045, Public Law 112–74; Section 7046, Public Law 112–74; E.O. 13637, 78 FR 16129.

■ 12. Section 126.4 is amended by revising paragraph (d) as follows:

§ 126.4 Shipments by or for United States Government agencies.

* * * * *

(d) An Electronic Export Information (EEI) filing, and a statement by the exporter that these requirements have been met, must be submitted to U.S. Customs and Border Protection using its electronic system(s) at the time of export, unless electronic submission of such information is unavailable, in which case U.S. Customs and Border Protection or the Department of Defense transmittal authority will issue instructions.

■ 13. Section 126.6 is amended by revising paragraphs (c)(5)(ii), (c)(5)(iii), and (c)(6)(iii) as follows:

§ 126.6 Foreign-owned military aircraft and naval vessels, and the Foreign Military Sales program.

* * * * *

(c) * * *

(5) * * *

(ii) At the time of shipment, U.S. Customs and Border Protection is provided the Electronic Export Information, Internal Transaction Number and any other documents required by U.S. Customs and Border Protection in carrying out its responsibilities. The invoices for the shipment must be annotated: ''This shipment is authorized for export pursuant to 22 CFR 126.6(c), under FMS Case [insert case identification]. The U.S. Government point of contact is ____, telephone number ____,'' and

(iii) Any classified hardware and related technical data involved in the transfer must have the requisite U.S. Government security clearance and transportation plan and be shipped in accordance with the Department of Defense National Industrial Security Program Operating Manual. The exporter shall provide an electronic copy of the transportation plan via the U.S. Customs and Border Protection's electronic system(s), unless electronic reporting of such information is unavailable, in which case U.S. Customs and Border Protection will issue instructions, or

(6) * * *

(iii) In instances when the defense service involves the transfer of classified technical data, the U.S. person transferring the defense service must have the appropriate USG security clearance and a transportation plan, if appropriate, in compliance with the Department of Defense National Industrial Security Program Operating Manual.

■ 14. Section 126.16 is amended by revising paragraphs (l)(1)(xv) and (l)(2) introductory text to read as follows:

§ 126.16 Exemption pursuant to the Defense Trade Cooperation Treaty between the United States and Australia.

* * * * *

(l) * * *

(1) * * *

(xv) The Internal Transaction Number for the Electronic Export Information filing using U.S. Customs and Border Protection's electronic system(s);

* * * * *

(2) *Filing of export information.* All exporters of defense articles under the Defense Trade Cooperation Treaty between the United States and Australia and this section must electronically file Electronic Export Information (EEI) using U.S. Customs and Border Protection's electronic system(s), citing one of the four below referenced codes in the appropriate field in the EEI for each shipment:

* * * * *

■ 15. Section 126.17 is amended by revising paragraphs (l)(1)(xv) and (l)(2) introductory text to read as follows:

§ 126.17 Exemption pursuant to the Defense Trade Cooperation Treaty between the United States and the United Kingdom.

* * * * *

(l) * * *

(1) * * *

(xv) The Internal Transaction Number for the Electronic Export Information filing using U.S. Customs and Border Protection's electronic system(s);

* * * * *

(2) *Filing of export information.* All exporters of defense articles under the Defense Trade Cooperation Treaty between the United States and the United Kingdom and this section must electronically file Electronic Export Information (EEI) using U.S. Customs and Border Protection's electronic system(s), citing one of the four below referenced codes in the appropriate field in the EEI for each shipment:

* * * * *

Dated: December 23, 2016.

Thomas Countryman,

Under Secretary (Acting), Arms Control and International Security, Department of State.

[FR Doc. 2016–31655 Filed 12–29–16; 11:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–1017]

RIN 1625–AA00

Safety Zone; Lower Mississippi River, Natchez, MS

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain waters of the Lower Mississippi River. This action is necessary to provide for the safety of life on these navigable waters near the bluffs, Natchez, MS, during a fireworks display on December 31, 2016. The safety zone will cover all navigable waters between mile markers 363.4 and 364.4 in the Lower Mississippi River located near the bluffs in Natchez, MS. This rulemaking will prohibit persons and vessels from being in the safety zone unless authorized by the Captain of the Port Memphis (COTP) or a designated representative.

DATES: This rule is effective from 9:40 p.m. on December 31, 2016 until 10:40 p.m. on January 1, 2017.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2016–1017 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 about this rulemaking, call or email Petty Officer Todd Manow, Waterways Management, Sector Lower Mississippi River, U.S. Coast Guard; telephone 901–521–4813, email *todd.m.manow@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

On August 12, 2016, Natchez Specialties notified the Coast Guard that it will be conducting a fireworks display from 10 to 10:15 p.m. on December 31, 2016, to celebrate New Year's Eve. The fireworks are to be launched from a barge in the Lower Mississippi River at mile marker 363.9 approximately 200 yards northwest of the bluffs in Natchez, MS at approximate position 31°33.83' N, 091°24.50' W. Hazards from firework displays include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. The Captain of the Port Memphis (COTP) has determined that potential hazards associated with the fireworks to be used in this display would be a safety concern for anyone within an area on the Lower Mississippi River from mile marker 363.4 to mile marker 364.4.

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because, although the event sponsor originally submitted notice to the Coast Guard on August 12, 2016, final details of the event, safety zone requirements, and regulatory patrol parameters were not finalized until November of 2016. It is impracticable to publish an NPRM because we must establish this safety zone by December 31, 2016.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. For these same reasons, the Coast Guard finds good cause for implementing this rule less than thirty days before the effective date.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The COTP has determined that potential hazards associated with this fireworks event would be a safety concern for anyone on the Lower Mississippi River from mile marker 363.4 to mile marker 364.4. Hazards from fireworks displays include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. This rule is needed to ensure the safety of vessels and the navigable waters before, during, and after the scheduled event.

IV. Discussion of the Rule

This rule establishes a safety zone from 9:40 p.m. to 10:40 p.m. on December 31, 2016. In the case of inclement weather on December 31, 2016, this safety zone will be enforced from 9:40 p.m. until 10:40 p.m. on January 1, 2017. The safety zone will cover all navigable waters of the Lower Mississippi River from mile marker 363.4 to mile marker 364.4 in the vicinity of the bluffs in Natchez, MS at approximate position 31°33.83′ N, 091°24.50′ W. The duration of the zone is intended to ensure the safety of waterway users on these navigable waters before, during, and after the scheduled fireworks display. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. The regulatory text appears at the end of this document.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the size, location, duration, and time-of-day of the safety zone. Vessel traffic will be restricted from entering this safety zone which will impact a small designated area of the Lower Mississippi River for one hour during the evening of New Year's Eve. This safety zone may be ended early if conditions allow. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule will allow 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 E.O. 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in E.O. 13132.

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting one hour that would prohibit entry into a one mile stretch of the Lower Mississippi River, one half mile to either side of a fireworks barge. Normally such actions are categorically excluded from further review under paragraph 34(g) of Figure 2–1 of Commandant Instruction M16475.lD. A preliminary environmental analysis checklist and 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 proposed 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 proposes to amend 33 CFR part 165 as follows:

PART 165 REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS.

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

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

■ 2. Add temporary § 165.T08–1017 to read as follows:

§ 165.T08–1017 Safety Zone; Mississippi River, Natchez, MS.

(a) *Location.* The following area is a safety zone: All waters of the Lower Mississippi River from mile marker 363.4 to mile marker 364.4 in the vicinity of the fireworks launch platform at approximate position 31°33.83′ N, 091°24.50′ W, 200 yards northwest of the Natchez bluffs.

(b) *Effective dates and enforcement times.* The safety zone will be in effect from 9:40 p.m. on December 31, 2016 until 10:40 p.m. on January 1, 2017. The safety zone will be enforced from 9:40 p.m. until 10:40 p.m. on December 31, 2016. In the case of inclement weather on December 31, 2016, this safety zone will be enforced from 9:40 p.m. until 10:40 p.m. on January 1, 2017.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into this zone is prohibited unless specifically authorized by the Captain of the Port Memphis (COTP) or a designated representative.

(2) Any vessel desiring to enter this safety zone must first obtain permission from the COPT or a designated representative, who may be contacted on VHF–FM Channel 16 or by telephone at 866–777–2784.

(d) *Informational broadcasts.* The COTP or a designated representative will inform the public through broadcast notices to mariners of the enforcement periods for the safety zone.

Dated: December 20, 2016.

T. J. Wendt,

Captain, U.S. Coast Guard, Captain of the Port, Memphis, Tennessee.

[FR Doc. 2016–31729 Filed 12–30–16; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–HQ–OAR–2016–0690; FRL–9957–29–OAR]

Extension of Deadline for Action on the November 2016 Section 126 Petition From Maryland

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In this action, the Environmental Protection Agency (EPA) is determining that 60 days is insufficient time to complete the technical and other analyses and public notice-and-comment process required for our review of a petition submitted by the state of Maryland pursuant to section 126 of the Clean Air Act (CAA). The petition requests that the EPA make a finding that 36 electric generating units located in the states of Indiana, Kentucky, Ohio, Pennsylvania, and West Virginia emit air pollution that significantly contributes to nonattainment and interferes with maintenance of the 2008 and 2015 ozone national ambient air quality standards (NAAQS) in state of Maryland. Under section 307(d)(10) of CAA, the EPA is authorized to grant a time extension for responding to a petition if the EPA determines that the extension is necessary to afford the public, and the agency, adequate opportunity to carry out the purposes of the section 307(d) notice-and-comment rulemaking requirements. By this action, the EPA is making that determination. The EPA is therefore extending the deadline for acting on the petition to no later than July 15, 2017.

DATES: This final rule is effective on January 3, 2017.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2016–0690. 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.,* 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 electronically through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Benjamin Gibson, Office of Air Quality Planning and Standards (C545–E), U.S. EPA, Research Triangle Park, North Carolina 27709, telephone number (919) 541–3277, email: *gibson.benjamin@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Legal Requirements for Interstate Air Pollution

This is a procedural action to extend the deadline for the EPA to respond to a petition from the state of Maryland filed pursuant to CAA section 126(b). The EPA received the petition on November 16, 2016. The petition requests that the EPA make a finding under section 126(b) of the CAA that the 36 electric generating units located in the states of Indiana, Kentucky, Ohio, Pennsylvania, and West Virginia are operating in a manner that emits air pollutants in violation of the provisions of section 110(a)(2)(D)(i)(I) of the CAA with respect to the 2008 and 2015 ozone NAAQS.

Section 126(b) of the CAA authorizes states to petition the EPA to find that a major source or group of stationary sources in upwind states emits or would emit any air pollutant in violation of the prohibition of CAA section 110(a)(2)(D)(i) [1] by contributing significantly to nonattainment or maintenance problems in downwind states. Section 110(a)(2)(D)(i)(I) of the CAA prohibits emissions of any air pollutant in amounts which will contribute significantly to nonattainment in, or interfere with maintenance by, any other state with respect to any NAAQS. The petition asserts that emissions from 36 electric generating units emit air pollutants in violation of CAA section 110(a)(2)(D)(i)(I) with respect to the 2008 8-hour ozone NAAQS, set at 0.075 parts per million (ppm), and the revised 2015 8-hour ozone NAAQS, set at 0.070 ppm.[2]

Pursuant to CAA section 126(b), the EPA must make the finding requested in the petition, or must deny the petition within 60 days of its receipt. Under CAA section 126(c), any existing sources for which the EPA makes the requested finding must cease operations within 3 months of the finding, except that the source may continue to operate if it complies with emission limitations and compliance schedules (containing increments of progress) that the EPA may provide to bring about compliance with the applicable requirements as expeditiously as practical but no later than 3 years from the date of the finding.

CAA section 126(b) further provides that the EPA must hold a public hearing on the petition. The EPA's action under section 126 is also subject to the procedural requirements of CAA section 307(d). *See* CAA section 307(d)(1)(N). One of these requirements is notice-and-comment rulemaking, under section 307(d)(3)–(6).

In addition, CAA section 307(d)(10) provides for a time extension, under certain circumstances, for a rulemaking subject to CAA section 307(d). Specifically, CAA section 307(d)(10) provides:

> Each statutory deadline for promulgation of rules to which this subsection applies which requires promulgation less than six months after date of proposal may be extended to not more than six months after date of proposal by the Administrator upon a determination that such extension is necessary to afford the public, and the agency, adequate opportunity to carry out the purposes of the subsection.

CAA section 307(d)(10) may be applied to section 126 rulemakings because the 60-day time limit under CAA section 126(b) necessarily limits the period for promulgation of a final rule after proposal to less than 6 months.

II. Final Rule

A. Rule

In accordance with CAA section 307(d)(10), the EPA is determining that the 60-day period afforded by CAA section 126(b) for responding to the petition from the state of Maryland is not adequate to allow the public and the agency the opportunity to carry out the purposes of CAA section 307(d). Specifically, the 60-day period is insufficient for the EPA to complete the necessary technical review, develop an adequate proposal, and allow time for notice and comment, including an opportunity for public hearing, on a proposed finding regarding whether the 36 electric generating units identified in

[1] The text of CAA section 126 codified in the United States Code cross references CAA section 110(a)(2)(D)(ii) instead of CAA section 110(a)(2)(D)(i). The courts have confirmed that this is a scrivener's error and the correct cross reference is to CAA section 110(a)(2)(D)(i). *See Appalachian Power Co.* v. *EPA, 249 F.3d 1032, 1040–44 (D.C. Cir. 2001).*

[2] On October 1, 2015, the EPA strengthened the ground-level ozone NAAQS, based on extensive scientific evidence about ozone's effects on public health and welfare. *See* 80 FR 65291 (October 26, 2015).

the CAA section 126 petition contribute significantly to nonattainment or interferes with maintenance of the 2008 ozone NAAQS or the 2015 ozone NAAQS in Maryland. Moreover, the 60-day period is insufficient for the EPA to review and develop response to any public comments on a proposed finding, or testimony supplied at a public hearing, and to develop and promulgate a final finding in response to the petition. The EPA is in the process of determining an appropriate schedule for action on the CAA section 126 petition. This schedule must afford the EPA adequate time to prepare a proposal that clearly elucidates the issues to facilitate public comment, and must provide adequate time for the public to comment and for the EPA to review and develop responses to those comments prior to issuing the final rule. As a result of this extension, the deadline for the EPA to act on the petition is July 15, 2017.

B. Notice and Comment Under the Administrative Procedure Act (APA)

This document is a final agency action, but may not be subject to the notice-and-comment requirements of the APA, 5 U.S.C. 553(b). The EPA believes that, because of the limited time provided to make a determination, the deadline for action on the CAA section 126 petition should be extended. Congress may not have intended such a determination to be subject to notice-and-comment rulemaking. However, to the extent that this determination otherwise would require notice and opportunity for public comment, there is good cause within the meaning of 5 U.S.C. 553(b)(3)(B) not to apply those requirements here. Providing for notice and comment would be impracticable because of the limited time provided for making this determination, and would be contrary to the public interest because it would divert agency resources from the substantive review of the CAA section 126 petition.

C. Effective Date Under the APA

This action is effective on January 3, 2017. Under the APA, 5 U.S.C. 553(d)(3), agency rulemaking may take effect before 30 days after the date of publication in the **Federal Register** if the agency has good cause to mandate an earlier effective date. This action—a deadline extension—must take effect immediately because its purpose is to extend by 6 months the deadline for action on the petition. As discussed earlier, the EPA intends to use the 6-month extension period to develop a proposal on the petition and provide time for public comment before issuing the final rule. It would not be possible for the EPA to complete the required notice and comment and public hearing process within the original 60-day period noted in the statute. These reasons support an immediate effective date.

III. Statutory and Executive Order Reviews

A. Executive Orders 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory

This action is exempt from review by the Office of Management and Budget because it simply extends the date for the EPA to take action on a petition.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. This good cause final action simply extends the date for the EPA to take action on a petition and does not impose any new obligations or enforceable duties on any state, local or tribal governments or the private sector. It does not contain any recordkeeping or reporting requirements.

C. Regulatory Flexibility Act (RFA)

This action is not subject to the RFA. The RFA applies only to rules subject to notice-and-comment rulemaking requirements under the APA, 5 U.S.C. 553, or any other statute. This rule is not subject to notice-and-comment requirements because the agency has invoked the APA ''good cause'' exemption under 5 U.S.C. 553(b).

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

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

This action does not have tribal implications, as specified in Executive Order 13175. This good cause final action simply extends the date for the EPA to take action on a petition. Thus, Executive Order 13175 does not apply to this rule.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard. This good cause final action simply extends the date for the EPA to take action on a petition and does not have any impact on human health or the environment.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. The CRA allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice-and-comment rulemaking procedures are impracticable, unnecessary or contrary to the public interest (5 U.S.C. 808(2)). The EPA has made a good cause finding for this rule as discussed in Section II.B of this document, including the basis for that finding.

IV. Statutory Authority

The statutory authority for this action is provided by sections 110, 126 and

307 of the CAA as amended (42 U.S.C. 7410, 7426 and 7607).

V. Judicial Review

Under section 307(b)(1) of the CAA, judicial review of this final rule is available only by the filing of a petition for review in the U.S. Court of Appeals for the appropriate circuit by March 6, 2017. Under section 307(b)(2) of the CAA, the requirements that are the subject of this final rule may not be challenged later in civil or criminal proceedings brought by us to enforce these requirements.

List of Subjects in 40 CFR Part 52

Environmental protection, Administrative practices and procedures, Air pollution control, Electric utilities, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Ozone.

Dated: December 15, 2016.

Gina McCarthy,

Administrator.

[FR Doc. 2016–31258 Filed 12–30–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 414, 416, 419, 482, 486, 488, and 495

[CMS–1656–CN]

RIN 0938–AS82

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Nonexcepted Off-Campus Provider-Based Department of a Hospital; Hospital Value-Based Purchasing (VBP) Program; Establishment of Payment Rates Under the Medicare Physician Fee Schedule for Nonexcepted Items and Services Furnished by an Off-Campus Provider-Based Department of a Hospital; Correction and Extension of Comment Period

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Correction and extension of comment period for final rule and interim final rule.

SUMMARY: This document corrects technical errors that appeared in the final rule with comment period and interim final rule with comment period published in the **Federal Register** on November 14, 2016, entitled ''Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Nonexcepted Off-Campus Provider-Based Department of a Hospital; Hospital Value-Based Purchasing (VBP) Program; Establishment of Payment Rates under the Medicare Physician Fee Schedule for Nonexcepted Items and Services Furnished by an Off-Campus Provider-Based Department of a Hospital.''

This document extends the comment period to January 3, 2017 for both the final rule with comment period and the interim final rule with comment period.

DATES: *Effective date:* This correction is effective January 1, 2017.

Comment period: The comment period for the final rule and interim final rule, published November 14, 2016 (81 FR 79562), is extended to 5 p.m. E.S.T. on January 3, 2017.

FOR FURTHER INFORMATION CONTACT:

Hospital Outpatient Prospective Payment System (OPPS), contact Lela Strong (410) 786–3213.

Electronic Health Record (EHR) Incentive Programs, contact Kathleen Johnson (410) 786–3295 or Steven Johnson (410) 786–3332.

Hospital Outpatient Quality Reporting (OQR) Program Administration, Validation, and Reconsideration Issues, contact Elizabeth Bainger at (410) 786–0529

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2016–26515 of November 14, 2016 (81 FR 79562), titled ''Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program; Establishment of Payment Rates Under the Medicare Physician Fee Schedule for Nonexcepted Items and Services Furnished by an Off-Campus Provider-Based Department of a Hospital'' (hereinafter referred to as the CY 2017 OPPS/ASC final rule), there were a number of technical errors that are identified and corrected in the Correction of Errors section below. The provisions in this correction document are effective as if they had been included in the document published November 14, 2016. Accordingly, the corrections are effective January 1, 2017.

II. Extension of Comment Period

We are extending the comment period. We inadvertently scheduled the comment period to end on December 31, 2016, a Saturday. We ordinarily do not end the comment period on a weekend or federal holiday. Therefore, we are extending the comment period for the final rule and interim final rule to end on the next business day, January 3, 2017.

III. Summary of Errors

A. Errors in the Preamble

1. Hospital Outpatient Prospective Payment System (OPPS) Corrections

On page 79566, in the Table of Contents, we inadvertently included a title that referred to the CY 2017 OPPS/ASC proposed rule instead of the final rule with comment period. We are correcting the title in this correcting document. On the same page, in the table of contents, we made a typographical error in the title of the sixth item, which we are correcting to match the title in the preamble of the document.

On page 79569, we incorrectly stated estimated total payments to OPPS providers as $773 million. We have corrected this figure to be $64 billion.

On page 79582, we incorrectly stated that status indicator ''J1'' procedure claims with modifier ''50'' were included in the C–APC claims accounting and the complexity adjustment evaluations as of January 1, 2015.'' Instead, these claims were included in the C–APC complexity adjustment evaluations presented in the CY 2017 OPPS/ASC final rule with comment period. The results of these evaluations were included in the C–APC complexity adjustment evaluations tab of Addendum J to the CY 2017 OPPS/ASC final rule with comment period.

On pages 79584, we inadvertently omitted discussion of one of the recommendations from the August 2016 meeting of the Advisory Panel on

Hospital Outpatient Payment (HOP Panel). The HOP Panel recommended that, ''CMS provide further information and data for stakeholders to review on how comprehensive APCs are created and their effects; and CMS provide more time for the public to review the information and make proposals to the Panel.'' In this correcting document, we address this recommendation.

On page 79587, due to the change in OPPS payment rates as a result of the updated OPPS weight scaler, we are also updating the payment rate listed for C–APC 5244 (Level 4 Blood Product Exchange and Related Services).

On page 79595, we made technical errors by inadvertently excluding the wage index data for 6 providers in Alaska, Virginia, Ohio, Mississippi, and Puerto Rico when calculating the weight scaler for budget neutrality. We have corrected the weight scaler for budget neutrality to include the wage index data for those 6 providers, which results in a change of the weight scaler from 1.4208 to 1.4214. This revised weight scaler affects all payments that are scaled for budget neutrality. As a result we are also providing corrected addenda as described in the ''Summary of Errors and Corrections to the OPPS and ASC Addenda Posted on the CMS Web site'' section below.

On pages 79607 through 79608, we use the payment rates available in Addenda A and B to display calculation of adjusted payment and copayment. Due to the change in OPPS payment rates as a result of the updated OPPS weight scaler, we are also updating the payment and copayment numbers used in the example to reflect the corrections.

On page 79621, due to the change in OPPS payment rates as a result of the updated OPPS weight scaler, we are also updating the payment rates in Table 13—Final CY 2017 Status Indicator (SI), APC Assignments, and Payment Rates for the Auditory Osseointegrated Procedures (81 FR 79621) for CPT codes 69714, 69715, 69717, and 69718.

On page 79622, due to the change in OPPS payment rates as a result of the updated OPPS weight scaler, we are also updating the payment rates in Table 14—Final CY 2017 Status Indicator (SI), APC Assignments, and Payment Rates for CPT Codes 28297 and 28740.

On page 79624, due to the change in OPPS payment rates as a result of the updated OPPS weight scaler, we are also updating the payment rates in Table 16—Final CY 2017 Status Indicator (SI), APC Assignments, and Payment Rates for the Percutaneous Vertebral Augmentation/Kyphoplasty Procedures.

On page 79627, due to the change in OPPS payment rates as a result of the updated OPPS weight scaler, we are also updating the payment rates in Table 18—Final CY 2017 Status Indicator (SI), APC Assignments, and Payment Rates for the Transcranial Magnetic Stimulation (TMS) Therapy Codes.

On page 79629, due to the change in OPPS payment rates as a result of the updated OPPS weight scaler, we are updating the payment rates for CPT code 75571 to $59.86, for CPT code 77080 to $112.73, and for APC 5822 (Level 2 Health and Behavior Services) to $70.26 for CY 2017.

On pages 79636 through 79637, due to the change in OPPS payment rates as a result of the updated OPPS weight scaler, we are also updating the payment rates in Table 23—Final CY 2017 Status Indicator (SI), APC Assignments, and Payment Rates for the Transprostatic Urethral Implant Procedures.

On pages 79638 through 79639, due to the change in OPPS payment rates as a result of the updated OPPS weight scaler, we are also updating the payment rates in Table 25—Final CY 2017 Status Indicator (SI), APC Assignments, and Payment Rates Certain Cryoablation Procedures.

On page 79641, due to the change in OPPS payment rates as a result of the updated OPPS weight scaler, we are also updating the payment rates in Table 28—Final CY 2017 Status Indicator (SI), APC Assignments, and Payment Rates for the Dialysis Circuit Procedures.

On page 79643, due to the change in OPPS payment rates as a result of the updated OPPS weight scaler, we are also updating the payment rate for CPT code 77371 to $7,455.99 as well as the payment rates in Table 30—Final CY 2017 Status Indicator (SI), APC Assignments, and Payment Rates for the Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) Procedures.

On page 79645, due to the change in OPPS payment rates as a result of the updated OPPS weight scaler, we are also updating the payment rates in Table 32—Final CY 2017 Status Indicator (SI), APC Assignments, and Payment Rates for the Smoking and Tobacco Use Cessation Counseling Services.

On page 79647, we used imprecise language in describing HCPCS codes G0237, G0238, and G0239. Specifically, we stated that ''we believe that we should reassign HCPCS codes G0237, G0238, and G0239 to status indictor ''S'' because these codes also describe pulmonary rehabilitation services.'' We are clarifying that these codes describe respiratory treatment services. We acknowledge that the original language could be interpreted to mean that these codes describe pulmonary rehabilitation services, which was not our intent.

On page 79648, due to the change in OPPS payment rates as a result of the updated OPPS weight scaler, we are also updating the payment rates in Table 34—Final CY 2017 Status Indicator (SI), APC Assignments, and Payment Rates for the Pulmonary Rehabilitation Services.

On page 79662, we incorrectly made certain Status Indicator (SI) and APC assignments in Table 35—Drugs and Biologicals For Which Pass-Through Payment Status Expires December 31, 2016. Specifically, we incorrectly assigned a SI of ''N'' (Items and Services Packaged into APC Rates) to a number of drugs that should have been assigned a SI of ''K'' (Nonpass-Through Drugs and Nonimplantable Biologicals, Including Therapeutic Radiopharmaceuticals). These drugs have also been assigned to APCs for CY 2017. Additionally, on page 79662, we incorrectly described two Long Descriptors (for HCPCS codes J7181 and 7201) that were displayed in Table 35. These Long Descriptors have been revised for CY 2017.

On page 79664, we incorrectly described two Long Descriptors (for HCPCS codes A9587 and A9588) that were displayed in Table 36—Drugs and Biologicals With Pass-Through Payment Status in CY 2017. These Long Descriptors have been revised for CY 2017.

On page 79671, we made technical errors to the description of certain Healthcare Common Procedure Coding System (HCPCS) codes that appeared in Table 37—Skin Substitute Assignments to High Cost and Low Cost Groups for CY 2017. Specifically, we are removing HCPCS codes Q4119, Q4120, and Q4129 to accurately show that these codes were deleted on December 31, 2016, and should not have appeared in Table 37. These codes were correctly assigned to OPPS SI ''D'' in the OPPS Addendum B that was released with the CY 2017 OPPS/ASC final rule.

On page 79708, we used imprecise language in the summary of final policy on how we would apply the ''billing .–. . prior to November 2, 2015,'' statutory language in determining whether an off-campus PBD is excepted or not. Specifically, we stated in the preamble that ''off campus PBDs would be eligible to receive OPPS payment as excepted off- campus PBDs for services that were furnished prior to November 2, 2015, and billed under the OPPS in accordance with timely filing limits.'' We are clarifying that the policy is not specific to services, but rather so long as an off-campus PBD furnished a covered

OPD service prior to November 2, 2015 and billed the OPPS within timely filing limits for that service that the off-campus PBD would be excepted from payment adjustment under the final section 603 payment policy for the items and services the off-campus PBD furnishes on or after January 1, 2017. As noted in the sentence prior (81 FR 79708), we agreed with the commenters that an interpretation of the ''billing under this subsection with respect to covered OPD services furnished prior to [November 2, 2015]'' statutory language could allow for an exception for off-campus PBDs that furnished a covered OPD service prior to November 2, 2015, but had not submitted a bill to Medicare for such service prior to November 2, 2015.

On page 79719, we described the changes to regulation and incorrectly stated the effective date to implement section 603 of Public Law 114–74 is effective January 1, 2017, for cost reporting periods beginning January 1, 2017. The effective date is for items and services furnished on or after January 1, 2017, regardless of when the cost reporting period begins. We have corrected this language to delete the reference to cost reporting periods.

On pages 79869 through 79870, we provided and described Table 52—Estimated Impact of the CY 2017 Changes for the Hospital Outpatient Prospective Payment System, based on rates which applied the incorrect scaler. We have updated the impact table and the description of the table to reflect these corrections.

On Page 79877, we incorrectly described implementation of Section 603 of the Bipartisan Budget Act of 2015 as reducing OPPS payments by $500 million in 2017. We have corrected this estimate to be a reduction of total Part B payments by $50 million in 2017.

2. Ambulatory Surgical Center (ASC) Payment System Corrections

On pages 79741 through 79742, in the discussion of additions to the list of ASC covered surgical procedures, we incorrectly stated that CPT code 22851 (Application of intervertebral biomechanical device(s) (*e.g.,* synthetic cage(s), methlmethacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure)) was deleted effective April 13, 2016. This code was deleted effective December 31, 2016.

On page 79743 in Table 51—Additions to the List of ASC Covered Surgical Procedures for CY 2017 (81 FR 79743), we inadvertently excluded CPT code 22585 (Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure)). This code has a CY 2017 ASC payment indicator of N1.

On pages 79752 through 79753, we inadvertently published an incorrect ASC conversion factor of $45.030 for ASCs that meet the quality reporting requirements. Also, on pages 79752 through 79753, we inadvertently published an incorrect ASC wage index budget neutrality adjustment of 0.9996 that is being corrected to 0.9997. For ASCs that do not meet the quality reporting requirements, we finalized an ASC conversion factor of $44.330. The ASC conversion factor for ASCs that meet the quality reporting requirements is the product of the CY 2016 conversion factor multiplied by the wage index budget neutrality adjustment of 0.9997 and the MFP-adjusted CPI–U payment update (81 FR 79752 to 79753). We have since determined that the 2016 conversion factor of $44.190 used to calculate the CY 2017 conversion factor is incorrect. The corrected 2016 ASC conversion factor for ASCs that meet the quality reporting requirements is $44.177, as finalized in the CY 2016 final rule with comment period (80 FR 70501). Using the correct 2016 ASC conversion factor of $44.177, we have recalculated the 2017 ASC conversion factor to be $45.003 for ASCs that meet quality reporting requirements and a conversion factor of $44.120 for ASCs that do not meet quality reporting requirements. The corrected conversion factor will slightly change payment for some ASC services; therefore we have revised payment rates in ASC addendum AA and addendum BB.

3. Interim Final Rule with Comment Period Corrections

On page 79725, we referenced table X.B.2, but did not include the table in the interim final rule with comment period. This table, Payment for Nonexcepted Items and Services by OPPS Status Indicator, has been posted to the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1656-FC-2017-OPPS-Status-Indicator.zip.*

4. Hospital Outpatient Quality Reporting Program Correction

On page 79784, there was a typographical error in the table entitled ''Previously Finalized and Newly Finalized Hospital OQR Program Measure Set for the CY 2020 Payment Determination and Subsequent Years''. As listed in the table, the measure OP–30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use incorrectly included three asterisks after the name Three asterisks indicates that a measure is voluntary. This measure should have had only two asterisks to indicate that the measure name was updated to reflect the National Quality Forum title, not three, as it is not a voluntary measure. Accordingly, we are correcting the table and updating the number of asterisks next to OP–30 from three to two asterisks.

B. Regulation Text Corrections

1. OPPS Corrections

To implement the provisions of section 1833(t) of the Act, as amended by section 603 of Public Law 114–74, in the CY 2017 OPPS/ASC final rule with comment period, we amended the Medicare regulations by (1) adding a new paragraph (v) to § 419.22 to specify that, effective January 1, 2017, for cost reporting periods beginning January 1, 2017, excluded from payment under the OPPS are items and services that are furnished by an off-campus provider-based department that do not meet the definition of excepted items and services; and (2) adding a new § 419.48 that sets forth the definition of excepted items and services, and also the definition of ''excepted off-campus provider-based department''. On page 79879, we incorrectly stated that the effective date was based on cost reporting periods and are striking that language. Also, on page 79880, we incorrectly implied that on-campus provider-based departments that furnish services after November 2, 2015, could no longer bill under the OPPS in the regulation text at 419.48(b). In addition, on page 79880, in the regulation text at 419.48(b), the definition of an ''excepted off-campus provider-based department'' does not accurately state that the department of a provider must also have billed within timely filing limits. The revised regulation text corrects these technical errors.

2. Electronic Health Record (EHR) Incentive Programs Corrections

In the CY 2017 OPPS/ASC final rule, we inadvertently omitted amendments to § 495.40 that were included in an earlier-published final rule with comment period titled ''Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria

for Physician-Focused Payment Models'' (referred to as the Quality Payment Program (QPP) final rule) (81 FR 77008, 77556–77557, November 4, 2016). We are making the corrections to § 495.40 described below in order to preserve the earlier amendments to that section as finalized in the QPP final rule.

On page 79892, in § 495.40, ''Demonstration of meaningful use criteria,'' paragraph (a), ''Demonstration by EPs,'' we inadvertently omitted a reference to § 495.22 in the introductory text. We are correcting the introductory text to state that an EP must demonstrate that he or she satisfies each of the applicable objectives and associated measures under § 495.20, § 495.22, or § 495.24. Additionally, we are correcting the introductory text to include the phrase ''supports information exchange and the prevention of health information blocking, and engages in activities related to supporting providers with the performance of CEHRT:'' as finalized in the QPP final rule (81 FR 77556), which updates requirements for demonstration of meaningful use to include activities related to health information technology.

On page 79892, in § 495.40, ''Demonstration of meaningful use criteria,'' we are correcting the inadvertent omission of § 495.40(a)(2)(i)(H) and (I) as finalized in the QPP final rule (81 FR 77556), which revise attestation requirements and require EPs to attest their cooperation with certain authorized health IT surveillance and direct review activities as part of demonstrating meaningful use under the Medicare and Medicaid EHR Incentive Programs.

On page 79892, in § 495.40, ''Demonstration of meaningful use criteria,'' paragraph (b), ''Demonstration by eligible hospitals and CAHs,'' we inadvertently omitted a cross reference to § 495.22 in the introductory text. We are correcting the introductory text to state that an eligible hospital or CAH must demonstrate that it satisfies each of the applicable objectives and associated measures under § 495.20, § 495.22, or § 495.24. Additionally, we are correcting the introductory text to include the phrase ''supports information exchange and the prevention of health information blocking, and engages in activities related to supporting providers with the performance of CEHRT:'' as finalized in the QPP (81 FR 77556), which updates the requirements for demonstration of meaningful use to include activities related to health information technology.

On page 79892, in § 495.40 (b), ''Demonstration by eligible hospitals and CAHs,'' we are correcting the inadvertent omission of § 495.40 (b)(2)(i)(H) and (I) as finalized in the QPP final rule (81 FR 77556 through 77557), which revises attestation requirements and requires eligible hospitals and CAHs to attest their cooperation with certain authorized health IT surveillance and direct review activities as part of demonstrating meaningful use under the Medicare and Medicaid EHR Incentive Programs.

C. Summary of Errors and Corrections to the OPPS and ASC Addenda Posted on the CMS Web site

In Addendum J, on the Complexity Adjustment tab, CPT code 36908—Transcatheter placement of an intravascular stent(s), central dialysis segment, performed through dialysis circuit, including all imaging radiological supervision and interpretation required to perform the stenting, and all angioplasty in the central dialysis segment (List separately in addition to code for primary procedure) was incorrectly written as 368x8. Also, CPT code 24200 (Removal of foreign body, upper arm or elbow; subcutaneous) was incorrectly excluded from Addendum J. The revised version of Addendum J is available via the Internet on the CMS Web site.

The payment and copayment rates in Addendum A (Final OPPS APCs for CY 2017), Addendum B (Final OPPS Payment by HCPCS Code for CY 2017), Addendum C (Final HCPCS Codes Payable Under the 2017 OPPS by APC), ASC Addendum AA (Final ASC Covered Surgical Procedures for CY 2016 (Including Surgical Procedures for Which Payment is Packaged)), ASC Addendum BB (Final ASC Covered Ancillary Services Integral to Covered Surgical Procedures for CY 2016 (Including Ancillary Services for Which Payment is Packaged)) and the payment rates in the 2017 Drug, Blood, Brachytherapy Costs Statistics file that were published on the CMS Web site in conjunction with the CY 2017 OPPS/ASC Final Rule with comment period have been updated to reflect corrections to the weight scaler. The payment rates included in the corrected versions of the Addenda have also been corrected within the text of the CY 2017 OPPS/ASC Final Rule with comment period, as well as under the columns titled ''Final CY 2017 OPPS Payment Rate'' in Tables 13, 14, 16, 18, 23, 25, 28, 30, 32, and 34.

IV. Waiver of Proposed Rulemaking and Delay in Effective Date

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rule in the **Federal Register** before the provisions of a rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment. In addition, section 553(d) of the APA, and section 1871(e)(1)(B)(i) mandate a 30-day delay in effective date after issuance or publication of a rule. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the notice and comment and delay in effective date APA requirements; in cases in which these exceptions apply, sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act provide exceptions from the notice and 60-day comment period and delay in effective date requirements of the Act as well. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal rulemaking requirements for good cause if the agency makes a finding that the notice and comment process are impracticable, unnecessary, or contrary to the public interest. In addition, both section 553(d)(3) of the APA and section 1871(e)(1)(B)(ii) of the Act allow the agency to avoid the 30-day delay in effective date where such delay is contrary to the public interest and an agency includes a statement of support.

We believe that this correcting document does not constitute a rulemaking that would be subject to these requirements. This correcting document corrects technical and typographic errors in the preamble, addenda, payment rates, tables, and appendices included or referenced in the CY 2017 OPPS/ASC final rule with comment period and interim final rule with comment period but does not make substantive changes to the policies or payment methodologies that were adopted in the final rule with comment period and interim final rule with comment period. As a result, the corrections made through this correcting document are intended to ensure that the information in the CY 2017 OPPS/ASC final rule with comment period and interim final rule with comment period accurately reflects the policies adopted in those rules.

In addition, even if this were a rulemaking to which the notice and comment procedures and delayed effective date requirements applied, we

find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the corrections in this document into the final rule with comment period and interim final rule with comment period or delaying the effective date would be contrary to the public interest because it is in the public's interest for providers to receive appropriate payments in as timely a manner as possible, and to ensure that the CY 2017 OPPS/ASC final rule with comment period and interim final rule with comment period accurately reflect our policies as of the date they take effect and are applicable.

Furthermore, such procedures would be unnecessary, as we are not altering our payment methodologies or policies, but rather, we are simply correctly implementing the policies that we previously proposed, received comment on, and subsequently finalized. This correcting document is intended solely to ensure that the CY 2017 OPPS/ASC final rule with comment period and interim final rule with comment period accurately reflects these payment methodologies and policies. For these reasons, we believe we have good cause to waive the notice and comment and effective date requirements.

V. Correction of Errors

In FR Doc. 2016–26515 of November 14, 2016 (81 FR 79562), make the following corrections:

Preamble Corrections

1. On page 79566, third column,

a. In line 44, Table of Contents, the title ''5. Summary of Proposals'' is corrected to read ''5. Summary of Final Policies''.

b. In line 45, Table of Contents, the title ''6. Final Changes to Regulations'' is corrected to read ''6. Changes to Regulations''.

2. On page 79569, second column, second full paragraph, under the bulleted item, ''OPPS Update,'' in line 20, replace ''$773 million'' with ''$64 billion''.

3. On page 79582, third column, second full paragraph, under a response to public comment, in lines 29 through 34, the last sentence of the paragraph is corrected to read ''Status indicator ''J1'' procedure claims with modifier ''50'' will be included in the complexity adjustment evaluation for CY 2017. This evaluation can be found in Addendum J to the CY 2017 OPPS/ASC final rule with comment period.''

4. On page 79584, first column, first partial paragraph, in line 21, the following language is inserted after ''. . . analyses of the C–APC payment policy.'' and before ''Regarding the comment about creating. . . .'': We are accepting the recommendation that the HOP Panel made at the August 22, 2016 meeting to ''provide further information and data for stakeholders to review on how comprehensive APCs are created and their effects and to provide more time for the public to review the information and make proposals to the Panel.'' We plan to provide the results of an analysis of our comprehensive packaging policies in CY 2017. In addition, we will consider scheduling future HOP Panel meetings on a date that allows stakeholders as much time as is practicable subsequent to display of the proposed rule to analyze and review our proposed policies and other data prior to the meeting.

5. On page 79587, third column, first full paragraph, in line 16, replace ''$27,752'' with ''$27,764''.

6. On page 79595, third column, third paragraph, replace ''1.4208'' with ''1.4214.''

7. On page 79607,

a. First column, bottom half of the page, last full paragraph—

(1) In line 17, replace ''$538.88'' with ''$539.11.''

(2) In line 21, replace ''$528.10'' with ''$528.33.''

b. In the second column, first partial paragraph,

(1) In lines 1 and 2, replace ''$418.26 (.60 * $538.88 * 1.2936).'' with ''$418.44 (.60 * $539.11 * 1.2936).''

(2) In line 5, replace ''$409.89 (.60 * $528.10 * 1.2936).'' with ''$410.07 (.60 * $528.33 * 1.2936).''

(3) In line 8, replace ''$215.55 (.40 * $538.88).'' with ''$215.64 (.40 * $539.11).''

(4) In line, replace ''$211.24 (.40 * $528.10).'' with ''$211.33 (.40 * $528.33).''

(5) In lines 15 and 16, replace ''$633.81 ($418.26 +$215.55).'' with ''$634.08 ($418.44 +$215.64).''

(6) In lines 18 and 19, replace ''$621.13 ($409.89 + $211.24).'' with ''$621.40 ($410.07 + $211.33).''

8. On page 79608, second column, third full paragraph, under ''Step 1,'' in lines 5 and 8, replace ''$107.78'' with $107.83'' and ''$538.88'' with ''$539.11.''

9. On page 79621, Table 13—Final CY 2017 Status Indicator (SI), APC, and Payment Rates for the Auditory Osseointegrated Procedures, is corrected to read as follows:

TABLE 13—FINAL CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR THE AUDITORY OSSEOINTEGRATED PROCEDURES

CPT code	Long descriptors	CY 2016 OPPS SI	CY 2016 OPPS APC	CY 2016 OPPS payment rate	Final CY 2017 OPPS SI	Final CY 2017 OPPS APC	Final CY 2017 OPPS payment rate
69714	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy.	J1	5125	$10,537.90	J1	5115	$9,561.23
69715	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy.	J1	5125	10,537.90	J1	5116	14,704.13
69717	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy.	J1	5123	4,969.26	J1	5114	5,221.57

TABLE 13—FINAL CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR THE AUDITORY OSSEOINTEGRATED PROCEDURES—Continued

CPT code	Long descriptors	CY 2016 OPPS SI	CY 2016 OPPS APC	CY 2016 OPPS payment rate	Final CY 2017 OPPS SI	Final CY 2017 OPPS APC	Final CY 2017 OPPS payment rate
69718	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy.	J1	5124	7,064.07	J1	5115	9,561.23

10. On page 79622, Table 14—Final CY 2017 Status Indicator (SI), APC Assignments, and Payment Rates for CPT Codes 28297 and 28740, is corrected to read as follows:

TABLE 14—FINAL CY 2017 STAUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR CPT CODES 28297 AND 28740

CPT code	Long descriptors	CY 2016 OPPS SI	CY 2016 OPPS APC	CY 2016 OPPS payment rate	Final CY 2017 OPPS SI	Final CY 2017 OPPS APC	Final CY 2017 OPPS payment rate
28297	Correction, hallux valgus (bunion), with or without sesamoidectomy; lapidus-type procedure.	J1	5124	$7,064.07	J1	5114	$5,221.57
28740	Arthrodesis, midtarsal or tarsometatarsal, single joint.	J1	5124	7,064.07	J1	5114	5,221.57

11. On page 79624, Table 16—Final CY 2017 Status Indicator (SI), APC Assignments, and Payment Rates for the Percutaneous Vertebral Augmentation/Kyphoplasty Procedures, is corrected to read as follows:

TABLE 16—FINAL CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR THE PERCUTANEOUS VERTEBRAL AUGMENTATION/KYPHOPLASTY PROCEDURES

CPT code	Long descriptors	CY 2016 OPPS SI	CY 2016 OPPS APC	CY 2016 OPPS payment rate	Final CY 2017 OPPS SI	Final CY 2017 OPPS APC	Final CY 2017 OPPS payment rate
22513	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic.	J1	5124	$7,064.07	J1	5114	$5,221.57
22514	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar.	J1	5124	7,064.07	J1	5114	5,221.57
22515	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; each additional thoracic or lumbar vertebral body (list separately in addition to code for primary procedure).	N	N/A	Packaged	N	N/A	Packaged

12. On page 79627, Table 18—Final CY 2017 Status Indicator (SI), APC Assignments, and Payment Rates for the Transcranial Magnetic Stimulation (TMS) Therapy Codes, is corrected to read as follows:

TABLE 18—FINAL CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR THE TRANSCRANIAL MAGNETIC STIMULATION (TMS) THERAPY CODES

CPT code	Long descriptors	CY 2016 OPPS SI	CY 2016 OPPS APC	CY 2016 OPPS payment rate	Final CY 2017 OPPS SI	Final CY 2017 OPPS APC	Final CY 2017 OPPS payment rate
90867	Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; initial, including cortical mapping, motor threshold determination, delivery and management.	S	5722	$220.35	S	5722	$232.31
90868	Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; subsequent delivery and management, per session.	S	5722	220.35	S	5722	232.31
90869	Therapeutic repetitive transcranial magnetic stimulation (tms) treatment; subsequent motor threshold re-determination with delivery and management.	S	5722	$220.35	S	5721	$127.10

13. On page 79629,

a. Second column,

1. First partial paragraph, last sentence, in line 19, replace ''$59.84'' with $59.86

2. Second full paragraph, last sentence, in line 27, replace ''$112.69'' with ''$112.73''.

b. Third column, first full paragraph, in line 16, replace ''70.23.'' with ''$70.26.''

14. On pages 79636 through 79637, Table 23—Final CY 2017 Status Indicator (SI), APC Assignments, and Payment Rates for the Transprostatic Urethral Implant Procedures, is corrected to read as follows:

TABLE 23—FINAL CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS AND PAYMENT RATES FOR THE TRANSPROSTATIC URETHRAL IMPLANT PROCEDURES

CPT/ HCPCS code	Long descriptors	CY 2016 OPPS SI	CY 2016 OPPS APC	CY 2016 OPPS payment rate	Final CY 2017 OPPS SI	Final CY 2017 OPPS APC	Final CY 2017 OPPS payment rate
C9739	Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants.	J1	5375	$3,393.73	J1	5375	$3,484.01
C9740	Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants.	T	1565	5,250.00	J1	5376	7,452.66
52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant.	B	N/A	N/A	B	N/A	N/A
52442	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (list separately in addition to code for primary procedure).	B	N/A	N/A	B	N/A	N/A

15. On pages 79638 through 79639, Table 25—Final CY 2017 Status Indicator (SI), APC Assignments, and Payment Rates Certain Cryoablation Procedures, is corrected to read as follows:

TABLE 25—FINAL CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR CERTAIN CRYOABLATION PROCEDURES

CPT/ HCPCS code	Long descriptors	CY 2016 OPPS SI	CY 2016 OPPS APC	CY 2016 OPPS payment rate	Final CY 2017 OPPS SI	Final CY 2017 OPPS APC	Final CY 2017 OPPS payment rate
20983	Ablation therapy for reduction or eradication of 1 or more bone tumors (eg, metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; cryoablation.	T	5352	$4,118.23	J1	5114	$5,221.57
47383	Ablation, 1 or more liver tumor(s), percutaneous, cryoablation.	T	5352	4,118.23	J1	5361	4,199.13
50593	Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy.	T	5352	4,118.23	J1	5362	6,969.84
0340T	Ablation, pulmonary tumor(s), including pleura or chest wall when involved by tumor extension, percutaneous, cryoablation, unilateral, includes imaging guidance.	T	5352	4,118.23	J1	5361	4,199.13
0440T	Ablation, percutaneous, cryoablation, includes imaging guidance; upper extremity distal/peripheral nerve.	J1	5361	4,001.15	J1	5432	4,151.86
0441T	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve.	J1	5361	4,001.15	J1	5432	4,151.86
0442T	Ablation, percutaneous, cryoablation, includes imaging guidance; nerve plexus or other truncal nerve (eg, brachial plexus, pudendal nerve).	T	5352	4,118.23	J1	5432	4,151.86

16. On page 79641, Table 28—Final CY 2017 Status Indicator (SI), APC Assignments, and Payment Rates for the Dialysis Circuit Procedures, is corrected to read as follows:

TABLE 28—FINAL CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR THE DIALYSIS CIRCUIT PROCEDURES

Proposed CY 2017 CPT code	Final CY 2017 CPT code	Short descriptors	CY 2016 OPPS SI	CY 2016 OPPS APC	CY 2016 OPPS payment rate	Final CY 2017 OPPS SI	Final CY 2017 OPPS APC	Final CY 2017 OPPS payment rate
36147	36147	Access av dial grft for eval	T	5181	$862.51	D	.....	.....
36148	36148	Access av dial grft for proc	N	.....	.....	D	.....	.....
369X1	36901	Intro cath dialysis circuit	.....	.....	.....	T	5181	$684.13
369X2	36902	Intro cath dialysis circuit	.....	.....	.....	J1	5192	4,825.20
369X3	36903	Intro cath dialysis circuit	.....	.....	.....	J1	5193	9,752.43
369X4	36904	Thrmbc/nfs dialysis circuit	.....	.....	.....	J1	5192	4,825.20
369X5	36905	Thrmbc/nfs dialysis circuit	.....	.....	.....	J1	5193	9,752.43
369X6	36906	Thrmbc/nfs dialysis circuit	.....	.....	.....	J1	5194	14,782.14
369X7	36907	Balo angiop ctr dialysis seg	.....	.....	.....	N	N/A	N/A
369X8	36908	Stent plmt ctr dialysis seg	.....	.....	.....	N	N/A	N/A
369X9	36909	Dialysis circuit embolj	.....	.....	.....	N	N/A	N/A

17. On page 79643,

a. First column, first partial paragraph, in line 14, replace ''$7, 453.'' with ''$7,456.''

b. Table 30—Final CY 2017 Status Indicator (SI), APC Assignments, and Payment Rates for the Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) Procedures, is corrected to read as follows:

TABLE 30—FINAL CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR THE MAGNETIC RESONANCE IMAGE GUIDED HIGH INTENSITY FOCUSED ULTRASOUND (MRgFUS) PROCEDURES

CPT/ HCPCS code	Long descriptors	CY 2016 OPPS SI	CY 2016 OPPS APC	CY 2016 OPPS payment rate	Final CY 2017 OPPS SI	Final CY 2017 OPPS APC	Final CY 2017 OPPS payment rate
0071T	Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume less than 200 cc of tissue.	T	5414	$1,861.18	J1	5414	$2,085.47

TABLE 30—FINAL CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR THE MAGNETIC RESONANCE IMAGE GUIDED HIGH INTENSITY FOCUSED ULTRASOUND (MRgFUS) PROCEDURES—Continued

CPT/ HCPCS code	Long descriptors	CY 2016 OPPS SI	CY 2016 OPPS APC	CY 2016 OPPS payment rate	Final CY 2017 OPPS SI	Final CY 2017 OPPS APC	Final CY 2017 OPPS payment rate
0072T	Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume greater or equal to 200 cc of tissue.	T	5414	1,861.18	J1	5414	2,085.47
0398T	Magnetic resonance image guided high intensity focused ultrasound (mrgfus), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed.	E	N/A	N/A	S	1537	9,750.50
C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance.	T	5122	2,395.59	J1	5114	2,085.47

18. On page 79645, Table 32—Final CY 2017 Status Indicator (SI), APC Assignments, and Payment Rates for the Smoking and Tobacco Use Cessation Counseling Services, is corrected to read as follows:

TABLE 32—FINAL CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR THE SMOKING AND TOBACCO USE CESSATION COUNSELING SERVICES

CPT/ HCPCS code	Long descriptors	CY 2016 OPPS SI	CY 2016 OPPS APC	CY 2016 OPPS payment rate	Final CY 2017 OPPS SI	Final CY 2017 OPPS APC	Final CY 2017 OPPS payment rate
99406	Smoking and tobacco use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes.	S	5821	$27.12	S	5821	$25.23
99407	Smoking and tobacco use cessation counseling visit; intensive, greater than 10 minutes.	S	5821	27.12	S	5821	25.23
G0436	Smoking and tobacco cessation counseling visit for the asymptomatic patient; intermediate, greater than 3 minutes, up to 10 minutes.	S	5821	27.12	D	N/A	N/A
G0437	Smoking and tobacco cessation counseling visit for the asymptomatic patient; intensive, greater than 10 minutes.	S	5822	69.65	D	N/A	N/A

19. On page 79647, first column, second full paragraph, under a response to public comment, the last two sentences of the paragraph are corrected to read ''However, the rationale for this modification of the proposal for these codes is not related to the statutory provision of section 144 of the Medicare Improvements for Patients and Providers Act of 2008. We believe that pulmonary rehabilitation (and the related respiratory treatment services) are not typically ancillary to the other HOPD services that may be furnished to beneficiaries. These services are typically part of a course of treatment that is prescribed after a diagnosis is made and often after other treatments are initiated or completed.''

20. On page 79648, Table 34—Final CY 2017 Status Indicator (SI), APC Assignments, and Payment Rates for the Pulmonary Rehabilitation Services, is corrected to read as follows:

TABLE 34—FINAL CY 2017 STATUS INDICATOR (SI), APC ASSIGNMENTS, AND PAYMENT RATES FOR THE PULMONARY REHABILITATION SERVICES

HCPCS code	Long descriptors	CY 2016 OPPS SI	CY 2016 OPPS APC	CY 2016 OPPS payment	Final CY 2017 OPPS SI	Final CY 2017 OPPS APC	Final CY 2017 OPPS payment
G0237	Therapeutic procedures to increase strength or endurance of respiratory muscles, face to face, one on one, each 15 minutes (includes monitoring).	Q1	5734	$91.18	S	5732	$28.38
G0238	Therapeutic procedures to improve respiratory function, other than described by g0237, one on one, face to face, per 15 minutes (includes monitoring).	Q1	5733	55.94	S	5732	28.38
G0239	Therapeutic procedures to improve respiratory function or increase strength or endurance of respiratory muscles, two or more individuals (includes monitoring).	Q1	5732	30.51	S	5732	28.38
G0424	Pulmonary rehabilitation, including exercise (includes monitoring), one hour, per session, up to two sessions per day.	Q1	5733	55.94	S	5733	54.55

21. On page 79662, Table 35—Drugs and Biologicals for Which Pass-Through Payment Status Expires December 31, 2016, is corrected to read as follows:

TABLE 35—DRUGS AND BIOLOGICALS FOR WHICH PASS–THROUGH PAYMENT STATUS EXPIRES DECEMBER 31, 2016

CY 2017 HCPCS code	CY 2017 Long descriptor	Final CY 2017 status indicator	Final CY 2017 APC
C9497	Loxapine, inhalation powder, 10 mg	K	9497
J1322	Injection, elosulfase alfa, 1mg	K	1480
J1439	Injection, ferric carboxymaltose, 1 mg	K	9441
J1447	Injection, TBO-Filgrastim, 1 micrograms	K	1748
J3145	Injection, testosterone undecanoate, 1 mg	N	N/A
J3380	Injection, vedolizumab, 1 mg	K	1489
J7181	Factor XIII (antihemophilic factor, recombinant), Tretten, per i.u	K	1746
J7200	Factor ix (antihemophilic factor, recombinant), Rixubus, per i.u	K	1467
J7201	Factor ix (antihemophilic factor, recombinant), Alprolix, per i.u	K	1486
J7205	Injection, factor viii, fc fusion protein, (recombinant), per i.u	K	1656
J7508	Tacrolimus, Extended Release, Oral, 0.1 mg	N	N/A
J9301	Injection, obinutuzumab, 10 mg	K	1476
J9308	Injection, ramucirumab, 5 mg	K	1488
J9371	Injection, Vincristine Sulfate Liposome, 1 mg	K	1466
Q4121	Theraskin, per square centimeter	N	N/A

22. On page 79664, Table 36—Drugs and Biologicals with Pass-Through Payment Status in CY 2017, the Long Descriptors for CY HCPCS codes A9588 and A9587 are revised to read as follows:

CORRECTIONS TO TABLE 36—DRUGS AND BIOLOGICALS WITH PASS–THROUGH PAYMENT STATUS IN CY 2017

CY 2016 HCPCS code	CY 2017 HCPCS code	CY 2017 Long descriptor	CY 2017 status indicator	CY 2017 APC
N/A	A9588	Fluciclovine f-18, diagnostic, 1 mCi	G	9052
N/A	A9587	Gallium Ga-68, dotatate, diagnostic, 0.1 mCi	G	9056

23. On page 79671, in Table 37—Assignments to High Cost and Low Cost Groups for CY 2017, remove HCPCS codes Q4119, Q4120, and Q4129.

24. On page 79708, third column, in lines 28 through 31, the words ''for services that were furnished prior to November 2, 2015, and billed under the OPPS in accordance with timely filing limits.'' are corrected to read ''if the PBD furnished a covered OPD service prior to November 2, 2015 and billed the OPPS within timely filing limits for that service.''

25. On page 79719, third column, first partial paragraph, in lines 6 and 7, remove the words ''for cost reporting periods beginning January 1, 2017,''.

26. On page 79741, third column, fourth full paragraph, in lines 10 and 11, the words ''was deleted by the AMA Editorial Panel in April 2016.'' are corrected to read ''will be deleted effective December 31, 2016.''

27. On page 79742, first column, first full paragraph, in lines 2 and 3, the words ''was deleted effective April 13, 2016,'' are corrected to read ''will be deleted effective December 31, 2016,''.

28. On page 79743, Table 51—Additions To The List of ASC Covered Surgical Procedures For CY 2017, CPT code 22585 is added in numerical order to read as follows:

CORRECTIONS TO TABLE 51—ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2017

CY 2017 CPT code	CY 2017 long descriptor	CY 2017 ASC payment indicator
22585	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure).	N1

29. On page 79752, third column, bottom half of the page, first full paragraph,

a. In line 11, replace ''0.9996'' with ''0.9997.''

b. In line 27, replace ''$45.030'' with ''$45.003.''

c. In line 30, replace ''$44.190'' with ''$44.177.''

d. In line 32, replace ''0.9996'' with ''0.9997.''

30. On page 79753,

a. First column, first partial paragraph,

(1) In line 9, replace ''$44.330'' with ''$44.120.''

(2) In line 12, replace ''$44.190'' with ''$44.177.''

(3) In line 14, replace ''0.9996'' with ''0.9997.''

b. Second column, second full paragraph, in line 7, replace ''$45.030'' with ''$45.003.''

31. On page 79784, the un-numbered table—PREVIOUSLY FINALIZED AND NEWLY FINALIZED HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2020 PAYMENT DETERMINATION AND SUBSEQUENT YEARS, is corrected by removing the three asterisks, ''***'' after the OP–30 measure name and adding in its place two asterisks, ''**'' to read as follows:

0659	OP–30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use. **

32. On page 79868,

a. Second column, first full paragraph, in line 3, replace ''1.7'' with ''1.8.''

b. Third column, first paragraph, in lines 15 and 16, ''an increase of 0.1 percent to 0.3 percent'' is corrected to read ''no change to an increase of 0.3 percent.''

33. On page 79869,

a. Second column, first full paragraph, in line 11, replace ''1.7'' with ''1.8.''

b. Third column, first full paragraph, in line 2, replace ''1.7'' with ''1.8.''

34. On pages 79869 through 79870, Table 52—Estimated Impact of the CY 2017

Changes for the Hospital Outpatient Prospective Payment System, is corrected to read as follows:

TABLE 52—IMPACT OF CHANGES FOR FINAL CY 2017 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

	Number of hospitals (1)	APC recalibration (all changes) (2)	New wage index and provider adjustments (3)	All budget neutral changes (combined cols 2,3) with market basket update (4)	All changes (5)
All Providers *	3906	0.0	0.0	1.7	1.8
All Hospitals (excludes hospitals held harmless and CMHCs)	3789	0.0	0.0	1.8	1.8
Urban Hospitals	2958	0.0	0.0	1.7	1.8
Large Urban (GT 1 Mill.)	1616	0.0	−0.1	1.6	1.7
Other Urban (LE 1 Mill.)	1342	0.1	0.1	1.8	1.8
Rural Hospitals	831	0.2	0.3	2.2	2.2
Sole Community	376	0.2	0.4	2.3	2.2
Other Rural	455	0.2	0.2	2.1	2.1
Beds (Urban):					
0–99 Beds	1045	−0.3	0.2	1.6	1.7
100–199 Beds	834	0.2	−0.1	1.8	1.8
200–299 Beds	465	0.2	0.0	1.9	1.9
300–499 Beds	405	0.1	0.0	1.8	1.9
500 + Beds	209	−0.2	0.0	1.4	1.5
Beds (Rural):					
0–49 Beds	340	0.3	0.5	2.6	2.5
50–100 Beds	299	0.2	0.4	2.4	2.3
101–149 Beds	108	0.1	−0.2	1.6	1.7
150–199 Beds	45	0.0	0.4	2.2	2.1
200 + Beds	39	0.2	0.2	2.1	2.1

TABLE 52—IMPACT OF CHANGES FOR FINAL CY 2017 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM—Continued

	Number of hospitals (1)	APC recalibration (all changes) (2)	New wage index and provider adjustments (3)	All budget neutral changes (combined cols 2,3) with market basket update (4)	All changes (5)
Region (Urban):					
New England	146	0.0	−1.1	0.6	0.6
Middle Atlantic	350	0.0	0.1	1.7	1.7
South Atlantic	465	0.1	0.0	1.7	1.8
East North Cent	473	0.1	0.1	1.8	1.9
East South Cent	177	−0.4	0.3	1.6	1.7
West North Cent	182	−0.1	0.0	1.6	1.5
West South Cent	527	−0.2	0.3	1.8	1.9
Mountain	206	0.2	1.0	2.9	3.0
Pacific	383	0.4	−0.3	1.7	1.8
Puerto Rico	49	0.5	−0.3	1.8	1.8
Region (Rural):					
New England	21	0.9	0.5	3.1	3.0
Middle Atlantic	55	0.1	1.2	3.0	3.0
South Atlantic	126	0.3	−0.3	1.7	1.7
East North Cent	121	0.2	0.3	2.2	2.2
East South Cent	158	0.0	0.2	1.9	1.9
West North Cent	100	0.0	0.4	2.1	2.0
West South Cent	168	0.2	0.7	2.6	2.6
Mountain	58	0.2	−0.1	1.9	1.8
Pacific	24	0.3	−0.1	1.9	1.9
Teaching Status:					
Non-Teaching	2712	0.1	0.1	1.9	2.0
Minor	731	0.1	0.0	1.9	1.9
Major	346	−0.2	−0.1	1.4	1.5
DSH Patient Percent:					
0	10	−1.7	−0.2	−0.2	−0.1
GT 0–0.10	305	−0.4	0.0	1.2	1.3
0.10–0.16	270	0.1	0.1	1.8	1.8
0.16–0.23	600	0.1	0.1	2.0	2.0
0.23–0.35	1135	0.1	0.1	1.9	1.9
GE 0.35	895	0.1	−0.1	1.7	1.7
DSH not Available**	574	−1.4	−0.2	0.1	0.2
Urban Teaching/DSH:					
Teaching & DSH	975	0.0	0.0	1.6	1.7
No Teaching/DSH	1425	0.1	0.1	1.9	1.9
No Teaching/No DSH	10	−1.7	−0.2	−0.2	−0.1
DSH Not Available2	548	−1.4	−0.3	0.0	0.1
Type of Ownership:					
Voluntary	1983	0.1	0.1	1.8	1.9
Proprietary	1306	0.0	0.1	1.7	1.8
Government	500	−0.1	−0.1	1.5	1.6
CMHCs	50	−15.0	−0.4	−13.9	−13.7

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all final CY 2017 OPPS policies and compares those to the CY 2016 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the final FY 2017 hospital inpatient wage index, including all hold harmless policies and transitional wages. The rural adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the cancer hospital adjustment is 1.003 because the payment-to-cost ratio target changes from 0.92 in CY 2016 to 0.91 in CY 2017.

Column (4) shows the impact of all budget neutrality adjustments and the addition of the final 1.65 percent OPD fee schedule update factor (2.7 percent reduced by 0.3 percentage points for the final productivity adjustment and further reduced by 0.75 percentage point in order to satisfy statutory requirements set forth in the Affordable Care Act). It also includes the impact of the additional adjustment of 1.0004 for Lab services with L1 Modifiers packaged into the OPPS.

Column (5) shows the additional adjustments to the conversion factor resulting from the frontier adjustment, a change in the pass-through estimate, and adding estimated outlier payments.

These 3,906 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.

** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

■ 35. On page 79871, third column, first partial paragraph, in the last line, replace ''$45.016'' with ''$45.003.''

■ 36. On page 79877, third column, last paragraph, in lines 2 and 3, the phrase ''OPPS payments by $500 million'' is corrected to read ''Part B payments by $50 million.''

Regulations Text Corrections

§ 419.22 [Corrected]

■ 37. On page 79879, second column, in § 419.22, ''Hospital services excluded

from payment under the hospital outpatient prospective payment system,'' the words ''for cost reporting periods beginning on or after January 1, 2017,'' are removed.

■ 38. On page 79880, first column, in § 419.48, paragraph (b) is corrected to read as follows:

§ 419.48, ''Definition of excepted items and services

* * * * *

(b) For the purpose of this section, ''excepted off-campus provider-based department'' means a ''department of a provider'' (as defined at § 413.65(a)(2) of this chapter) that is located on the campus (as defined in § 413.65(a)(2) of this chapter) or within the distance described in such definition from a ''remote location of a hospital'' (as defined in § 413.65(a)(2) of this chapter) that meets the requirements for provider-based status under § 413.65 of this chapter. This definition also includes an off-campus department of a provider that was furnishing services prior to November 2, 2015 that were billed under the OPPS in accordance with timely filing limits.

* * * * *

■ 39. Section 495.40 is corrected as follows:

■ a. On page 79892, in the first column, in amendment 27, redesignate instructions d through f as instructions e through g respectively and add a new instruction d to read ''d. Adding paragraphs (a)(2)(i)(H) and (I).''

■ b. On page 79892, in the second column, in amendment 27, correct redesignated instruction g to read ''g. Adding new paragraphs (b)(2)(i)(G), (H), and (I).''

■ c. On page 79892, in the second column, paragraph (a) introductory text is correctly revised.

■ d. On page 79892, in the second column, paragraphs (a)(2)(i)(H) and (I) are added.

■ e. On page 79892, in the second column, paragraph (b) introductory text is correctly revised.

■ f. On page 79892, in the third column paragraphs (b)(2)(i)(H) and (I) are added.

The revisions and additions read as follows:

§ 495.40 Demonstration of meaningful use criteria.

(a) Demonstration by EPs. An EP must demonstrate that he or she satisfies each of the applicable objectives and associated measures under § 495.20, § 495.22 or § 495.24, supports information exchange and the prevention of health information blocking, and engages in activities related to supporting providers with the performance of CEHRT:

* * * * *

(2) * * *

(i) * * *

(H) *Supporting providers with the performance of CEHRT (SPPC).* To engage in activities related to supporting providers with the performance of CEHRT, the EP—

(*1*) Must attest that he or she:

(*i*) Acknowledges the requirement to cooperate in good faith with ONC direct review of his or her health information technology certified under the ONC Health IT Certification Program if a request to assist in ONC direct review is received; and

(*ii*) If requested, cooperated in good faith with ONC direct review of his or her health information technology certified under the ONC Health IT Certification Program as authorized by 45 CFR part 170, subpart E, to the extent that such technology meets (or can be used to meet) the definition of CEHRT, including by permitting timely access to such technology and demonstrating its capabilities as implemented and used by the EP in the field.

(*2*) Optionally, may also attest that he or she:

(*i*) Acknowledges the option to cooperate in good faith with ONC–ACB surveillance of his or her health information technology certified under the ONC Health IT Certification Program if a request to assist in ONC–ACB surveillance is received; and

(*ii*) If requested, cooperated in good faith with ONC–ACB surveillance of his or her health information technology certified under the ONC Health IT Certification Program as authorized by 45 CFR part 170, subpart E, to the extent that such technology meets (or can be used to meet) the definition of CEHRT, including by permitting timely access to such technology and demonstrating capabilities as implemented and used by the EP in the field.

(I) *Support for health information exchange and the prevention of information blocking.* For an EHR reporting period in CY 2017 and subsequent years, the EP must attest that he or she—

(*1*) Did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology.

(*2*) Implemented technologies, standards, policies, practices, and agreements reasonably calculated to ensure, to the greatest extent practicable and permitted by law, that the certified EHR technology was, at all relevant times—

(*i*) Connected in accordance with applicable law;

(*ii*) Compliant with all standards applicable to the exchange of information, including the standards, implementation specifications, and certification criteria adopted at 45 CFR part 170;

(*iii*) Implemented in a manner that allowed for timely access by patients to their electronic health information; and

(*iv*) Implemented in a manner that allowed for the timely, secure, and trusted bidirectional exchange of structured electronic health information with other health care providers (as defined by 42 U.S.C. 300jj(3)), including unaffiliated providers, and with disparate Certified EHR technology and vendors.

(*3*) Responded in good faith and in a timely manner to requests to retrieve or exchange electronic health information, including from patients, health care providers (as defined by 42 U.S.C. 300jj(3)), and other persons, regardless of the requestor's affiliation or technology vendor.''

* * * * *

(b) Demonstration by eligible hospitals and CAHs. An eligible hospital or CAH must demonstrate that it satisfies each of the applicable objectives and associated measures under § 495.20, § 495.22, or § 495.24, supports information exchange and the prevention of health information blocking, and engages in activities related to supporting providers with the performance of CEHRT:

* * * * *

(2) * * *

(i) * * *

(H) *Supporting providers with the performance of CEHRT (SPPC).* To engage in activities related to supporting providers with the performance of CEHRT, the eligible hospital or CAH—

(*1*) Must attest that it:

(*i*) Acknowledges the requirement to cooperate in good faith with ONC direct review of his or her health information technology certified under the ONC Health IT Certification Program if a request to assist in ONC direct review is received; and

(*ii*) If requested, cooperated in good faith with ONC direct review of its health information technology certified under the ONC Health IT Certification Program as authorized by 45 CFR part 170, subpart E, to the extent that such technology meets (or can be used to meet) the definition of CEHRT, including by permitting timely access to such technology and demonstrating its capabilities as implemented and used by the eligible hospital or CAH in the field.

(*2*) Optionally, may attest that it:

(*i*) Acknowledges the option to cooperate in good faith with ONC–ACB surveillance of his or her health information technology certified under the ONC Health IT Certification Program if a request to assist in ONC–ACB surveillance is received; and

(*ii*) If requested, cooperated in good faith with ONC–ACB surveillance of his or her health information technology certified under the ONC Health IT Certification Program as authorized by 45 CFR part 170, subpart E, to the extent that such technology meets (or can be used to meet) the definition of CEHRT, including by permitting timely access to such technology and demonstrating its capabilities as implemented and used by the eligible hospital or CAH in the field.

(I) *Support for health information exchange and the prevention of information blocking.* For an EHR reporting period in CY 2017 and subsequent years, the eligible hospital or CAH must attest that it—

(*1*) Did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology.

(*2*) Implemented technologies, standards, policies, practices, and agreements reasonably calculated to ensure, to the greatest extent practicable and permitted by law, that the certified EHR technology was, at all relevant times—

(*i*) Connected in accordance with applicable law;

(*ii*) Compliant with all standards applicable to the exchange of information, including the standards, implementation specifications, and certification criteria adopted at 45 CFR part 170;

(*iii*) Implemented in a manner that allowed for timely access by patients to their electronic health information; and

(*iv*) Implemented in a manner that allowed for the timely, secure, and trusted bidirectional exchange of structured electronic health information with other health care providers (as defined by 42 U.S.C. 300jj(3)), including unaffiliated providers, and with disparate certified EHR technology and vendors.

(*3*) Responded in good faith and in a timely manner to requests to retrieve or exchange electronic health information, including from patients, health care providers (as defined by 42 U.S.C. 300jj(3)), and other persons, regardless of the requestor's affiliation or technology vendor.''.

* * * * *

Dated: *December 27, 2016.*

Madhura Valverde,

Executive Secretary to the Department, Department of Health and Human Services.

[FR Doc. 2016–31774 Filed 12–30–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 431, 433, 438, 440, 457, and 495

[CMS–2390–F3]

RIN–0938–AS25

Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability; Corrections

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule; correcting amendment.

SUMMARY: This document corrects technical errors that appeared in the final rule published in the May 6, 2016 **Federal Register** (81 FR 27498 through 27901) entitled, ''Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability.'' The effective date for the rule was July 5, 2016.

DATES: *Effective Date:* This correcting document is effective December 30, 2016.

Applicability Date: The corrections indicated in this document are applicable beginning immediately.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2016–09581 (81 FR 27498 through 27901), the final rule entitled, ''Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability'' there were technical errors that are identified and corrected in this correcting document. These corrections are applicable immediately.

II. Summary of Errors

A. Summary of Errors in the Preamble

On page 27560 we made a technical error in the response to comments of § 438.6(e). In this response, we inadvertently identified the effective date and the date by which we would enforce compliance for the regulation, which is correctly identified in the Compliance section on page 27499.

On page 27679 we made a technical error in the preamble text of § 438.330 (Quality Assessment and Performance Improvement Program) in a response to comment. We stated, ''Note that standards for risk adjustment are provided in §§ 438.5(g) and 438.7(b)(5).'' We inadvertently omitted the words ''for payment purposes'' after ''risk adjustment'' in this sentence to clarify that these cross-referenced sections are related to risk adjustment for payment purposes.

On page 27708 we made a technical error in the preamble text of § 438.358 (Activities Related to External Quality Review) in a response to comment about § 438.358(b)(iv) (Validation of MCO, PIHP, or PAHP validation of network adequacy). We inadvertently included PIHPs and PAHPs in a statement about the match rate for this EQR-related activity for MCOs. We stated, ''. . . the validation of MCOs, PIHPs, and PAHPs would be eligible for the 75 percent match rate under § 438.370(a).'' This was in error, as it conflicts with § 438.370 of the final rule and the preamble discussion of that section on pages 27715 through 27717.

On page 27712 we made a technical error in the preamble text of § 438.360 (Nonduplication of mandatory activities with Medicare or accreditation review) in a response to comment about updating the EQR protocols to incorporate data from a Medicare or private accrediting entity review. We referenced three of the mandatory EQR-related activities using the citation from the proposed rule (§ 438.358(b)(1) to (b)(3)), rather than the citation from the final rule (§ 438.358(b)(1)(i) to (b)(1)(iii)).

On page 27738 we made a technical error in the response to comments of § 438.242(b)(2). In this response, we inadvertently mistyped ''T–MSIS.''

On page 27766 we made a technical error in the preamble text of § 457.1233. We inadvertently did not note that CHIP is also adopting the changes discussed in the Medicaid preamble to include PCCM entities as subject to § 438.230 in

response to public comments and consideration of a managed care plan's subcontracted or delegated obligations, services, or activities.

B. Summary of Errors in Regulation Text

On page 27860 we made a technical error in the regulation text of § 438.6(c)(2)(i). In this paragraph, we inadvertently omitted ''actuarial'' before ''principles and practices.''

On page 27862 we made a technical error in the regulation text of § 438.8(e)(1). In this paragraph, we inadvertently referenced fraud reduction activities instead of fraud prevention activities.

On page 27863 we made a technical error in the regulation text of § 438.8(f)(2)(i). In this paragraph, we inadvertently included an extra word ''to.''

On page 27867 we made a technical error in the regulation text of § 438.10(g)(2)(xiii). In this paragraph, we inadvertently included an extra word ''in.''

On page 27879 we made a technical error in the regulation text of § 438.210(a)(2). In this paragraph, we inadvertently referenced part 440 instead of part 441.

On page 27884 we made a technical error in the regulation text of § 438.350(d). We incorrectly cross-referenced § 438.364(a)(1)(i) through (iv) instead of § 438.364(a)(2)(i) through (iv).

On page 27885 we made a technical error in the regulation text of § 438.358(a)(2) (Activities related to external quality review). We incorrectly cross-referenced § 438.364(a)(i) through (iv) instead of § 438.364(a)(2)(i) through (iv).

On page 27885 we made a technical error in the regulation text of § 438.358(c)(3) (Activities related to external quality review). We incorrectly cross-referenced § 438.358(b)(2) instead of § 438.358(b)(1)(ii).

On page 27885 we made a technical error in the regulation text of § 438.358(c)(4) (Activities related to external quality review). We incorrectly cross-referenced § 438.358(b)(1) instead of § 438.358(b)(1)(i).

On page 27891 we made a technical error in the regulation text of § 438.604(a)(2). In this paragraph, we inadvertently referenced § 438.3 instead of § 438.4.

On page 27898 we made a technical error in the regulation text of § 457.1201(l). In this paragraph, we inadvertently cross-referenced the Medicaid requirements related to MHPAEA at § 438.3(n) instead of CHIP MHPAEA requirements at § 457.496. Both the Medicaid and CHIP MHPAEA provisions were issued on March 30, 2016, at 81 FR 18390, 18436 and 18442. They are parallel provisions and the change in the cross-reference will not result in any substantive change in the applicable requirements.

On page 27898 we made a technical error in the regulation text of § 457.1201(n)(2). In this paragraph, we inadvertently omitted a cross-reference to § 438.330(b)(2) as we discussed in the preamble on page 27757.

On page 27898 we made a technical error in the regulation text of § 457.1203(a). In this paragraph, we inadvertently included a parenthesis before the word ''implementing.''

On page 27898 we made a technical error in the regulation text of § 457.1203(e). In this paragraph, we inadvertently did not include a comma after the word ''MCOs'' and we inadvertently included the word ''to'' after the word ''under.''

On page 27899 we made a technical error in the regulation text of § 457.1210(c)(2) and § 457.1210(c)(4). In this paragraph, we incorrectly used the word ''Explains'' instead of the word ''Explain.''

On page 27899 we made a technical error in the regulation text of § 457.1214. In this section, we referenced § 438.58, the conflict of interest safeguards required for Medicaid managed care plans. However, we inadvertently did not specify that references to § 438.54(b) (relating to the Medicaid managed care enrollment processes) in § 438.58 should refer to the enrollment processes for CHIP described in § 457.1210(a).

On page 27899 we made a technical error in the regulation text of § 457.1228. We inadvertently omitted the words ''and poststabilization care'' before the word ''services.'' Additionally, we are replacing the cross-reference to § 457.10 with a cross reference to § 438.114 to reflect the intended alignment with Medicaid definitions that was clearly expressed in the preamble on page 27764 in discussing § 457.1228. In that preamble discussion, we expressly indicated that we would be adopting the definitions at § 438.114.

On page 27899 we made a technical error in the regulation text of § 457.1230(c). We inadvertently did not provide that the applicability date for the Medicaid requirements in § 438.208(d) does not apply to CHIP.

On page 27899 we made a technical error in the regulation text of § 457.1230(d). We inadvertently did not provide the applicability date for the Medicaid requirements in § 438.210(f) does not apply to CHIP.

On page 27900 we made a technical error in the regulation text of § 457.1233(b). As indicated in the preamble on page 27766, we intended to align the structure and operation standards for CHIP managed care entities with parallel Medicaid standards, but we inadvertently omitted PCCM entities from the list of managed care entities that the state must ensure are in compliance with § 438.230.

On page 27900 we made technical errors in the regulation text of § 457.1240(e). We inadvertently left in an obsolete cross reference from the proposed rule to § 438.340(e).

On page 27900 we made technical errors in the regulation text of § 457.1240(f). In this paragraph, we incorrectly spelled ''PCCM entities'' as ''PPCM entities.''

On page 27900 we made technical errors in the regulation text of § 457.1250(a), relating to external quality review. We inadvertently did not provide that while the terms of Medicaid external quality review provisions at § 438.350 applies to PCCM entities, § 438.362, which is cross-referenced in § 438.350, does not apply to PCCM entities in CHIP.

On page 27900 we made technical errors in the regulation text of § 457.1260. We inadvertently did not include an exception to the Medicaid applicability date as described in § 438.400(c).

III. Waiver of Proposed Rulemaking and Delay in Effective Date

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rule in the **Federal Register** before the provisions of a rule take effect. In addition, section 553(d) of the APA mandates a 30-day delay in effective date after issuance or publication of a rule. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the APA notice and comment, and delay in effective date requirements. Section 553(b)(B) of the APA authorizes an agency to dispense with normal notice and comment rulemaking procedures for good cause if the agency makes a finding that the notice and comment process is impracticable, unnecessary, or contrary to the public interest; and includes a statement of the finding and the reasons for it in the notice.

In our view, this correcting document does not constitute a rulemaking that would be subject to these requirements. This document merely corrects technical errors in the Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed

Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability final rule. The corrections contained in this document are consistent with, and do not make substantive changes to, the policies and payment methodologies that were adopted subject to notice and comment procedures in the Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability final rule. As a result, the corrections made through this correcting document are intended to ensure that the Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability final rule accurately reflects the policies adopted in that rule.

Even if this were a rulemaking to which the notice and comment and delayed effective date requirements applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the corrections in this document into the Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability final rule or delaying the effective date of the corrections would be contrary to the public interest because it could result in a period of confusion about the applicability of the rules while those procedures are pending. Further, such procedures would be unnecessary, because the corrections in this document do not make substantive changes in the underlying policies but are limited to elimination of typographical errors, incorrect cross references, confusing or inconsistent language, and obvious errors. This correcting document is intended solely to ensure that the Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability final rule accurately reflects the final policy determinations that were set forth in the overall rulemaking record. For these reasons, we believe there is good cause to waive the requirements for notice and comment and delay in effective date.

Corrections of Errors

In FR Doc. 2016–09581 of May 6, 2016 (81 FR 27498), make the following corrections:

1. On page 27560, in the first column; in the second full paragraph, line 13, the phrase ''for contracts starting on or after July 1, 2017'' is corrected to read ''no later than the effective date of this rule''.

2. On page 27679, in the third column; in the first full paragraph, line eight, the phrase ''Note that standards for risk adjustment . . . .'' is corrected to read ''Note that standards for risk adjustment for payment purposes. . . .''.

3. On page 27708, in the second column; in the first full paragraph, beginning at line seven, the phrase ''validation of MCOs, PIHPs, and PAHPs'' is corrected to read ''validation of MCOs''.

4. On page 27712, in the second column; in the fourth full paragraph, line 20, the phrase ''§ 438.358(b)(1) to (b)(3)'' is corrected to read ''§ 438.358(b)(1)(i) to (b)(1)(iii)''.

5. On page 27738, in the third column; in the fifth full paragraph, line 11, the term ''TSIS'' is corrected to read ''T–MSIS''.

6. On page 27766, in the second column; in the second full paragraph, beginning with line one, the sentence ''After consideration of the public comments, we are adding a cross reference to § 457.1110 in a new paragraph (e), and otherwise finalizing § 457.1233 as proposed.'' is corrected to read ''After consideration of the public comments, we are adding a cross reference to § 457.1110 in a new paragraph (e) and adopting the changes to § 438.230 to include PCCM entities as discussed in the Medicaid preamble above. The remaining provisions of § 457.1233 are finalized as proposed.''.

List of Subjects

42 CFR Part 438

Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 457

Administrative practice and procedure, Grant programs-health, Health insurance, Reporting and recordkeeping requirements.

Accordingly, 42 CFR chapter IV is corrected by making the following correcting amendments to parts 438 and 457:

PART 438—MANAGED CARE

■ 1. The authority citation for part 438 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

§ 438.6 [Amended]

■ 2. In § 438.6 amend paragraph (c)(2)(i) by removing the phrase ''accepted principles and practices'' and adding in its place the phrase ''accepted actuarial principles and practices''.

§ 438.8 [Amended]

■ 3. In § 438.8—

■ a. Amend paragraph (e)(1) by removing the phrase ''fraud reduction activities'' and adding in its place the phrase ''fraud prevention activities''.

■ b. Amend paragraph (f)(2)(i) by removing the phrase ''under to § 438.6(d).'' and adding in its place the phrase ''under § 438.6(d).''.

§ 438.10 [Amended]

■ 4. In § 438.10 amend paragraph (g)(2)(xiii) by removing the phrase ''in in alternative formats or languages.'' and adding in its place the phrase ''in alternative formats or languages.''.

§ 438.210 [Amended]

■ 5. In § 438.210 amend paragraph (a)(2) by removing the phrase ''of part 440'' and adding in its place ''of part 441''.

§ 438.350 [Amended]

■ 6. In § 438.350 amend paragraph (d) by removing the reference ''§ 438.364(a)(1)(i) through (iv).'' and adding in its place the reference ''§ 438.364(a)(2)(i) through (iv).''.

§ 438.358 [Amended]

■ 7. In § 438.358 amend paragraph (a)(2) by removing the reference ''§ 438.364(a)(i) through (iv).'' and adding in its place the reference ''§ 438.364(a)(2)(i) through (iv).''.

§ 438.358 [Amended]

■ 8. In § 438.358 amend paragraph (c)(3) by removing the reference ''§ 438.358(b)(2)'' and adding in its place the reference ''§ 438.358(b)(1)(ii)''.

§ 438.358 [Amended]

■ 9. In § 438.358 amend paragraph (c)(4) by removing the reference ''§ 438.358(b)(1)'' and adding in its place the reference ''§ 438.358(b)(1)(i)''.

§ 438.604 [Amended]

■ 10. In § 438.604 amend paragraph (a)(2) by removing the reference ''§ 438.3'' and adding in its place the reference ''§ 438.4''.

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 11. The authority citation for part 457 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

§ 457.1201 [Amended]

■ 12. In § 457.1201—

■ a. Amend paragraph (l) by removing the reference ''§ 438.3(n).'' and adding in its place the reference ''§ 457.496.''.

■ b. Amend paragraph (n)(2) by removing the phrase ''(cross-referencing § 438.330(b)(3), (c),'' and adding in its place the phrase ''(cross-referencing § 438.330(b)(2), (b)(3), (c),''.

§ 457.1203 [Amended]

■ 13. In § 457.1203—

■ a. Amend paragraph (a) by removing the open parenthesis ''('' before the word ''implementing''.

■ b. Amend paragraph (e) by adding a comma '','' after the term ''MCOs'' and by removing the word ''to'' after the word ''under''.

§ 457.1210 [Amended]

■ 14. In § 457.1210—

■ a. Amend paragraph (c)(2) by removing the word ''Explains'' and adding in its place the word ''Explain''.

■ b. Amend paragraph (c)(4) by removing the word ''Explains'' and adding in its place the word ''Explain''.

■ 15. Section 457.1214 is revised to read as follows:

§ 457.1214 Conflict of interest safeguards.

The State must have in effect safeguards against conflict of interest in accordance with the terms of § 438.58 of this chapter, except that references to § 438.54(b) should be read to refer to the enrollment processes described in § 457.1210(a).

■ 16. Section 457.1228 is revised to read as follows:

§ 457.1228 Emergency and poststabilization services.

The State must ensure that emergency and poststabilization care services are available and accessible to enrollees in accordance with the terms of § 438.114 of this chapter.

■ 17. Section 457.1230 is amended by revising paragraphs (c) and (d) to read as follows:

§ 457.1230 Access Standards

* * * * *

(c) *Coordination and continuity of care.* The State must ensure, through its contracts, that each MCO, PIHP and PAHP complies with the coordination and continuity of care requirements in accordance with the terms of § 438.208 of this chapter, except that the applicability date in § 438.208(d) does not apply.

(d) *Coverage and authorization of services.* The State must ensure, through its contracts, that each MCO, PIHP or PAHP complies with the coverage and authorization of services requirements in accordance with the terms of § 438.210 of this chapter, except that the following do not apply: § 438.210(a)(5) of this chapter (related to medical necessity standard); § 438.210(b)(2)(iii) of this chapter (related to authorizing LTSS), and § 438.210(f) (relating to the applicability date).

§ 457.1233 [Amended]

■ 18. In § 457.1233 amend paragraph (b) by removing the phrase ''and PAHP'' and adding in its place the term ''PAHP, and PCCM''.

■ 19. Section 457.1240 is amended by revising paragraph (e) and correcting the heading for paragraph (f) to read as follows:

§ 457.1240 Quality measurement and improvement.

* * * * *

(e) *Managed care quality strategy.* The State must draft and implement a written quality strategy for assessing and improving the quality of health care and services furnished CHIP enrollees as described in § 438.340 of this chapter.

(f) *Applicability to PCCM entities.*

* * *

■ 20. Section 457.1250 is amended by revising paragraph (a) to read as follows:

§ 457.1250 External quality review.

(a) Each State that contracts with MCOs, PIHPs, or PAHPs must follow all applicable external quality review requirements as set forth in §§ 438.350 (except for references to §§ 438.362), 438.352, 438.354, 438.356, 438.358, 438.360 (only with respect to nonduplication of EQR activities with private accreditation) and § 438.364 of this chapter. In the case of a contract with a PCCM entity described in § 457.1240(f), § 438.350 (except for references to § 438.362) of this chapter applies.

* * * * *

■ 21. Section 457.1260 is revised by adding a sentence at the end of the section to read as follows:

§ 457.1260 Grievance system.

* * * The applicability date in § 438.400(c) does not apply to CHIP.

Dated: December 21, 2016.

Wilma M. Robinson,

Deputy Executive Secretary to the Department, Department of Health and Human Services.

[FR Doc. 2016–31650 Filed 12–30–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Parts 204, 206, and 207

[Docket ID: FEMA–2016–0034]

RIN 1660–AA89

Update of FEMA's Public Assistance and Fire Management Assistance Grant Regulations To Reflect the Terminology of Uniform Administrative Requirements, Cost Principles, and Audit Requirements

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: The Federal Emergency Management Agency (FEMA) is amending its Public Assistance and Fire Management Assistance Grant regulations to update the terms it uses to describe grantees and subgrantees, to reflect the terminology used in the Office of Management and Budget (OMB) Uniform Guidance on Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.

DATES: *Effective* January 3, 2017.

FOR FURTHER INFORMATION CONTACT: Christopher Logan, Director, Public Assistance Division, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, 202–646–3834.

SUPPLEMENTARY INFORMATION:

I. Background

The Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended (Stafford Act), Title 42 of the United States Code (U.S.C.) 5121 *et seq.,* authorizes the President to provide Federal assistance when the magnitude of an incident or threatened incident exceeds the affected State, Territorial, Indian Tribal, and local government capabilities to respond or recover. FEMA provides assistance to State, Territorial, Indian Tribal, and local governments and certain types of private nonprofit (PNP) organizations via its Public Assistance program. Through the Public Assistance program, FEMA provides supplemental Federal disaster grant assistance for debris removal, emergency protective measures, and the restoration of disaster-damaged, publicly owned facilities and the facilities of certain PNP organizations. The Public Assistance program also encourages protection of these damaged facilities from future events by providing

assistance for hazard mitigation measures. FEMA regulations for the Public Assistance program are found at 44 CFR part 206. The regulations at 44 CFR part 207, ''Management Costs,'' also apply to Public Assistance awards.

Fire Management Assistance is available to States, local and tribal governments, for the mitigation, management, and control of fires on publicly or privately owned forests or grasslands, which threaten such destruction as would constitute a major disaster. FEMA Regional Administrators (RAs) have the authority to issue Fire Management Assistance Grant (FMAG) declarations for wildfires that threaten such destruction that would constitute a major disaster. The regulations governing the FMAG program are found at 44 CFR part 204.

The Office of Management and Budget (OMB) establishes Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, found at 2 CFR part 200. These regulations apply to awards under FEMA's Public Assistance and FMAG programs.

II. The Adoption of Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards

On December 26, 2013, OMB published final government-wide guidance entitled, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.* 78 FR 78589. The Uniform Guidance set standard requirements for Federal awards across the entire Federal government and consolidated the language from OMB circulars into one set of guidance that is located at 2 CFR part 200. In December 2014, OMB and Federal award-making agencies published a joint interim final rule that implemented the Uniform Guidance. 79 FR 75871. DHS adopted the Uniform Guidance at 2 CFR part 3002.

In the interim final rule, FEMA amended 44 CFR via a technical amendment that removed part 13 (FEMA's grant administration regulations) and replaced all references to part 13 with references to 2 CFR parts 200 and 3002. FEMA replaced general references to part 13 with the general citations to 2 CFR parts 200 and 3002. To the extent applicable, FEMA also replaced references to specific portions of part 13 with the corresponding pinpoint citations to 2 CFR parts 200 and 3002.

FEMA adopted the interim final rule as final, with one change, on October 2, 2015. 80 FR 59549. The change was a reinsertion of a provision that was inadvertently removed by the interim final rule.

III. Revisions to 44 CFR Parts 204 and 206

In this final rule, FEMA is updating its Public Assistance and FMAG program regulations to reflect two terms used in 2 CFR part 200. The Uniform Guidance uses the terms ''recipient'' and ''subrecipient'' when referring to entities that receive Federal awards, whereas FEMA's regulations use the terms ''grantee'' and ''subgrantee'' when referring to entities that receive Federal awards under FEMA Public Assistance and FMAG grant programs. To improve consistency with the Uniform Guidance, FEMA is replacing the term ''grantee'' with ''recipient'' and the term ''subgrantee'' with ''subrecipient'' throughout 44 CFR part 204 and 44 CFR part 206, subparts G, H, and I. Although grantees and subgrantees, as defined in 44 CFR parts 204 and 206, are considered to be recipients and subrecipients under 2 CFR part 200, FEMA intends to use comparable terms to avoid confusion and provide consistency between applicable regulations and Public Assistance policy.[1]

FEMA is not making substantive revisions to the current definitions for the terms ''grantee'' and ''subgrantee.'' The Uniform Guidance provides that ''[d]ifferent definitions [of the terms ''recipient'' and ''subrecipient,'' among other terms] may be found in Federal statutes or regulations that apply more specifically to particular programs or activities.'' 2 CFR 200.1. As such, although FEMA is replacing the terms ''grantee'' and ''subgrantee'' with the terms ''recipient'' and ''subrecipient,'' respectively, FEMA is continuing to use the definitions for these terms at 44 CFR part 204 and 44 CFR part 206, subpart G, which apply more specifically to the Public Assistance and FMAG programs.[2]

FEMA is also replacing remaining references to 44 CFR part 13 with references to 2 CFR part 200. This is a technical change to correct citations that were not updated by the December 19, 2014 joint interim final rule. Finally, FEMA is correcting two typographical errors to citations in 44 CFR part 206. In § 206.222(b), the reference to § 205.221(e) will be corrected to § 206.221(e). In § 206.226(f)(2), the reference to paragraph (d)(1) will be corrected to paragraph (f)(1).

IV. Revisions to 44 CFR Part 207

The regulations at 44 CFR part 207, ''Management Costs,'' apply to Public Assistance and Hazard Mitigation Grant Program (HMGP) awards. To ensure consistency with the terminology used in both Public Assistance and HMGP regulations, FEMA is revising the definitions of ''Grantee'' and ''Subgrantee'' in 44 CFR part 207 to make clear that in part 207 as well, the terms ''Grantee'' and ''Recipient'' are interchangeable, as are the terms ''Subgrantee'' and ''Subrecipient.'' This is a non-substantive change to make it clear that the terms are interchangeable and that 44 CFR part 207 applies to Public Assistance and HMGP awards regardless of the terminology used in the program regulations.

This rule makes technical and nomenclature changes intended to reduce confusion and encourage the use of consistent terminology in the administration of Public Assistance and FMAG awards.

V. Regulatory Analyses

A. Administrative Procedure Act

FEMA did not undertake notice and comment for this regulation because it is making purely technical and non-substantive terminology changes. The Administrative Procedure Act (APA) provides that an agency may dispense with notice and comment rulemaking procedures when an agency, for good cause, finds those procedures are impracticable, unnecessary, or contrary to the public interest. 5 U.S.C. 553(b). FEMA finds that such procedures are unnecessary for this rule because this rule makes technical updates and non-substantive terminology changes to improve consistency with 2 CFR part 200, and does not change any regulatory requirements. For instance, this rule will not change the requirements to request assistance, the eligibility requirements to receive assistance, the amount of assistance available, or the appeals process under the FMAG or Public Assistance programs. The changes made by this rule do not change or confer any substantive rights, benefits or obligations. For the same reasons, under 5 U.S.C. 553(d)(3), FEMA finds that it has good cause to make this final rule effective immediately.

[1] FEMA has updated its Public Assistance program policy to reflect terms used in 2 CFR part 200. Public Assistance Program and Policy Guide, FP 104–009–2 (January 2016).

[2] Because FEMA is replacing the terms in existing definitions, we are redesignating the paragraphs in § 206.201 to maintain alphabetical order.

B. Executive Order 12866, as Amended, Regulatory Planning and Review; Executive Order 13563, Improving Regulation and Regulatory Review

Executive Orders 13563 and 12866 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget. As this rule involves non-substantive changes that will not change FEMA's administration of the subject regulations, FEMA expects that the rule will not impose any costs on the public.

C. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, as amended, (5 U.S.C. 601–612), agencies must consider the impact of their rulemakings on ''small entities'' (small businesses, small organizations and local governments) when issuing a notice of proposed rulemaking. As FEMA is not issuing a proposed rule for this action, the Regulatory Flexibility Act does not apply.

List of Subjects

44 CFR Part 204

Administrative practice and procedure, Fire prevention, Grant programs, and Reporting and recordkeeping requirements.

44 CFR Part 206

Administrative practice and procedure, Coastal zone, Community facilities, Disaster assistance, Fire prevention, Grant programs-housing and community development, Housing, Insurance, Intergovernmental relations, Loan programs-housing and community development, Natural resources, Penalties, and Reporting and recordkeeping requirements.

44 CFR Part 207

Administrative practice and procedure, Disaster assistance, Grant programs, and Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, and under the authorities listed below, the Federal Emergency Management Agency amends 44 CFR Chapter I as follows:

PART 204—FIRE MANAGEMENT ASSISTANCE GRANT PROGRAM

■ 1. The authority citation for part 204 continues to read as follows:

Authority: 42 U.S.C. 5121 through 5207; 6 U.S.C. 101 *et seq.;* Department of Homeland Security Delegation 9001.1.

§ 204.3 [Amended]

■ 2. In § 204.3—

■ a. Revise the defined term ''Grantee'' to read ''*Recipient*'' and place the definition in appropriate alphabetical order;

■ b. Revise the defined term ''Subgrantee'' to read ''*Subrecipient*'' and place the definition in appropriate alphabetical order;

■ c. Remove the word ''Grantee'' wherever it appears and add in its place the word ''recipient'';

■ d. Remove the word ''grantee'' wherever it appears and add in its place the word ''recipient''; and

■ e. Remove the word ''subgrantee'' wherever it appears and add in its place the word ''subrecipient''.

§ 204.25 [Amended]

■ 3. In § 204.25(a), remove the word ''Grantee'' and add in its place the word ''recipient''.

§ 204.41 [Amended]

■ 4. In § 204.41(a) introductory text, remove the word ''Grantee'' and add in its place the word ''recipient''.

§ 204.42 [Amended]

■ 5. In § 204.42(a)(3), remove the word ''Grantees'' and add in its place the word ''Recipients'' and remove the word ''subgantees'' and add in its place the word ''subrecipients''.

§ 204.43 [Amended]

■ 6. In § 206.43(c), remove the word ''subgrantee's'' and add in its place the word ''subrecipient's''.

§ 204.51 [Amended]

■ 7. In § 204.51, remove the word ''Grantee'' wherever it appears and add in its place the word ''recipient''.

§ 204.52 [Amended]

■ 8. In § 204.52, remove the word ''Grantee'' wherever it appears and add in its place the word ''recipient''.

§ 204.53 [Amended]

■ 9. In § 204.53(a), remove the word ''Grantee'' and add in its place the word ''recipient''.

§ 204.54 [Amended]

■ 10. In § 204.54—

■ a. In the introductory text, remove the word ''subgrantee'' and add in its place the word ''subrecipient'' and remove the word ''grantee'' and add in its place the word ''recipient'';

■ b. In paragraph (a), remove the words ''grantee-related'' and add in their place the words ''recipient-related'', remove the word ''grantee'' wherever it appears and add in its place the word ''recipient'', and remove the word ''subgrantee'' wherever it appears and add in its place the word ''subrecipient'';

■ c. In paragraph (c)(2), remove the word ''subgrantee'' and add in its place the word ''subrecipient'' and in paragraph (c)(3), remove the word ''grantee'' wherever it appears and add in its place the word ''recipient''; and

■ d. In paragraph (d), remove the word ''grantee'' and add in its place the word ''recipient''.

§ 204.62 [Amended]

■ 11. In § 204.62(c), remove the word ''Grantee'' and add in its place the word ''recipient'' and remove the word ''subgrantee'' and add in its place the word ''subrecipient''.

§ 204.63 [Amended]

■ 12. In § 204.63(b), remove the word ''Grantee's'' and add in its place the word ''recipient's''.

§ 204.64 [Amended]

■ 13. In § 204.64(b)(1), remove the word ''Grantee'' and add in its place the word ''recipient'' and remove the word ''subgrantees'' and add in its place the word ''subrecipients''.

PART 206—FEDERAL DISASTER ASSISTANCE

■ 14. The authority citation for part 206 continues to read as follows:

Authority: Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 through 5207; Homeland Security Act of 2002, 6 U.S.C. 101 *et seq.;* Department of Homeland Security Delegation 9001.1; sec. 1105, Pub. L. 113–2, 127 Stat. 43 (42 U.S.C. 5189a note).

§ 206.120 [Amended]

■ 15. In § 206.120(d)(4)(iv)(A), remove the words ''44 CFR 13.41'' and add in their place the words ''2 CFR 200.327''.

§ 206.200 [Amended]

■ 16. In § 206.200(b), remove the word ''Grantee'' wherever it appears and add in its place the word ''recipient'', remove the word ''subgrantee'' and add in its place the word ''subrecipient'';

and remove the word ''subgrantees'' wherever it appears and add in its place the word ''subrecipients''.

■ 17. In § 206.201—

■ a. In paragraph (a), remove the word ''Grantee'' and add in its place the word ''recipient'';

■ b. Remove paragraph (e);

■ c. Redesignate paragraph (e) as paragraph (m); and redesignate paragraphs (f) through (m) as paragraphs (e) through (l);

■ d. In newly redesignated paragraph (l), remove the word ''Grantee'' and add in its place the word ''recipient'';

■ e. Add new paragraph (m);

■ f. In paragraph (n), remove the word ''grantee'' and add in its place the word ''recipient''; and remove the word ''subgrantee'' and add in its place the word ''subrecipient''; and

■ g. Revise the paragraph (o) heading to read ''Subrecipient'' and in paragraph (o), remove the word ''grantee'' and add in its place the word ''recipient''.

The addition reads as follows:

§ 206.201 Definitions used in this part.

* * * * *

(m) *Recipient.* Recipient means the government to which a grant is awarded, and which is accountable for the use of the funds provided. The recipient is the entire legal entity even if only a particular component of the entity is designated in the grant award document. Generally, except as provided in § 206.202(f), the State for which the emergency or major disaster is declared is the recipient. However, an Indian Tribal government may choose to be a recipient, or it may act as a subrecipient under the State. If an Indian Tribal government is the recipient, it will assume the responsibilities of the ''recipient'' or ''State'' as described in this part with respect to administration of the Public Assistance program.

* * * * *

§ 206.202 [Amended]

■ 18. In § 206.202—

■ a. In paragraph (a), remove the word ''Grantee'' wherever it appears and add in its place the word ''recipient'';

■ b. In the paragraph (b) heading, remove the word ''Grantee'' and add in its place the word ''Recipient'';

■ c. In paragraph (b)(1), remove the word ''subgrantees'' and add in its place the word ''subrecipients'';

■ d. In paragraphs (c) and (e), remove the word ''Grantee'' wherever it appears and add in its place the word ''recipient'';

■ e. In paragraph (f)(1)(i), remove the word ''grantee'' and add in its place the word ''recipient''; and

■ f. In paragraph (f)(2), remove the word ''Grantees'' and add in its place the word ''recipient'', remove the word ''grantee's'' and add in its place the word ''recipient's'', and remove the word ''subgrantee's'' and add in its place the word ''subrecipient's''.

§ 206.203 [Amended]

■ 19. In § 206.203—

■ a. In paragraph (c)(1), remove the word ''grantee'' and add in its place the word ''recipient'';

■ b. In paragraph (d)(1), remove the word ''subgrantee'' and add in its place the word ''subrecipient''; and remove the word ''Grantee's'' and add in its place the word ''recipient's'';

■ c. In paragraph (d)(2) introductory text, remove the word ''subgrantee'' and add in its place the word ''subrecipient'' and remove the word ''Grantee'' and add in its place the word ''recipient''; and

■ d. In paragraph (d)(2)(v), remove the word ''Grantee'' wherever it appears and add in its place the word ''recipient''.

§ 206.204 [Amended]

■ 20. In § 206.204—

■ a. In paragraph (c)(2), remove the word ''Grantee'' wherever it appears and add in its place the word ''recipient'' and in paragraph (c)(2)(ii), remove the word ''subgrantee'' and add in its place the word ''subrecipient'';

■ b. In paragraph (d) introductory text, remove the word ''Grantee's'' and add in its place the word ''recipient's'' and remove the word ''Grantee'' and add in its place the word ''recipient'';

■ c. In paragraph (d)(2), remove the word ''Grantee'' and add in its place the word ''recipient''; and remove the word ''grantee'' and add in its place the word ''recipient'';

■ d. In paragraph (e), remove the word ''subgrantee'' wherever it appears and add in its place the word ''subrecipient'';

■ e. In paragraph (e)(2), remove the word ''Grantee'' wherever it appears and add in its place the word ''recipient''; and

■ f. In paragraph (f), remove the word ''Grantee'' wherever it appears and add in its place the word ''recipient'' and remove the word ''grantee'' and add in its place the word ''recipient''.

§ 206.205 [Amended]

■ 21. In § 206.205(a) and (b), remove the word ''Grantee'' wherever it appears and add in its place the word ''recipient''; and remove the word ''subgrantee'' wherever it appears and add in its place the word ''subrecipient''.

§ 206.206 [Amended]

■ 22. In § 206.206—

■ a. In the introductory text and paragraphs (a), (c), and (d), remove the word ''grantee'' wherever it appears, and add in its place the word ''recipient''; and remove the word ''subgrantee'' wherever it appears and add in its place the word ''subrecipient''; and

■ b. In paragraph (a), remove the words ''grantee-related'' and add in their place the words ''recipient-related''.

§ 206.207 [Amended]

■ 23. In § 206.207—

■ a. In paragraph (b)(1)(iii)(D), remove the word ''subgrantees'' and add in its place the word ''subrecipients'';

■ b. In paragraph (b)(1)(iii)(F), remove the word ''grantee'' and add in its place the word ''recipient'';

■ c. In paragraph (b)(1)(iii)(K), remove the word ''grantee'' and add in its place the word ''recipient'', remove the word ''subgrantees'' and add in its place the word ''subrecipients'', and remove the word ''subgrantee'' and add in its place the word ''subrecipient'';

■ d. In paragraph (b)(2), remove the word ''Grantee'' and add in its place the word ''recipient'';

■ e. In paragraph (b)(3) and (4), remove the word ''Grantee'' wherever it appears and add in its place the word ''recipient''; and

■ f. In paragraph (c)(1), remove the word ''grantees'' and add in its place the word ''recipients'' and remove the word ''subgrantees'' and add in its place the word ''subrecipients''.

§ 206.208 [Amended]

■ 24. In § 206.208, in paragraphs (a), (b) introductory text, and (e)(1) and (2), remove the word ''Grantee'' wherever it appears and add in its place the word ''recipient''.

§ 206.209 [Amended]

■ 25. In § 206.209—

■ a. In paragraph (b) introductory text, remove the word ''subgrantee'' and add in its place the word ''subrecipient'';

■ b. In paragraphs (e), (f), and (i)(2), remove the word ''Grantee'' wherever it appears and add in its place the word ''recipient''; and

■ c. In paragraph (e)(3), remove the word ''Grantee's'' and add in its place the word ''recipient's''.

■ 26. In § 206.210—

■ a. In paragraph (a), remove the word ''subgrantee'' and add in its place the word ''subrecipient'';

■ b. In paragraph (b), remove the definition of ''Grantee'' and add a definition for ''Recipient'' in alphabetical order;

■ c. In paragraph (b), remove the word ''grantee'' wherever it appears and add in its place the word ''recipient'';
■ d. In paragraphs (f), (g), (h)(1)(i) and (ii), (h)(2)(iii), and (h)(3), remove the word ''grantee'' wherever it appears and add in its place the word ''recipient'';
■ e. In the paragraph (h)(1) heading, remove the word ''*Grantee*'' and add in its place the word ''*Recipient*'';* and
■ f. In paragraph (h)(1)(i), remove the word ''grantee's'' and add in its place the word ''recipient's''.

The addition reads as follows:

§ 206.210 Dispute Resolution Pilot Program.

* * * * *

(b) * * *

Recipient is used throughout this regulation text and it refers to the definition in FEMA's regulations at 44 CFR 206.201(m).

* * * * *

§ 206.222 [Amended]

■ 27. In § 206.222(b), remove the reference ''§ 205.221(e)'' and add in their place the reference ''§ 206.221(e)''.

§ 206.226 [Amended]

■ 28. In § 206.226—
■ a. In paragraph (a)(2), remove the word ''grantees'' and add in its place the word ''recipients'';
■ b. In paragraph (b), remove the word ''grantee'' and add in its place the word ''recipient''; and
■ c. In paragraph (f)(2), remove the words ''paragraph (d)(1)'' and add, in their place, the words ''paragraph (f)(1)''.

§ 206.228 [Amended]

■ 29. In § 206.228—
■ a. In the introductory text, remove the words ''44 CFR 13.22'' and add in their place the words ''2 CFR 200, subpart E'' and remove the words ''44 CFR 13.4 and 13.6'' and add in their place the words ''2 CFR 200, subpart E and 2 CFR 200.102''; and
■ b. In paragraphs (a)(2) introductory text and (a)(2)(ii), remove the word ''grantee's'' wherever it appears and add in its place the word ''recipient's'' and remove the word ''subgrantee's'' wherever it appears and add in its place the word ''subrecipient's''.

§ 206.250 [Amended]

■ 30. In § 206.250(b), remove the word ''Grantee'' and add in its place the word ''recipient''.

§ 206.252 [Amended]

■ 31. In § 206.252—
■ a. In paragraph (c), remove the word ''Grantee'' and add in its place the word ''recipient'' and remove the word ''grantee'' and add in its place the word ''recipient''; and
■ b. In paragraph (d), remove the word ''grantee'' and add in its place the word ''recipient'' and remove the word ''subgrantee'' and add in its place the word ''subrecipient''.

§ 206.253 [Amended]

■ 32. In § 206.253—
■ a. In paragraphs (a), (c), and (e), remove the word ''Grantee'' wherever it appears and add in its place the word ''recipient''; and
■ b. In paragraphs (b)(1) and (c), remove the word ''grantee'' wherever it appears and add in its place the word ''recipient''.

PART 207—MANAGEMENT COSTS

■ 33. The authority citation for part 207 continues to read as follows:

Authority: Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 through 5206; Reorganization Plan No. 3 of 1978, 43 FR 41943, 3 CFR, 1978 Comp., p. 329; Homeland Security Act of 2002, 6 U.S.C. 101; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376; E.O. 12148, 44 FR 43239, 3 CFR, 1979 Comp., p. 412; E.O. 13286, 68 FR 10619, 3 CFR, 2003 Comp., p. 166.

§ 207.2 [Amended]

■ 34. In § 207.2—
■ a. Revise the defined term ''Grantee'' to read ''*Grantee (alternatively, Recipient)*'';* and
■ b. Revise the defined term ''Subgrantee'' to read ''*Subgrantee (alternatively, Subrecipient)*''.

Dated: December 21, 2016.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–31380 Filed 12–30–16; 8:45 am]

BILLING CODE 9111–66–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Humanities

45 CFR Part 1171

RIN 3136–AA37

Regulations Implementing the FOIA Improvement Act of 2016

AGENCY: National Endowment for the Humanities, National Foundation On the Arts and the Humanities.

ACTION: Final rule.

SUMMARY: On June 30, 2016, President Obama signed the Freedom of Information Act (''FOIA'') Improvement Act of 2016 (the ''FOIA Improvement Act''). Section 3 of the FOIA Improvement Act requires, that not later than 180 days after the date of its enactment, the head of each agency review and revise the agency's regulations to implement the FOIA Improvement Act's amendments. The FOIA Improvement Act specifically requires that the regulations of each agency include procedures for engaging in dispute resolution through the FOIA Public Liaison and the Office of Government Information Services. After undertaking a review of its FOIA regulations in accordance with Section 3 of the FOIA Improvement Act, NEH is revising its FOIA regulations to incorporate the statutory mandates.

DATES: This rule is effective February 2, 2017.

FOR FURTHER INFORMATION CONTACT: Adam Kress, Attorney-Advisor, Office of the General Counsel, National Endowment for the Humanities, 400 7th Street SW., Room 4060, Washington, DC 20506, (202) 606–8322, *akress@neh.gov.*

SUPPLEMENTARY INFORMATION: NEH is amending its FOIA regulations published at 45 CFR part 1171 to incorporate changes required by the FOIA Improvement Act.

Background

Section 10 of the National Foundation on the Arts and the Humanities Act of 1965 (20 U.S.C. 959) authorizes the Chairperson of NEH to prescribe such regulations as he or she deems necessary governing the manner in which the Chairperson's functions shall be carried out.

This rulemaking amends NEH's existing regulations providing Public Access to NEH Records Under the Freedom of Information Act (45 CFR part 1171) by incorporating changes to the FOIA by the FOIA Improvement Act. Among other things, the FOIA Improvement Act requires that agencies (i) make records that have been both released previously and requested three or more times available to the public in electronic format, (ii) establish a minimum of ninety days for requesters to appeal an adverse determination, and (iii) provide, or direct requesters to, dispute resolution services at various times throughout the FOIA process. The FOIA Improvement Act also updates how agencies may charge search, duplication and review fees.

NEH amends 45 CFR part 1171 as follows:

• By amending 45 CFR 1171.4 to ''make available for public inspection in an electronic format'' records that have

been previously released and either (i) are likely to be subject to subsequent requests for substantially the same records, or (ii) ''that have been requested three or more times.''

• By amending 45 CFR 1171.7 & 1171.8 to indicate that the requester may seek assistance from NEH's Public Liaison and/or the Office of Government Information Services at various times throughout the FOIA process.

• By amending 45 CFR 1171.10 to change the appeals deadline from thirty days to ninety days.

• By amending 45 CFR 1171.11 to provide additional limitations on the fees charged by NEH.

Good Cause for Final Adoption

NEH ordinarily promulgates amendments to the Code of Federal Regulations in accordance with the notice-and-comment rulemaking procedure in Section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553). That provision requires that agencies publish notice of a proposed rule or amended rule in the **Federal Register**, and that such agencies solicit and consider public comment on the proposed rule or amendment, and publish any final rule at least thirty days prior to its effective date.

Section 553 of the APA, however, allows agencies to dispense with the above notice and comment procedures when the agency has ''good cause'' for concluding that such procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under the APA, an agency may issue a final rule without seeking comment prior to the rulemaking, for good cause.

NEH's proposed amendments to its FOIA regulations are required by the FOIA Improvement Act, do not reflect or empower agency discretion, and provide additional protection to the public. For these reasons, NEH finds good cause to conclude that it is not necessary for the public to have notice and an opportunity to comment on the amendments described below.

Regulatory Analysis of the Proposed Amendments

These amendments do not constitute a ''significant regulatory action'' under Executive Order 12866 (58 FR 51735, Oct. 4, 1993) and therefore are not subject to Office of Management and Budget (OMB) review.

The Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*) is inapplicable to this rulemaking because it is not one for which a notice of proposed rulemaking is required under 5 U.S.C. 553(b) or any other statute.

For purposes of the Unfunded Mandates Reform Act of 1995, Public Law 104–4 (2 U.S.C. 1531–1538), these amendments will not result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, nor will they significantly or uniquely affect small governments.

These amendments are not ''major rules'' as defined by section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801, *et seq.*). Moreover, they are exempt from the reporting requirements of that Act because they are rules of agency procedure and practice that do not substantially affect the rights or obligations of non-agency parties.

The Paperwork Reduction Act (44 U.S.C. 3501, *et seq.*), does not apply to these amendments because they do not contain any new information collection requirements that need OMB approval.

List of Subjects in 45 CFR Part 1171

Administrative practice and procedure, Fees, Freedom of Information.

For the reasons discussed in the preamble, NEH amends 45 CFR part 1171 as follows:

PART 1171—PUBLIC ACCESS TO NEH RECORDS UNDER THE FREEDOM OF INFORMATION ACT

■ 1. The authority citation for part 1171 is revised to read as follows:

Authority: 5 U.S.C. 552; 20 U.S.C. 959; 31 U.S.C. 3717; E.O. 12600.

■ 2. Amend § 1171.4 by revising paragraphs (a) and (b) to read as follows:

§ 1171.4 Public availability of records.

(a) In accordance with 5 U.S.C. 552(a)(2), the NEH will make the following records available for public inspection in an electronic format (unless they are published and copies are offered for sale) without a FOIA request:

(1) Final opinions, including concurring and dissenting opinions, as well as orders made in the adjudication of cases,

(2) Statements of policy and interpretations which have been adopted by the agency and are not published in the **Federal Register**,

(3) Administrative staff manuals and instructions to staff that affect a member of the public,

(4) Copies of all records, regardless of format, which have been released to any person under 5 U.S.C. 552(a)(3) and which because of their subject matter, the NEH determines have become or are likely to become subject to subsequent requests for substantially the same records, or have been requested three (3) or more times; and

(5) A general index of the records referred to in paragraph (b) of this section.

(b) The NEH will also maintain and make available for public inspection in an electronic format current indexes as required by 5 U.S.C. 552(a)(2) of the FOIA. However, since the NEH has determined that publication and distribution of these indexes is unnecessary and impracticable, the NEH will provide these indexes upon request at a cost not to exceed the direct cost of the duplication.

* * * * *

■ 3. Amend § 1171.7 by revising paragraph (d)(1)(ii) to read as follows:

§ 1171.7 Timing of responses to requests.

* * * * *

(d) * * *

(1) * * *

(ii) If the extension will be for more than ten (10) working days, the NEH will provide the requester with an opportunity either to modify the request so that it may be processed within the time limit or to arrange an alternative time period to process the request or a modified request. To aid the requester, NEH shall make available its FOIA Public Liaison, who shall assist in the resolution of any disputes between the requester and the agency, and shall notify the requester of his or her right to seek dispute resolution services from the Office of Government Information Services.

* * * * *

■ 4. Amend § 1171.8 by revising paragraphs (b) and (c) to read as follows:

§ 1171.8 Responses to requests.

* * * * *

(b) *Grants of requests.* If the NEH makes a determination to grant a request in whole or in part, it will notify the requester in writing of such determination and the reasons therefore, and the requester's right to seek assistance from NEH's FOIA Public Liaison. The NEH will inform the requester of any applicable fees and will disclose records to the requester promptly on payment of any applicable fees. The NEH will mark or annotate records disclosed in part to show the amount of information deleted pursuant to a FOIA exemption, unless doing so would harm an interest protected by an applicable FOIA exemption. If technically feasible, the NEH will also indicate, on the agency record(s) it

provides, the location of the information deleted.

(c) *Denials of requests.* If the NEH makes a determination to deny a request in any respect, the NEH will also notify the requester in writing of:

(1) The name and title or position of the person responsible for the denial;

(2) A brief statement of the reason(s) for the denial, including any FOIA exemption applied by the NEH in denying the request;

(3) An estimate of the volume of records or information withheld, if applicable, although such an estimate is not required if the volume is otherwise indicated through deletion on the records disclosed in part, or if providing such an estimate would harm an interest protected by an applicable exemption;

(4) The requester's right to seek dispute resolution services from NEH's FOIA Public Liaison or the Office of Government Information Services; and

(5) A statement that the requester may appeal the denial under § 1171.10 and a description of the requirements to appeal.

■ 5. Amend § 1171.10 by revising paragraph (a) to read as follows:

§ 1171.10 Administrative appeals.

(a) You may appeal a denial of your request for NEH records (except NEH OIG records) and/or FCAH records to The Deputy Chairman, National Endowment for the Humanities, 400 7th Street SW., Room 4053, Washington, DC 20506. You may also send your appeal to the NEH General Counsel by facsimile at 202–606–8600, by email at *gencounsel@neh.gov,* or through the NEH's electronic FOIA request system, which is available on the NEH Web site at *www.neh.gov.* For a denial of your request for OIG records, you may appeal by facsimile at 202–606–8329, by email at *oig@neh.gov* or by mail to The Inspector General, National Endowment for the Humanities, 400 7th Street SW., Room 2200, Washington, DC 20506. Your appeal must be in writing and received by NEH within ninety (90) days of the date of the letter denying your request in whole or in part. Your appeal letter must clearly identify the NEH decision that you are appealing and contain the tracking number, if assigned. You should clearly mark your appeal letter and envelope ''Freedom of Information Act Appeal.''

* * * * *

■ 6. Amend § 1171.11 by revising paragraph (d)(3) to read as follows:

§ 1171.11 Fees.

* * * * *

(d) * * *

(3) If NEH fails to comply with the FOIA's time limits in which to respond to a request, it may not charge search fees, or, in the instances of requests from requesters described in paragraphs (b)(4) through (6) of this section, may not charge duplication fees, except as described in paragraphs (d)(3)(i) through (iii) of this section.

(i) If NEH has determined that unusual circumstances, as defined by the FOIA, apply and NEH has provided timely written notice to the requester in accordance with the FOIA, a failure to comply with the time limit shall be excused for an additional ten (10) working days.

(ii) If NEH has determined that unusual circumstances, as defined by the FOIA, apply and more than 5,000 pages are necessary to respond to the request, NEH may charge search fees, or, in the case of requesters described in paragraphs (b)(4) through (6) of this section, may charge duplication fees, provided NEH provided timely written notice of unusual circumstances to the requester in accordance with the FOIA and NEH discussed with the requester via written mail, email, or telephone (or made not less than three good-faith attempts to do so) how the requester could effectively limit the scope of the request in accordance with 5 U.S.C. 552(a)(6)(B)(ii).

(iii) If a court has determined that exceptional circumstances exist, as defined by the FOIA, a failure to comply with the time limits shall be excused for the length of time provided by the court order.

* * * * *

Dated: December 23, 2016.

Elizabeth Voyatzis,

Deputy General Counsel.

[FR Doc. 2016–31521 Filed 12–30–16; 8:45 am]

BILLING CODE 7536–01–P

FEDERAL MARITIME COMMISSION

46 CFR Part 502

[Docket No. 16–08]

RIN 3072–AC64

Rules of Practice and Procedure; Presentation of Evidence in Commission Proceedings; Correction

AGENCY: Federal Maritime Commission.

ACTION: Final rule; correction.

SUMMARY: This document contains a correction to the effective date of the final rule published in the **Federal Register** of December 22, 2016, concerning Presentation of Evidence in Commission Proceedings.

DATES: Effective on January 27, 2017.

FOR FURTHER INFORMATION CONTACT: Rachel E. Dickon, Assistant Secretary, Federal Maritime Commission, 800 North Capitol Street NW., Washington, DC 20573–0001, Phone: (202) 523–5725, Email: *secretary@fmc.gov.*

SUPPLEMENTARY INFORMATION: The final rule published on December 22, 2016, 81 FR 93831, contained an incorrect effective date due to a typographical error. The correct effective date is January 27, 2017.

Corrections

In FR Rule Doc. 2016–30745, in the **Federal Register** of December 22, 2016 (81 FR 93831), the following correction is made:

1. On page 93831, in the first column, in the **DATES** section, correct ''January 27, 2016'' to read ''January 27, 2017.''

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2016–31412 Filed 12–30–16; 8:45 am]

BILLING CODE 6731–AA–P

GENERAL SERVICES ADMINISTRATION

48 CFR Part 504

[GSAR Change 80; GSAR Case 2016–G508; Docket No. 2016–0020; Sequence No. 1]

RIN 3090–AJ80

General Services Administration Acquisition Regulation (GSAR); Update Contract Reporting Responsibilities

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Final rule.

SUMMARY: The General Services Administration (GSA) is amending the General Services Administration Acquisition Regulation (GSAR) to remove the section regarding contract reporting in the Federal Procurement Data System (FPDS) and to add a nonregulatory section in the General Services Acquisition Manual (GSAM).

DATES: *Effective:* January 3, 2017.

FOR FURTHER INFORMATION CONTACT: Ms. Janet Fry, Procurement Analyst, at 703–605–3167, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755. Please cite GSAR Case 2016–G508.

SUPPLEMENTARY INFORMATION:

I. Discussion of Changes

In accordance with FAR section 4.604, the GSA Senior Procurement

Executive, in coordination with the head of contracting activities, established internal procedures to monitor contractual actions entered into FPDS by the GSA acquisition workforce. The internal GSA procedures were incorrectly published in the GSAR. Therefore the GSA is amending the GSAR to remove section 504.604 regarding the internal processes for reporting and reviewing the accuracy of contract actions reported.

The internal GSA procedures will be established as a nonregulatory section in the GSAM and communicated to the GSA acquisition workforce through a GSA internal policy letter (*i.e.,* GSA Order). Even though the GSAM guidance is not included with the regulatory changes of this rule, it will be publicly available on *https://www.acquisition.gov/?q=browsegsam.*

II. Public Comments Not Required

41 U.S.C. 1707, Publication of proposed regulations, applies to the publication of the General Services Administration Acquisition Regulation. Paragraph (a)(1) of the statute requires that a procurement policy, regulation, procedure or form (including amendment or modification thereof) must be published for public comment if it 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 contractor or offerors. This final rule is not required to be published for public comment, because there is no affect beyond internal operating procedures, nor does the rule impact contractors or offerors.

III. Executive Order 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 Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

The Regulatory Flexibility Analysis does not apply to this rule because this final rule does not constitute a significant GSAR revision and 41 U.S.C. 1707 does not require publication for public comment.

V. Paperwork Reduction Act

This final rule does not contain any information collection that requires additional 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 Part 504

Government procurement.

Dated: December 23, 2016.

Nicholas West,

Acting Senior Procurement Executive, Acting Director, Office of Acquisition Policy, Office of Governmentwide Policy.

Therefore, GSA is amending 48 CFR part 504 as set forth below:

PART 504—ADMINISTRATIVE MATTERS

■ 1. The authority citation for 48 CFR part 504 continues to read as follows:

Authority: 40 U.S.C. 121(c).

504.604 [Removed]

■ 2. Remove section 504.604.

[FR Doc. 2016–31529 Filed 12–30–16; 8:45 am]

BILLING CODE 6820–EP–P

Proposed Rules

Federal Register
Vol. 82, No. 1
Tuesday, January 3, 2017

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–9550; Directorate Identifier 2016–CE–026–AD]

RIN 2120–AA64

Airworthiness Directives; Piper Aircraft, Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Piper Aircraft, Inc. Models PA–31, PA–31–300, PA–31–325, and PA–31–350 airplanes. This proposed AD was prompted by fatigue cracking in the fuselage station (FS) 332.00 bulkhead common to the horizontal stabilizer front spar attachment. This proposed AD would require repetitive inspections to detect cracks in the bulkhead and any necessary repairs. This proposed AD also provides an optional modification if no cracks are found that will greatly reduce the likelihood of the specified cracks. We are issuing this proposed AD to correct the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by February 17, 2017.

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

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

For service information identified in this NPRM, contact Piper Aircraft, Inc., Customer Service, 2926 Piper Drive, Vero Beach, Florida 32960; telephone: (877) 879–0275; fax: none; email: *customer.service@piper.com;* Internet: *www.piper.com.* You may view this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9550; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Gregory ''Keith'' Noles, Aerospace Engineer, FAA, Atlanta Aircraft Certification Office, 1701 Columbia Avenue, College Park, Georgia 30337; phone: (404) 474–5551; fax: (404) 474–5606; email: *gregory.noles@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2016–9550; Directorate Identifier 2016–CE–026–AD at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

We received reports of fatigue cracking in the FS 332.00 bulkhead common to the horizontal stabilizer front spar attachment on Piper Aircraft, Inc. PA–31 airplanes. Cracks in the bulkhead could compromise the structural component's capability to carry flight loads, increasing the potential to overload and fail adjacent structure. This proposed AD also provides an optional modification if no cracks are found that will greatly reduce the likelihood of the specified cracks. We are proposing this AD to detect and repair cracks in the bulkhead that could lead to structural failure and result in loss of control.

Related Service Information Under 1 CFR Part 51

We reviewed Piper Aircraft, Inc. Service Bulletin No. 1289A, dated October 26, 2016. The service information describes procedures for the repetitive inspections, necessary repairs, and the optional modification of the bulkhead. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of these same type designs.

Proposed AD Requirements

This proposed AD would require repetitive inspections to detect cracks in the bulkhead and any necessary repairs. This proposed AD also provides an optional modification if no cracks are found that will greatly reduce the likelihood of the specified cracks. We are proposing this AD to detect and repair cracks in the bulkhead, that could lead to structural failure and result in loss of control.

Costs of Compliance

We estimate that this proposed AD affects 955 airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspect for cracks in the bulkhead	1 work-hour × $85 per hour = $85	Not Applicable	$85	$81,175

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

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Repair/Modification	26 work-hours × $85 per hour = $2,210	$296	$2,506

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

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

(3) Will not affect intrastate aviation in Alaska, and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Piper Aircraft, Inc.: Docket No. FAA–2016–9550; Directorate Identifier 2016–CE–026–AD.

(a) Comments Due Date

We must receive comments by February 17, 2017.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Piper Aircraft, Inc. Navajo Models PA–31, PA–31–300, and PA–31–325, serial numbers 31–2 through 31–900, and 31–7300901 through 31–8312019; and Chieftain/T–1020 Models PA–31–350, serial numbers 31–5001 through 31–5004, and 31–7305005 through 31–8553002, certificated in any category.

Note 1 to paragraph (c) of this AD: The Model PA–31 may also be identified as a PA–31–310 even though the PA–31–310 is not a model recognized by the Federal Aviation Administration (FAA) on the type certificate data sheet.

(d) Subject

Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 5312: Fuselage—Main Bulkhead.

(e) Unsafe Condition

This AD was prompted by fatigue cracking in the fuselage station (FS) 332.00 bulkhead common to the horizontal stabilizer front spar attachment. We are proposing repetitive inspections to detect cracks in the bulkhead and any necessary repairs. This proposed AD also provides an optional modification if no cracks are found that will greatly reduce the likelihood of the specified cracks. Cracks in the bulkhead could compromise the structural components capability to carry flight loads, increasing the potential to overload and fail adjacent structure and lead to loss of control.

(f) Compliance

Comply with paragraphs (g)(1) through (3) of this AD within the compliance times specified, unless already done.

(g) Actions

(1) *For airplanes with 3,000 hours time-in-service (TIS) or less as of the effective date of this AD:* Initially within 500 hours TIS after reaching 3,000 hours TIS and repetitively thereafter every 200 hours TIS, inspect the fuselage station (FS) 332.00 bulkhead assembly for cracks following the instructions in Part I of Piper Aircraft, Inc. Service Bulletin (SB) No. 1289A, dated October 26, 2016.

(2) *For airplanes with over 3,000 hours TIS as of the effective date of this AD:* Initially within the next 500 hours TIS after the effective date of this AD and repetitively thereafter every 200 hours TIS, inspect the FS 332.00 bulkhead assembly for cracks, following the instructions in Part I of Piper Aircraft, Inc. SB No. 1289A, dated October 26, 2016.

(3) If cracks are found during any of the inspections required in paragraphs (g)(1) or (2) of this AD, before further flight, repair the cracks following the modification instructions in Part II of Piper Aircraft, Inc. SB No. 1289A, dated October 26, 2016, and one of the following as applicable:

(i) If the crack does not extend beyond the inspection/template area of Figure 2 of Piper

Aircraft, Inc. SB No. 1289A, dated October 26, 2016, and meets the minimum acceptable distance in Figure 3 and Table 2 of Part II of Piper Aircraft, Inc. SB No. 1289A, dated October 26, 2016, then the installation of Piper Kit 88578–001 Revision B, dated June 23, 2016, is acceptable as a repair and is considered terminating action for the repetitive inspection requirement in paragraphs (g)(1) and (2) of this AD.

(ii) If the crack extends beyond the inspection/template area of Figure 2 of Piper Aircraft, Inc. SB No. 1289A, dated October 26, 2016, or does not meet the minimum acceptable distance in Figure 3 and Table 2 of Part II of Piper Aircraft, Inc. SB No. 1289A, dated October 26, 2016, then the installation of Piper Kit 88578–001 Revision B, dated June 23, 2016, is not an acceptable repair. You must obtain an alternative method of compliance (AMOC) for any repair or modification in this area. You may contact Piper Aircraft, Inc. for repair instruction development specific to this condition. For contact information refer to paragraph (j) of this AD.

(4) If no cracks are found, you may install Piper Kit 88578–001 Revision B, dated June 23, 2016, on an uncracked bulkhead following the Modification instructions in Part II of Piper Aircraft, Inc. SB No. 1289A, dated October 26, 2016. Installation of Piper Kit 88578–001 Revision B, dated June 23, 2016, on an uncracked bulkhead is considered terminating action for the repetitive inspection requirement in paragraphs (g)(1) and (2) of this AD.

(h) Special Flight Permit

A special flight permit is allowed for this AD per 14 CFR 39.23 with limitations. Permits are not allowed if cracks are discovered during any inspection following Part I of Piper Aircraft, Inc. SB No. 1289A, dated October 26, 2016. Any cracks found during any inspection must be repaired before further flight.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Atlanta Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (k) of this AD.

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

(j) Related Information

(1) For more information about this AD, contact Gregory ''Keith'' Noles, Aerospace Engineer, FAA, Atlanta Aircraft Certification Office, 1701 Columbia Avenue, College Park, Georgia 30337; phone: (404) 474–5551; fax: (404) 474–5606; email: *gregory.noles@faa.gov.*

(2) For service information identified in this AD, contact Piper Aircraft, Inc., Customer Service, 2926 Piper Drive, Vero Beach, Florida 32960; telephone: (877) 879–0275; fax: none; email: *customer.service@piper.com;* Internet: *www.piper.com.* You may review the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on December 13, 2016.

Robert P. Busto,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–30716 Filed 12–30–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–9519; Directorate Identifier 2016–NM–099–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Airbus Model A318, A319, A320, and A321 series airplanes. This proposed AD was prompted by in-service experience and further analysis, which showed that the galley 5 without kick-load retainers, was unable to withstand the expected loading during several flight phases or in case of emergency landing. This proposed AD would require modification of galley 5 by adding kick-load retainers. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by February 17, 2017.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- For service information identified in this NPRM, contact Airbus, Airworthiness Office–EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425 227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9519; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

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

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2016–9519; Directorate Identifier 2016–NM–099–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

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

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent

for the Member States of the European Union, has issued EASA Airworthiness Directive, 2016–0040, dated March 2, 2016, (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Airbus Model A318, A319, A320, and A321 series airplanes. The MCAI states:

Following in-service experience and further analyses, it was ascertained that the galley 5 without kick-load retainers on external position could not withstand the expected loading during several flight phases or in case of emergency landing.

This condition, if not corrected, could lead to galley/trolley detachment and collapse into an adjacent cabin aisle or cabin zone, possibly spreading loose galley equipment items, compartment doors or leaking fluids, blocking an evacuation route, and consequently resulting in injury to crew or passengers.

To address this potential unsafe condition, Airbus issued 6 Service Bulletins (SB) to provide modification instructions for the affected aeroplanes.

For the reasons described above, this [EASA] AD requires modification of galley 5 trolley compartments to install kick-load retainers.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9519.

Related Service Information Under 1 CFR Part 51

We reviewed the following Airbus service information: Airbus Service Bulletin A320–25–1B29, dated June 19, 2014, and Airbus Service Bulletin A320–25–1B30, dated June 19, 2014. The service information describes procedures for installing kick-load retainers on certain galley 5 trolley compartments. These documents are distinct since they apply to different airplane configurations. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This Proposed AD

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

Costs of Compliance

We estimate that this proposed AD affects 19 airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Modification	2 work-hours × $85 per hour = $170	$0	$170	$3,230

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

3. Will not affect intrastate aviation in Alaska; and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus: Docket No. FAA–2016–9519; Directorate Identifier 2016–NM–099–AD.

(a) Comments Due Date

We must receive comments by February 17, 2017.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Model A318–112, A319–115, A320–214, A320–232, and A321–111 airplanes, certificated in any category, with manufacturer's serial numbers 1479, 3096, 3693, 3713, 3739, 3791, 3896, 3902, 3907, 3931, 3949, 3969, 4030, 4045, 4049, 4059, 4066, 4077, 4083, 4124, 4146, 4158, 4188, 4198, 4206, 4209, 4218, 4235, 4255, 4264, 4304, 4321, 4371, 4374, 4395, 4411, 4417, 4431, 4485, 4492, 4502, 4528, 4541, 4548, 4592, 4595, 4638, 4651, 4669, 4703, 4724, 4737, 4746, 4770, 4780, 4783, 4826, 4827, 4860, 4863, 4865, 4902, 4934, 4945, 4951, 4952, 4971, 4996, 5023, 5029, 5042, 5088, 5095, 5132, 5159, 5164, 5171, 5175, 5192, 5210, 5227, 5241, 5247, 5251, 5275, 5277, 5297, 5306, 5340, 5343, 5348, 5356, 5366, 5370, 5385, 5387, 5392, 5396, 5400, 5407, 5418, 5427, 5438, 5456, 5458, 5469, 5495, 5517, 5555, 5624, 5674, 5678, 5698, 5699, 5704, 5709, 5714, 5791, 5745, 5753, 5761, 5781, 5786, 5788, 5789, 5798, 5804, 5810, 5821, 5827, 5842, 5874, 5882,

5889, 5903, 5907, 5916, 5924, 5958, 5984, 5994, 6000, 6004, 6054, 6080, 6107, 6166, 6176, 6234, 6266, 6293, 6335, 6344, 6365, 6430, and 6444.

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/furnishings.

(e) Reason

This AD was prompted by in-service experience and further analysis, which showed that the galley 5 without kick-load retainers was unable to withstand the expected loading during several flight phases or in case of emergency landing. We are issuing this AD to prevent galley/trolley detachment and collapse into an adjacent cabin aisle or cabin zone, possibly spreading loose galley equipment items or compartment doors, or leaking fluids. These hazards could block an evacuation route and result in injury to crew or passengers.

(f) Compliance

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

(g) Install Kick-Load Retainers

Within 12 months after the effective date of this AD, install kick-load retainers on the galley 5 trolley compartments as specified in paragraph (g)(1), (g)(2), or (g)(3) of this AD, as applicable.

(1) For Airbus Model A319 airplanes, manufacturer's serial numbers 5678, 5698, 5704, 5745, 5753, 5761, 5781, 5786, 5788, 5789, 5798, 5810, 5827, and 5842, do the installation in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–25–1B29, dated June 19, 2014.

(2) For Airbus Model A320 airplanes, manufacturer's serial numbers 5458, 5517, 5624, 5672, and 5804, do the installation in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–25–1B30, dated June 19, 2014.

(3) For airplanes not identified in paragraph (g)(1) or (g)(2) of this AD, use a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA).

(h) Other FAA AD Provisions

The following provisions also apply to this AD:

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

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

(i) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2016–0040, dated March 2, 2016, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9519.

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

Issued in Renton, Washington, on December 15, 2016.

Victor Wicklund,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–30806 Filed 12–30–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–9380; Directorate Identifier 2016–NE–21–AD]

RIN 2120–AA64

Airworthiness Directives; CFE Company Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain CFE Company (CFE) turbofan engines. This proposed AD was prompted by a quality escape for high-pressure compressor (HPC) impellers made from forgings with nonconforming material grain size. This proposed AD would require removal of the HPC impeller. We are proposing this AD to correct the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by February 17, 2017.

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

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

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9380; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Martin Adler, Aerospace Engineer, Engine Certification Office, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7157; fax: 781–238–7199; email: *martin.adler@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2016–9380; Directorate Identifier 2016–NE–21–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

We propose to adopt an AD for certain CFE CFE738–1–1B model turbofan engines with HPC impeller, part number (P/N) 6079T77P07 or P/N 6079T77P09 installed. This proposed AD was prompted by a quality escape for HPC impellers made from forgings with nonconforming material grain size. This condition, if not corrected, could result in failure of the HPC impeller, damage to the engine, and damage to the airplane.

Related Service Information Under 1 CFR Part 51

We reviewed CFE Service Bulletin (SB) CFE738–72–8080, Revision 0, dated August 18, 2016. The SB describes procedures for replacing specific serial numbered HPC impellers, P/N 6079T77P07 or P/N 6079T77P09. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require removal of affected HPC impellers from service and replacement with a part eligible for installation.

Costs of Compliance

We estimate that this proposed AD affects 176 engines installed on airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Pro-rated HPC impeller	$0.00	$42,240	$42,240	$7,434,240

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

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

(3) Will not affect intrastate aviation in Alaska, and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

CFE Company: Docket No. FAA–2016–9380; Directorate Identifier 2016–NE–21–AD.

(a) Comments Due Date

We must receive comments by February 17, 2017.

(b) Affected ADs

None.

(c) Applicability

This AD applies to CFE Company (CFE) CFE738–1–1B model turbofan engines with a high-pressure compressor (HPC) impeller, part number (P/N) 6079T77P07 or P/N 6079T77P09, with a serial number listed in CFE Service Bulletin (SB) CFE738–72–8080, Revision 0, dated August 18, 2016, installed.

(d) Subject

Joint Aircraft System Component (JASC) of America Code 7230, Turbine Engine Compressor Section.

(e) Unsafe Condition

This AD was prompted by a quality escape for HPC impellers made from forgings with nonconforming material grain size. We are issuing this AD to prevent uncontained failure of the HPC impeller, damage to the engine, and damage to the airplane.

(f) Compliance

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

(g) Required Action

Remove all affected HPC impellers from service at the next piece-part exposure and replace with a part eligible for installation.

(h) Definition

For the purposes of this AD, ''piece-part exposure'' is defined as separation of the impeller from the compressor rotor assembly.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Engine Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: *ANE-AD-AMOC@faa.gov.*

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

(j) Related Information

(1) For more information about this AD, contact Martin Adler, Aerospace Engineer, Engine Certification Office, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7157; fax: 781–238–7199; email: *martin.adler@faa.gov*.

(2) For service information identified in this proposed AD, contact CFE Company, 111 S. 34th Street, Phoenix, Arizona 85034–2802; phone: 800–601–3099; Internet: *https://www.myaerospace.com*.

(3) You may view this service information at FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Issued in Burlington, Massachusetts, on December 15, 2016.

Colleen M. D'Alessandro,

Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2016–30951 Filed 12–30–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–9520; Directorate Identifier 2016–NM–163–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all The Boeing Company Model 777 airplanes. This proposed AD was prompted by reports of cracks on the underwing longerons. This proposed AD would require repetitive inspections of the left and right side underwing longerons for any crack, and related investigative and corrective actions if necessary. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by February 17, 2017.

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

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

For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone: 562–797–1717; Internet: *https://www.myboeingfleet.com*. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9520.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9520; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Eric Lin, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6412; fax: 425–917–6590; email: *eric.lin@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2016–9520; Directorate Identifier 2016–NM–163–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

We have received a report indicating that cracks have been found which led to an underwing longeron becoming severed. The first underwing longeron crack was discovered in service. An operator had reports of a fuel smell in the forward cargo area. During a subsequent investigation, a crack was found in the center wing tank that was attributed to the longeron crack. All models except some Model 777–200 airplanes without a center wing tank are affected by the potential for a fuel leak into the forward cargo area.

Subsequently, three more operators have reported cracks on the left underwing longeron. The cracks have been reported in Model 777–300ER and 777–200 airplanes. The cracks have been reported as early as 3,784 flight cycles and 31,240 flight hours. As the cracks grow in the longeron, further cracking has been reported and three operators noted the lower front spar chord had cracked. This condition, if not corrected, could result in fuel leakage into the forward cargo area and consequent increased risk of a fire or, in a more severe case, could adversely affect the structural integrity of the airplane.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Alert Service Bulletin 777–53A0081, dated September 8, 2016 (''ASB 777–53A0081, Revision 0''). The service information describes procedures for repetitive detailed inspections, ultrasonic inspections, and high frequency eddy current (HFEC) inspections of the left and right side longerons, and related investigative and corrective actions if necessary. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously, except as discussed under

''Differences Between this Proposed AD and the Service Information.'' For information on the procedures and compliance times, see this service information at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9520.

The phrase ''related investigative actions'' is used in this proposed AD. Related investigative actions are follow-on actions that (1) are related to the primary action, and (2) further investigate the nature of any condition found. Related investigative actions in an AD could include, for example, inspections.

The phrase ''corrective actions'' is used in this proposed AD. Corrective actions correct or address any condition found. Corrective actions in an AD could include, for example, repairs.

Differences Between This Proposed AD and the Service Information

ASB 777–53A0081, Revision 0, specifies to contact the manufacturer for certain instructions, but this proposed AD would require using repair methods, modification deviations, and alteration deviations in one of the following ways:

- In accordance with a method that we approve; or
- Using data that meet the certification basis of the airplane, and that have been approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) whom we have authorized to make those findings.

Costs of Compliance

We estimate that this proposed AD affects 201 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Option 1: Detailed Inspection	4 work-hours × $85 per hour = $340 per inspection cycle.	$0	$340 per inspection cycle	$68,340 per inspection cycle.
Option 2: Detailed and HFEC or Ultrasonic Inspection.	12 work-hours × $85 per hour = $1,020 per inspection cycle.	$0	$1,020 per inspection cycle ...	$205,020 per inspection cycle.

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

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Left side or right side longeron replacement	102 work-hours × $85 per hour = $8,670 per side.	$31,000 per side	$39,670 per side.

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions, other than the replacement, specified in this proposed AD.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

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

(3) Will not affect intrastate aviation in Alaska, and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2016–9520; Directorate Identifier 2016–NM–163–AD.

(a) Comments Due Date

We must receive comments by February 17, 2017.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all The Boeing Company Model 777–200, –200LR, –300, –300ER, and 777F series airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage and 57, Wings.

(e) Unsafe Condition

This AD was prompted by reports of cracks on the underwing longerons. We are issuing this AD to detect and correct cracks in the underwing longerons, which could result in fuel leakage into the forward cargo area and consequent increased risk of a fire or, in a more severe case, could adversely affect the structural integrity of the airplane.

(f) Compliance

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

(g) Inspections

Except as specified in paragraph (i)(1) of this AD, at the applicable times specified in tables 1 through 6 of paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 777–53A0081, dated September 8, 2016 (''ASB 777–53A0081, Revision 0''): Do detailed inspections for any crack of the left and right side underwing longerons; or do detailed inspections, and high frequency eddy current (HFEC) or ultrasonic inspections, as applicable, for any crack of the left and right side underwing longerons; and do all applicable related investigative and corrective actions; in accordance with the Accomplishment Instructions of ASB 777–53A0081, Revision 0, except as required by paragraph (i)(2) of this AD. Do all applicable related investigative and corrective actions before further flight. Repeat the inspections thereafter at the times specified in tables 1 through 6 of paragraph 1.E., ''Compliance,'' of ASB 777–53A0081, Revision 0, as applicable. Replacing an underwing longeron, including doing all applicable related investigative and corrective actions, in accordance with the Accomplishment Instructions of ASB 777–53A0081, Revision 0, except as required by paragraph (i)(2) of this AD, terminates the repetitive inspections required by this paragraph for that longeron only.

(h) Repetitive Post-Replacement Inspections and Corrective Actions

For airplanes on which any longeron replacement has been done as specified in ASB 777–53A0081, Revision 0: At the applicable times specified in tables 7 through 14 of paragraph 1.E., ''Compliance,'' of ASB 777–53A0081, Revision 0, do detailed inspections of all replaced longerons for any crack, or do detailed inspections and ultrasonic inspections of all replaced longerons for any crack, and do all applicable corrective actions; in accordance with the Accomplishment Instructions of ASB 777–53A0081, Revision 0, except as required by paragraph (i)(2) of this AD. Do all applicable corrective actions before further flight. Repeat the inspections thereafter at intervals not to exceed the applicable time specified in tables 7 through 14 of paragraph 1.E., ''Compliance,'' of ASB 777–53A0081, Revision 0.

(i) Service Information Exceptions

(1) Where ASB 777–53A0081, Revision 0, specifies a compliance time ''after the issue date of this service bulletin,'' this AD requires compliance within the specified compliance time after the effective date of this AD.

(2) Where ASB 777–53A0081, Revision 0, specifies to contact Boeing for appropriate action: Before further flight, repair using a method approved in accordance with the procedures specified in paragraph (j) of this AD.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (k)(1) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) Except as required by paragraph (i)(2) of this AD: For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (j)(4)(i) and (j)(4)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or sub-step is labeled ''RC Exempt,'' then the RC requirement is removed from that step or sub-step. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(k) Related Information

(1) For more information about this AD, contact Eric Lin, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6412; fax: 425–917–6590; email: *eric.lin@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone: 562–797–1717; Internet: *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on December 15, 2016.

Victor Wicklund,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–30807 Filed 12–30–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Office of the Secretary

15 CFR Part 4

[Docket No. 161103999–6999–01]

RIN 0605–AA46

Public Information, Freedom of Information Act and Privacy Act Regulations

AGENCY: Department of Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: This rule proposes revisions to the Department of Commerce's (Department) regulations under the Privacy Act. The Department has issued a notice of its intent to establish a new system of records entitled ''COMMERCE/DEPARTMENT–27, Investigation and Threat Management Records,'' which includes system exemptions from certain provisions of the Privacy Act. The Privacy Act regulations are being updated to make technical changes to the applicable exemptions as a result of the new system of records, COMMERCE/DEPARTMENT–27. The Privacy Act regulations are also being updated to reflect organization changes affecting the Department's officials authorized to deny requests for records under the Freedom of Information Act, and

requests for records and for correction or amendment under the Privacy Act.

DATES: To be considered, written comments must be submitted on or before February 2, 2017. If no comments are received, the rule will become effective as proposed on the date of publication of a subsequent notice in the **Federal Register**.

ADDRESSES: You may submit comments, identified by Regulatory Information Number (RIN) 0605–AA46, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 482–0827. Include the RIN 0605–AA46 in the subject line.
- *Mail:* Dr. Michael J. Toland, Deputy Chief Freedom of Information Act Officer and Department Privacy Act Officer, Office of Privacy and Open Government, 1401 Constitution Ave. NW., Room 52010, Washington, DC 20230.

Instructions: All submissions received must include the agency name and docket number or RIN for this rulemaking. All comments received will be posted without change to *regulations.gov*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Dr. Michael J. Toland, Deputy Chief Freedom of Information Act Officer and Department Privacy Act Officer, Office of Privacy and Open Government, 1401 Constitution Ave. NW., Room 52010, Washington, DC 20230.

SUPPLEMENTARY INFORMATION: This rule proposes revisions to the Department's regulations under the Privacy Act. In particular, the action will amend the Department's Privacy Act regulations regarding applicable exemptions to reflect a new Department wide systems of records notice published since the last time the regulations were updated. The Department has issued a notice of its intent to establish a new system of records entitled ''COMMERCE/DEPARTMENT–27, Investigation and Threat Management Records,'' which includes system exemptions from certain provisions of the Privacy Act. The revisions of the Privacy Act regulations in subpart B of part 4 incorporate changes to the language of the regulations in the following provisions: § 4.33 (General exemptions); and § 4.34 (Specific exemptions). Specifically, pursuant to 5 U.S.C. 552a(j)(2), all information about an individual in the record which meets the criteria stated in 5 U.S.C. 552a(j)(2) are exempted from the notice, access and contest requirements of the agency regulations and from all parts of 5 U.S.C. 552a except subsections (b), (c)(1) and (2), (e)(4)(A) through (F), (e)(6), (7), (9), (10), and (11), and (i). Pursuant to 5 U.S.C. 552a(k)(1), (k)(2) and (k)(5) on condition that the 5 U.S.C. 552a(j)(2) exemption is held to be invalid, all investigatory material in the record which meets the criteria stated in 5 U.S.C. 552a(k)(1), (k)(2) and (k)(5) are exempted from the notice, access, and contest requirements (under 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), and (I), and (f)) of the agency regulations because of the necessity to exempt this information and material in order to accomplish the law enforcement function of the agency, to prevent disclosure of classified information as required by Executive Order 13526, to assure the protection of the President, to prevent subjects of investigation from frustrating the investigatory process, to prevent the disclosure of investigative techniques, to fulfill commitments made to protect the confidentiality of information, and to avoid endangering these sources and law enforcement personnel.

Additionally, the revisions of the Privacy Act regulations in subpart B of part 4 incorporate changes to the language of the regulations in Appendix B (Officials Authorized To Deny Requests for Records Under the Freedom of Information Act, and Requests for Records and Requests for Correction or Amendment Under the Privacy Act). Specifically, this proposed action removes the reference to the ''Office of Administrative Services: Director,'' and replaces it with the ''Office of Facilities and Environmental Quality: Director; Deputy Director,'' under the Assistant Secretary for Administration (ASA). The Department's ASA realigned the functions formerly under the ''Office of Administrative Services'' to existing administrative functions and aligned facility-related programs and operations under the ''Office of Facilities and Environmental Quality.'' The proposed actions better allocated responsibilities, aligned similar functions, improved internal controls and streamline reporting relationships. This proposed amendment updates the rules to implement that change. *See* Department Administrative Order 20–1, sections 1 and 4. This proposed action adds as a denying official the Deputy Chief FOIA Officer under the Office of Privacy and Open Government (OPOG). Previously, the Director of OPOG served as the Deputy Chief FOIA Officer, but now this position serves as the Department's Chief FOIA Officer. This action also removes the reference to the ''Bureau of Economic Analysis: Director,'' and replaces it with the ''Bureau of Economic Analysis: Freedom of Information Act Officer'' under the Economics and Statistics Administration (ESA). Previously, the ESA FOIA Officer administered the FOIA program for the Bureau of Economic Analysis (BEA). This proposed action merely separates the administration of the BEA FOIA program from the ESA program, as well as designates a BEA FOIA Officer and aligns the BEA FOIA program with other FOIA programs in the Department.

Public Participation: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by the Department. If you want to submit personal identifying information (such as your name, address, *etc.*) as part of your comment, but do not want it to be posted online, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also locate all the personal identifying information you do not want posted online in the first paragraph of your comment and identify what information you want redacted. If you want to submit confidential business information as part of your comment but do not want it to be posted online, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of the comment may not be posted on *http://www.regulations.gov.* Personal identifying information and confidential business information identified and located as set forth above will be placed in the agency's public docket file, but not posted online. If you wish to inspect the agency's public docket file in person by appointment, please *see* the **FOR FURTHER INFORMATION CONTACT** paragraph.

Classification

Regulatory Flexibility Act

The Chief Counsel for Regulation for the Department of Commerce has certified to the Chief Counsel for

Advocacy of the Small Business Administration that this rule will not have a significant economic impact on a substantial number of small entities. This final rule amends the Department's Privacy Act regulations regarding applicable exemptions to reflect new Department wide systems of records notices published since the last time the regulations were updated. These amendments are administrative in nature and will not impose a financial or regulatory impact on anyone, including small entities. The applicable exemptions apply to information collected to establish identity, accountability, and audit control of electronic or other digital certificates of assigned personnel who require access to Department of Commerce electronic and physical assets. The information collected is provided on a voluntary basis, with no cost incurred by individuals.

Executive Order 12866

It has been determined that this notice is not significant for purposes of E.O. 12866.

Paperwork Reduction Act

This regulation does not contain a ''collection of information'' as defined by the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 15 CFR Part 4

Freedom of information, Privacy.

Michael J. Toland,

Department of Commerce, Deputy Chief FOIA Officer, Department Privacy Act Officer.

For the reasons stated in the preamble, the Department of Commerce proposes to amend 15 CFR part 4 as follows:

PART 4—DISCLOSURE OF GOVERNMENT INFORMATION

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

Authority: 5 U.S.C. 301; 5 U.S.C. 552; 5 U.S.C. 553; 31 U.S.C. 3717; 41 U.S.C. 3101; Reorganization Plan No. 5 of 1950.

■ 2. Amend § 4.33 by adding paragraph (b)(5) to read as follows:

§ 4.33 General exemptions.

* * * * *

(5) *Investigation and Threat Management Records*—COMMERCE/DEPT–27. Pursuant to 5 U.S.C. 552a(j)(2), these records are hereby determined to be exempt from all provisions of the Act, except 5 U.S.C. 552a(b), (c)(1) and (2), (e)(4)(A) through (F), (e)(6), (7), (9), (10), and (11), and (i). These exemptions are necessary to ensure the proper functioning of the law enforcement activity of the agency, to prevent disclosure of classified information as required by Executive Order 13526, to assure the protection of the President, to prevent subjects of investigation from frustrating the investigatory process, to prevent the disclosure of investigative techniques, to fulfill commitments made to protect the confidentiality of information, and to avoid endangering these sources and law enforcement personnel.

■ 3. Amend § 4.34 by revising paragraph (a)(1), (b)(1), and (b)(4)(i); and by adding (b)(2)(i)(G) to read as follows:

§ 4.34 Specific exemptions.

(a)(1) Certain systems of records under the Act that are maintained by the Department may occasionally contain material subject to 5 U.S.C. 552a(k)(1), relating to national defense and foreign policy materials. The systems of records published in the **Federal Register** by the Department that are within this exemption are: COMMERCE/BIS–1, COMMERCE/ITA–2, COMMERCE/ITA–3, COMMERCE/NOAA–11, COMMERCE–PAT–TM–4, COMMERCE/DEPT–12, COMMERCE/DEPT–13, COMMERCE/DEPT–14, COMMERCE/DEPT–25, and COMMERCE/DEPT–27.

* * * * *

(b)(1) Exempt under 5 U.S.C. 552a(k)(1). The systems of records exempt hereunder appear in paragraph (a) of this section. The claims for exemption of COMMERCE/DEPT–12, COMMERCE/BIS–1, COMMERCE/NOAA–5, COMMERCE/DEPT–25, and COMMERCE/DEPT–27 under this paragraph are subject to the condition that the general exemption claimed in § 4.33(b) is held to be invalid.

* * * * *

(2)(i) * * *

(G) Investigation and Threat Management Records—COMMERCE/DEPT–27, but only on condition that the general exemption claimed in § 4.33(b)(4) is held to be invalid;

* * * * *

(b)(4)(i) Exempt under 5 U.S.C. 552a(k)(5). The systems of records exempt (some only conditionally), the sections of the Act from which exempted, and the reasons therefor are as follows:

(A) Applications to U.S. Merchant Marine Academy (USMMA)—COMMERCE/MA–1;

(B) USMMA Midshipman Medical Files—COMMERCE/MA–17;

(C) USMMA Midshipman Personnel Files—COMMERCE/MA–18;

(D) USMMA Non-Appropriated Fund Employees—COMMERCE/MA–19;

(E) Applicants for the NOAA Corps—COMMERCE/NOAA–1;

(F) Commissioned Officer Official Personnel Folders—COMMERCE/NOAA–3;

(G) Conflict of Interest Records, Appointed Officials—COMMERCE/DEPT–3;

(H) Investigative and Inspection Records—COMMERCE/DEPT–12, but only on condition that the general exemption claimed in § 4.33(b)(3) is held to be invalid;

(I) Investigative Records—Persons within the Investigative Jurisdiction of the Department COMMERCE/DEPT–13;

(J) Litigation, Claims, and Administrative Proceeding Records—COMMERCE/DEPT–14;

(K) Access Control and Identity Management System—COMMERCE/DEPT–25, but only on condition that the general exemption claimed in § 4.33(b)(4) is held to be invalid; and

(L) Investigation and Threat Management Records—COMMERCE/DEPT–27, but only on condition that the general exemption claimed in § 4.33(b)(4) is held to be invalid.

* * * * *

■ 4. Amend Appendix B to Part 4 by revising the entries for ''ASSISTANT SECRETARY FOR ADMNISTRATION'' and ''ECONOMICS AND STATISTICS ADMINISTRATION'' to read as follows:

Appendix B to Part 4—Officials Authorized To Deny Requests for Records Under the Freedom of Information Act, and Requests for Records and Requests for Correction or Amendment Under the Privacy Act

* * * * *

Assistant Secretary for Administration

Office of Civil Rights: Director
Office of Budget: Director
Office of Privacy and Open Government: Director; Deputy Chief FOIA Officer; Departmental Freedom of Information Officer
Office of Program Evaluation and Risk Management: Director
Office of Financial Management: Director
Office of Human Resources Management: Director; Deputy Director
Office of Facilities and Environmental Quality: Director; Deputy Director
Office of Security: Director
Office of Acquisition Management: Director
Office of Acquisition Services: Director
Office of Small and Disadvantaged Business Utilization: Director

* * * * *

Economics and Statistics Administration

Office of Administration: Director
Bureau of Economic Analysis: Freedom of Information Act Officer

Bureau of the Census: Freedom of Information Act Officer

* * * * *

[FR Doc. 2016–31314 Filed 12–30–16; 8:45 am]

BILLING CODE 3510–BX–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1015

Procedures for Disclosure or Production of Information Under the Freedom of Information Act; Amendments

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Consumer Product Safety Commission (Commission, CPSC, or we) is issuing this notice of proposed rulemaking (NPR) to update its Freedom of Information Act (FOIA) rule. We are proposing to revise the rule to conform to the amendments of the FOIA Improvement Act of 2016 (the 2016 FOIA) to the FOIA. The Commission also proposes to update the rule to reflect changes in Commission procedures, update Commission contact information, including current methods of submitting requests for records to the Commission, revise employee titles, and make various technical changes and corrections. This NPR seeks comments on the proposed changes to the rule.

DATES: Submit comments by March 20, 2017.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2016–0030, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at *https://www.regulations.gov/.* Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (email), except through: *https://www.regulations.gov/.* The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written comments by mail/hand delivery/courier to: Office of the Secretariat, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this proposed rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: *https://www.regulations.gov/.* Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted by mail/hand delivery/courier.

Docket: For access to the docket to read background documents or comments received, go to: *https://www.regulations.gov/,* and insert the docket number, CPSC–2016–0030, into the ''Search'' box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Renee McCune, Office of the General Counsel, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, (301) 504–7673; or Todd A. Stevenson, Chief Freedom of Information Officer, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, (301) 504–6836.

SUPPLEMENTARY INFORMATION: The Commission is proposing to amend the agency's procedures for disclosure or production of information under the Freedom of Information Act. 16 CFR part 1015.

Table of Contents

I. Background Information
II. Section-by-Section Analysis of the Proposed Revisions of the Procedures for Disclosure or Production of Information Under the Freedom of Information Act
III. Environmental Issues
IV. Regulatory Flexibility
V. Paperwork Reduction
VI. Preemption
VII. Effective Date
VIII. Request for Comments

I. Background Information

On June 30, 2016, the President signed into law the 2016 FOIA, Public Law 114–185 (2016). The 2016 FOIA amends the Freedom of Information Act, 5 U.S.C. 552, requiring an agency to review its FOIA regulations and issue regulations on procedures for the disclosure of records under the new amendments. Specifically, the 2016 FOIA requires: Certain records be available for public inspection in an electronic format; agencies to make available for public inspection in an electronic format records that have been requested three or more times; that an agency not withhold information under FOIA unless the agency reasonably foresees that disclosure would harm an interest protected by a FOIA Exemption or disclosure is prohibited by law; extending the number of days for an administrative appeal of an adverse determination from 30 to 90 days; limiting the FOIA Exemption for records created 25 years or more before the date on which the records were requested; the assessment of fees be limited in certain circumstances; and requesters be notified of available dispute resolution services from the FOIA Public Liaison of the agency or the Office of Government Information Services.

The Commission proposes amendments to its regulations implementing the 2016 FOIA, 16 CFR part 1015, to incorporate these new statutory requirements. The proposed amendments would revise the Commission's FOIA regulations to comply with the FOIA, as amended by the 2016 FOIA, and would update Commission procedures, contact information, and methods of submitting requests for records to the Commission, in addition to other conforming and technical revisions. Updating Commission procedures and Commission contact information would provide clarity for requesters seeking records from the Commission.

II. Section-by-Section Analysis of the Proposed Revision of the Procedures for Disclosure or Production of Information Under the Freedom of Information Act

Subpart A—Production or Disclosure Under 5 U.S.C. 552(a)

Proposed Changes to § 1015.1 (Purpose and Scope)

Initially, we would update § 1015.1(a) to add the Children's Gasoline Burn Prevention Act, the Virginia Graeme Baker Pool and Spa Safety Act, and the Child Nicotine Poisoning Prevention Act to the scope of statutes for which records must be maintained in connection with the Commission's responsibilities and functions under those acts because they were enacted after the last revision to the regulation in 1997.

The proposal also would revise § 1015.1(b) to reflect new FOIA 5 U.S.C. 552(a)(8)(A), requiring agencies to analyze under a foreseeable harm standard the withholding of information permitted by the exemptions set forth in 5 U.S.C. 552(b). The proposal would allow information to be withheld pursuant to the exemptions, only if the Commission reasonably foresees that disclosure would harm an interest protected by a specific FOIA exemption, or if disclosure is otherwise prohibited by law. This proposal, consistent with the 2016 FOIA, would not require disclosure of information otherwise prohibited from disclosure by law, or otherwise exempted from disclosure

under 5 U.S.C. 552(b)(3) (FOIA Exemption 3), which prohibits the disclosure of matters specifically exempted from disclosure by another statute. The proposal would specify that the Commission will consider the record's age, content, and character in assessing whether it reasonably foresees that disclosure of the document would harm an interest protected by an exemption. Additionally, consistent with the FOIA as amended by the 2016 FOIA, we also propose a revision that would require that we consider partial disclosure when full disclosure of a record is not possible and that we take reasonable steps to segregate and release nonexempt information.

Under the proposed revision, for example, Commission records that currently fall within the parameters of 5 U.S.C. 552(b)(5) (FOIA Exemption 5) would be subject to the foreseeable harm standard. FOIA Exemption 5 incorporates, among other privileges, the deliberative process privilege, which is considered a discretionary exemption, meaning that withholding of records resides within the discretion of the agency, rather than mandated by law. As the Senate report on the FOIA amendment explains: ''[t]he foreseeable harm standard applies only to those FOIA Exemptions under which discretionary disclosures can be made. Several FOIA Exemptions, by their own existing terms, cover information that is prohibited from disclosure or exempt from disclosure under a law outside the four corners of the FOIA. Such information is not subject to discretionary disclosure and is therefore not subject to the foreseeable harm standard.'' Senate Report No. 114–4, p 8 (February 23, 2015). Under this analysis and Department of Justice guidance, records protected by the deliberative process privilege under FOIA Exemption 5 shall be considered for release under the foreseeable harm standard, even if the records may otherwise be properly withheld under this exemption. In deciding whether to make a discretionary release of records protected by the deliberative process privilege, the Commission may consider, in addition to the record's age, content, and character, the nature of the decision at issue, the status of that decision, and the personnel involved.

The foreseeable harm standard, however, would not be applied to disclosures prohibited by law or covered by FOIA Exemption 3, which pertains to matters specifically exempted from disclosure by another statute. Exemption 3 would include disclosures prohibited under section 6 of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2055(a)(2), and thus, the proposal to apply the foreseeable harm standard would not alter, or otherwise limit, the information disclosure restrictions set forth in section 6. Current § 1015.1(b) already references disclosures prohibited by law under Section 6(a)(2) of the CPSA. The proposal, as revised, would preserve that prohibition, consistent with the statutory direction, and it would clarify that information covered by FOIA Exemption 3 is prohibited from disclosure and not subject to analysis under the foreseeable harm standard. Specifically, the proposed revision would state that Commission records subject to Section 6 and 25(c) of the CPSA, 15 U.S.C. 2055 and 2074(c), fall within the scope of FOIA Exemption 3.

The proposal also would revise § 1015.1(c) to remove the existing statement that the Attorney General's Memorandum on the 1974 Amendments to the FOIA may be consulted in considering questions arising under the FOIA. That memorandum is outdated and should not be consulted in considering questions arising under the FOIA because the FOIA has been statutorily amended multiple times since 1974.

In place of the current § 1015.1(c), we propose a new § 1015.1(c) to reflect that the Commission Secretariat serves as the agency's Chief FOIA Officer. The 2016 FOIA amends the FOIA at 5 U.S.C. 552(j) to require each agency to designate a Chief FOIA Officer, who shall be a senior official of the agency, and shall have, subject to the authority of the head of the agency, among other responsibilities, responsibility for compliance and implementation of section (j) of the FOIA. The revised § 1015.1(c) would state that the Commission's Chief Freedom of Information Officer, a senior official at the Commission, would be the Secretariat. Therefore, for clarity and consistency with the provisions of § 1015.4, which vests ultimate authority for responding to FOIA requests in the Commission's Secretariat, and in conformance with amendments made to the FOIA, we propose new language explaining that the Secretariat of the Commission is the Chief Freedom of Information Officer, who, subject to the authority of the Chairman, is responsible for compliance with, and implementation of, 5 U.S.C. 552(j).

We additionally propose minor and non-substantive changes in grammar.

Proposed Changes to § 1015.2 (Public Reference Facilities)

To reflect amendments in the 2016 FOIA that focus on public inspection in an electronic format, we are proposing to revise the title of this section to ''*Public inspection.*'' Additionally, we propose removing ''and copying'' from § 1015.2(a) and (b), and replacing that phrase with ''in an electronic format,'' to conform to the amendments to the FOIA at 5 U.S.C. 552(a).

We also propose removing the statements in § 1015.2(b) regarding additional Commission public reference facilities. With changes in technology, public inspection at the Commission headquarters is rare, and we do not anticipate a need for additional public reference facilities. To provide additional information to the public about the Commission's electronic reading room, we propose adding the Commission's Web site address to § 1015.2(c) and a statement indicating that records that the Commission must make available for public inspection in an electronic format may be accessed through the e-FOIA Public Access Link at the Commission's Web site address.

Additionally, to conform with amendments to the FOIA at 5 U.S.C. 552(a)(2)(D), we are proposing a new § 1015.2(d), which requires the agency, subject to any restrictions imposed by section 6 of the CPSA, to make available for public inspection in an electronic format, copies of certain records, regardless of form. Specifically, the Commission shall make available for public inspection, records that have been released under FOIA, records that, because of the nature of the subject matter, the agency determines are likely to become the subject of subsequent requests for substantially the same records, and records that have been requested three or more times.

We additionally propose correcting ''Secretary'' to the current title of ''Secretariat'' throughout this paragraph and updating the room number of the Office of the Secretariat.

Proposed Changes to § 1015.3 (Requests for Records and Copies)

We propose a revision to the title of this section by removing ''and copies'' to reflect amendments to the FOIA at 5 U.S.C. 552(a).

To reflect current practice, we also propose updating § 1015.3(a) on the ways requesters may submit requests for records to the Commission, to include electronic methods. In addition to submitting requests by mail, requesters would be able to submit a request through the Commission's e-FOIA Public Access Link, email, or facsimile. We also propose a technical correction to reflect the Commission's address. To promote good FOIA customer service, we also propose to revise § 1015.3(b) to

state that, before submitting requests, requesters may contact the Commission's FOIA contact or FOIA Public Liaison to discuss the records the submitter seeks and to receive assistance in describing the records.

Additionally, throughout this section we propose changing ''Secretary'' to ''Secretariat'' to update the position to its current title.

Proposed Changes to § 1015.4 (Responses To Requests for Records; Responsibility)

We propose changing ''Secretary'' to ''Secretariat'' throughout this section to reflect the name of the position to its current title.

Proposed Changes to Rule § 1015.5 (Time Limitations on Responses to Requests for Records and Requests for Expedited Processing)

We propose updating § 1015.5(a) to incorporate new procedural requirements and to reflect current Commission practices and advances in technology. We propose clarifying that time limitations on responses to requests submitted by postal mail would begin to run at the time the request is received and date-stamped by the Office of the Secretary (which we propose revising to the Office of the Secretariat). We would also update the regulation to reflect the current practice that the Office of the Secretariat will date-stamp requests the same day that it receives the requests. We also propose that time limitations on responses to requests submitted electronically would begin to run at the time the request is electronically received, if the request is submitted during ''working hours,'' which we define as 8 a.m. to 4:30 p.m. EST. For responses submitted electronically during non-working hours, the proposed change would require that time limitations begin to run the next working day after the request is submitted.

If the Commission is unable to respond to a request within this time frame, the current § 1015.5(b) allows the Secretariat, at the initial stage, or the General Counsel, at the appellate stage, to extend the time for responding to requests up to 10 additional working days, if a request satisfies the criteria for ''unusual circumstances.'' Moreover, as explained in current § 1015.5(d), if the Secretariat or General Counsel determines that an extension of more than 10 days is required, the Secretariat or General Counsel must give the requester an opportunity to limit the scope of the request or arrange for an alternative timeframe to process the request. Under the new FOIA amendments, in those circumstances, agencies are required to make available its FOIA Public Liaison to assist in the resolution of any disputes between the requester and the agency. The 2016 FOIA additionally requires agencies to notify requesters of the right to seek dispute resolution services from the Office of Government Information Services. Therefore, we propose adopting language stating that if an extension of time greater than 10 working days is necessary, the Commission will make available its FOIA Public Liaison for purposes of dispute resolution. Additionally, we propose providing information about where on the Commission's Web site, the Commission's designated FOIA Liaison(s) is listed and also stating that the Commission will notify requesters in writing of the availability of the Office of Government Information Services to provide dispute resolution services, as required by the 2016 FOIA. We propose inserting this language into a new § 1015.5(e), and we propose re-designating the succeeding paragraphs in § 1015.5 to conform to this change.

We also propose adding a statement to the current § 1015.5(f)(2), clarifying that requests for expedited processing may be submitted through any of the methods described in the proposed § 1015.3(a), in which we propose updating the regulation to reflect new electronic methods of submission.

We additionally propose revising Secretary'' to ''Secretariat'' throughout, to change the name of the position to its current title.

Proposed Changes to § 1015.6 (Form and Content)

To reflect the current organizational structure of the agency and to align with the 2016 FOIA amendments to the FOIA, indicating that documents for public inspection will be made available in electronic format, we propose revising § 1015.6(a) to state that when a requested record has been identified, requesters shall be supplied with a copy or notified of where and when the document will be made available for public inspection in an electronic format. We also propose removing the reference to making records available at a requested regional office. This option is outdated and no longer applicable because the Commission does not have regional offices that the public can visit.

We additionally propose amending § 1015.6(a) to conform with the 2016 FOIA amendments to 5 U.S.C. 552(a)(6)(A)(i), which require the Commission, when responding to a records request, to notify requesters of their right to seek assistance from the Commission's FOIA Public Liaison.

In the case of a denial, we propose revisions to conform with the 2016 FOIA amendments to 5 U.S.C. 552(a)(6)(A)(i)(III)(aa), which requires that agencies notify requesters when there is an adverse determination that requesters have the right to appeal within a period determined by the head of the agency that is not less than 90 days after the date of such determination. Accordingly, we propose revising § 1015.6(b)(4) to change ''30 calendar days'' to ''90 calendar days.'' We also propose adding a new § 1015.6(b)(5), which would require the Commission, in the case of a denial, to notify requesters of their right to seek dispute resolution services from the Office of Government Information Services.

We additionally propose revising ''Secretary'' to ''Secretariat'' throughout the section, to revise the title of the position to its current title.

Proposed Changes to § 1015.7 (Appeals From Initial Denials; Reconsideration by the Secretary)

We propose revising the deadline for appealing a denial of a records request from 30 days to 90 calendar days in § 1015.7(a) to conform with the 2016 FOIA amendments described above regarding proposed changes to § 1015.6.

We additionally propose updating the regulation at § 1015.7(a) to list the ways, including electronic methods, that a requester may appeal a denial to the General Counsel of the Commission.

To reflect changes in Commission procedures due to advances in information technology, we propose updating § 1015.7(b) to specify that time limitations on appeals submitted by postal mail would begin to run when the appeal is received and date-stamped by the Office of the Secretary (proposed to be changed to the Office of the Secretariat). We would also update the regulation to reflect the current practice that the Office of the Secretariat will date-stamp requests the same day that it receives the requests. We also propose that time limitations on appeals submitted electronically would begin to run at the time the appeal is electronically received, if the request is submitted during ''working hours,'' which we define as 8 a.m. to 4:30 p.m. EST. For responses submitted electronically during non-working hours, the proposed change would require that time limitations begin to run the next working day.

To conform with the 2016 FOIA amendments to 5 U.S.C. 552(a)(6)(A)(i)(III)(bb), which require

agencies to provide notification in an adverse determination of the right to seek dispute resolution services from the FOIA Public Liaison of the agency or the Office of Government Information Services, we propose including a statement in § 1015.7(e) stating that the Commission will provide such a notification.

We additionally propose revising ''Secretary'' to ''Secretariat'' throughout the section, including in the title, to correct the name of this position.

Proposed Changes to § 1015.9 (Fees for Production of Records.)

We propose to make technical changes throughout this section, including a revision to § 1015.9(b) to reflect updated ways to effectuate fee payment. We also propose to account for efforts expended to locate and retrieve electronic information by revising the term ''search'' in § 1015.9(c)(2) and the definition of ''duplication'' in § 1015.9(c)(3) and to account for new technology changes that are not reflected in the regulation. The proposal would also account for the efforts to scan documents through a revision of § 1015.9(e)(1), which would require a requester to pay the direct costs associated with scanning documents.

We also propose to revise § 1015.9(f)(6) to conform to the 2016 FOIA amendments to 5 U.S.C. 552(a)(4)(A)(viii)(II). The changes would require the Commission to waive fees where the agency fails to comply with a time limit that it has extended because the agency has determined that unusual circumstances apply. However, if the extension for unusual circumstances involves more than 5,000 responsive pages, the Commission may continue to charge fees, provided it has given timely notice to the requester and has discussed with the requester how to effectively limit the scope of the request. Thus, the regulation would be revised to prevent the Commission from assessing search fees for any requester or duplication fees for an educational institution, non-commercial scientific instiution, or a representative of the news media requester, if the Commission fails to comply with an extended time limit, unless 5,000 pages are responsive to the request, and the Commission has made three good faith attempts to discuss with the FOIA requester limiting the scope of the request.

We additionally propose revising ''Secretary'' to ''Secretariat'' throughout the section, including in the title, to correct the name of this position.

Proposed Changes to § 1015.10 (Commission Report of Actions to Congress)

We propose revisions to this section to conform to the 2016 FOIA amendments to 5 U.S.C. 552(e)(1). Specifically, we propose adding a statement that the Commission must submit the report to the Director of the Office of Government Information Services in addition to its current requirement to submit the report to the Attorney General of the United States. We also propose adding, in conformance with the statute, new § 1015.10(h), stating that the report shall include the number of times the Commission denied a request for records under 5 U.S.C. 552(c) and new § 1015.10(i), stating that the report shall include the number of records that were made available for public inspection in an electronic format under 5 U.S.C. 552(a)(2).

Proposed Changes to Rule § 1015.11 (Disclosure of Trade Secrets to Consultants and Contractors; Nondisclosure to Advisory Committees and Other Government Agencies)

We propose to add language to § 1015.11 to clarify that the reference in § 1015.11(a) and (b) to 5 U.S.C. 552(b)(4) includes not only trade secrets, but also includes commercial or financial information.

We also propose revising § 1015.11(b) to incorporate an amendment to the CPSA, 15 U.S.C. 2078(f), by the Consumer Product Safety Improvement Act of 2008, Public Law 110–314 (2008), which permits the Commission to share information with federal, state, and local agencies, if certain requirements are satisfied.

Subpart B—Exemptions From Production and Disclosure Under 5 U.S.C. 552(b)

Proposed Changes to § 1015.15 (Purpose and Scope)

We propose removing language in § 1015.15(a) that references the internal Commission procedure for withholding exempt records because, as explained below in *Proposed Changes to Rule § 1015.17 (Internal Commission procedure for withholding exempt records.),* we propose removing § 1015.17 entirely.

We also propose revisions to § 1015.15(b) to conform to the 2016 FOIA amendment to 5 U.S.C. 552(a)(8)(A), which provides that agencies shall withhold information under 5 U.S.C. 552, only if the agency reasonably foresees that disclosure would harm an interest protected by an exemption described in 5 U.S.C. 552(b), or disclosure is otherwise prohibited by law. Currently, the rule states that the Commission will make available, to the extent permitted by law, records authorized to be withheld under 5 U.S.C. 552(b), unless the Commission determines that disclosure is contrary to the public interest. To align with the 2016 FOIA amendments, we propose revising this section to state that the Commission will make available records authorized to be withheld under one of the FOIA exemptions, ''unless the Commission reasonably foresees that disclosure would harm an interest protected by the exemption or disclosure is prohibited by law or otherwise exempted from disclosure under 5 U.S.C. 552(b)(3).''

Additionally, we propose updating § 1015.15(c) to reflect the focus of the 2016 FOIA on public inspection of documents in an electronic format, which is consistent with current practice. The proposal would require that briefing packages, or portions thereof, which the Secretary (which we propose revising to Secretariat), upon the advice of the Office of the General Counsel, has determined would be released, upon request, would be made available for public inspection in an electronic format through the Commission's Web site. Specifically, we propose removing the language stating that such briefing packages would be publicly available in the public reference facility established under § 1015.2, and replacing it with proposed language indicating that the information will be available electronically on the Commission's Web site.

We also propose revising ''Secretary'' to ''Secretariat'' in § 1015.15(c), to correct the name of this position and propose a non-substantive grammatical revision in the first sentence of § 1015.15(b).

Proposed Changes to § 1015.16 (Exemptions (5 U.S.C. 552(b)).)

The 2016 FOIA amends 5 U.S.C. 552(b)(5) to include a sunset provision on the deliberative process privilege so that it does not apply to records created 25 years or more before the date on which the records were requested. We propose amending § 1015.16(e) to add language reflecting this change.

We also propose non-substantive technical corrections to §§ 1015.16(e) and (f) to track the statutory language.

Proposed Changes to § 1015.17 (Internal Commission Procedure for Withholding Exempt Records)

We propose removing all of § 1015.17 and reserving this section. Section

1015.17 describes an internal Commission procedure that allows a Commission bureau or office director who believes that it is against the public interest to disclose a Commission record prepared by his/her office that may be exempt from disclosure under the inter-intra-agency memorandum exemption at 5 U.S.C. 552(b)(5) or the investigatory file exemption at 5 U.S.C. 552(b)(7) to request that the Secretary withhold the document, and, if necessary, appeal that decision to the Commission. The current § 1015.17(a)(1) states that if the Secretary agrees to withhold the document, the requester shall be notified in writing of the denial and of his/her right to appeal. Section 1015.17 is not necessary and should be removed because procedures for Commission responses to requests based on an analysis of harm to the public interest would now be described in detail in proposed § 1015.1(b) and § 1015.6 and include additional updated requirements not in § 1015.17. Accordingly, we propose removing § 1015.17 because it does not reflect current internal Commission procedures. Moreover, even if the provisions were not outdated, we would propose removing this provision because it describes an internal procedure that is more appropriate for including in a Commission Directive on staff procedure than in a regulatory scheme.

Subpart C—Disclosure of Commission Accident or Investigation Reports Under 15 U.S.C. 2074(c)

Proposed Changes to § 1015.20 (Public Availability of Accident or Investigation Reports)

We propose updating § 1015.20(a) to reflect current Commission procedure. The rule currently states that accident or investigation reports are available to the public under the procedures set forth in subpart A and that no portion of such reports are subject to the investigatory file exemption. Current Commission procedure allows for the withholding of accident or investigation reports, if the requirements of the investigatory file exemption are met. Therefore, we propose revising this section to state that accident or investigation reports are available to the public under the procedures set forth in subpart A, unless such reports are subject to the investigatory file exemption.

III. Environmental Considerations

The Commission's regulations address whether the Commission is required to prepare an environmental assessment or an environmental impact statement. 16 CFR part 1021. These regulations provide a categorical exclusion for certain CPSC actions that normally have ''little or no potential for affecting the human environment.'' 16 CFR 1021.5(c)(1). This proposed rule falls within the categorical exclusion.

IV. Regulatory Flexibility Analysis

Under section 603 of the Regulatory Flexibility Act (RFA), when the Administrative Procedure Act (APA) or another law requires an agency to publish a general notice of proposed rulemaking, the agency must prepare an initial regulatory flexibility analysis (IFRA), assessing the economic impact of the proposed rule on small entities or certify that the rule will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 603(a), 605. The Commission chooses to provide notice and comment for this rulemaking. However, because this is a ''rule of agency organization, procedure, or practice,'' the APA does not require a notice of proposed rulemaking. 5 U.S.C. 553. Additionally, we note that the rule would merely set out in a regulation the procedural requirements stated in the FOIA of 2016, update Commission procedures, and make other technical changes and corrections. We expect that the proposed rule will not have a significant economic impact on a substantial number of small entities.

V. Paperwork Reduction Act

The Paperwork Reduction Act (PRA) establishes certain requirements when an agency conducts or sponsors a ''collection of information.'' 44 U.S.C. 3501–3520. The proposed rule would amend the Commission's rule to conform to the 2016 FOIA and to update Commission procedures and make other technical changes and corrections. The proposed rule would not impose any information collection requirements. The existing rule and the proposed revisions do not require or request information from firms, but rather, explain the Commission's FOIA procedures. Thus, the PRA is not implicated in this proposed rulemaking.

VI. Executive Order 12988 (Preemption)

According to Executive Order 12988 (February 5, 1996), agencies must state in clear language the preemptive effect, if any, of new regulations. Section 26 of the CPSA explains the preemptive effect of consumer product safety standards issued under the CPSA. 15 U.S.C. 2075. The proposed rule is not a consumer product safety standard, but rather, would revise a rule of agency practice and procedure by implementing the FOIA of 2016 and making technical revisions or corrections. Therefore, section 26 of the CPSA would not apply to this rulemaking.

VII. Effective Date

In accordance with the APA's general requirement that the effective date of a rule be at least 30 days after publication of the final rule, the Commission proposes that the effective date be 30 days after the date of publication of a final rule in the **Federal Register**. 5 U.S.C. 553(d).

VIII. Request for Comments

The Commission requests comments on all aspects of the proposed rule. Comments should be submitted in accordance with the instructions in the **ADDRESSES** section at the beginning of this document. Written comments must be received by March 20, 2017.

List of Subjects in 16 CFR 1015

Administrative practice and procedure; Consumer protection; Disclosure of information; Freedom of information.

For the reasons set forth in the preamble, the Commission proposes to amend 16 CFR part 1015 to read, as follows:

PART 1015 —PROCEDURES FOR DISCLOSURE OR PRODUCTION OF INFORMATION UNDER THE FREEDOM OF INFORMATION ACT

■ 1. The authority citation for part 1015 is revised to read, as follows:

Authority: 15 U.S.C. 2051–2084; 15 U.S.C. 1261–1278; 15 U.S.C. 1471–1476; 15 U.S.C. 1211–1214; 15 U.S.C. 1191–1204; 15 U.S.C. 8001–8008; 110 P.L. 278, 122 Stat. 2602; 5 U.S.C. 552.

■ 2. Amend § 1015.1 by revising the third sentence in paragraph (a) and revising paragraphs (b) and (c) to read, as follows:

§ 1015.1 Purpose and scope.

(a) * * * These records include those maintained in connection with the Commission's responsibilities and functions under the Consumer Product Safety Act, as well as those responsibilities and functions transferred to the Commission under the Federal Hazardous Substances Act, the Poison Prevention Packaging Act of 1970, the Refrigerator Safety Act, the Flammable Fabrics Act, the Children's Gasoline Burn Prevention Act, the Virginia Graeme Baker Pool and Spa Safety Act, and the Child Nicotine Poisoning Prevention Act, and those maintained under any other authorized activity. * * *

(b) The Commission's policy with respect to requests for records is that disclosure is the rule and withholding is the exception. All records or portions of records not exempt from disclosure will be made available. Records which may be exempted from disclosure will be made available unless: (1) Disclosure is prohibited by law; (2) the Commission reasonably foresees that disclosure would harm an interest protected by an exemption described in 5 U.S.C. 552(b); or (3) disclosure is exempted under 5 U.S.C. 552(b)(3). See § 1015.15(b). Section 6(a)(2) of the Consumer Product Safety Act, 15 U.S.C. 2055(a)(2), prohibits the disclosure of trade secrets or other matters referred to in 18 U.S.C. 1905; Section 6(b) and Section 25(c) of the CPSA. The Commission will consider the record's age, content, and character in assessing whether it reasonably foresees that disclosure of the document would harm an interest protected by an exemption. Additionally, the Commission will consider whether partial disclosure of information is possible whenever the Commission determines that a full disclosure of a requested record is not possible and will take reasonable steps necessary to segregate and release nonexempt information.

(c) The Secretariat of the Commission is the designated Chief Freedom of Information Officer who, subject to the authority of the Chairman, is responsible for compliance with and implementation of 5 U.S.C. 552(j).

■ 3. Amend § 1015.2 by:

■ a. Revising the section heading;

■ b. Revising paragraphs (a), (b) and (c); and

■ c. Adding paragraph (d).

The revisions read, as follows:

§ 1015.2 Public inspection.

(a) The Consumer Product Safety Commission will maintain in a public reference room or area the materials relating to the Consumer Product Safety Commission that are required by 5 U.S.C. 552(a)(2) and 552(a)(5) to be made available for public inspection in an electronic format. The principal location will be in the Office of the Secretariat of the Commission. The address of this office is: Office of the Secretariat, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814.

(b) This public reference facility will maintain and make available for public inspection in an electronic format a current index of the materials available at that facility which are required to be indexed by 5 U.S.C. 552(a)(2).

(c) The Consumer Product Safety Commission will maintain an ''electronic reading room'' on the World-Wide Web at *https://www.cpsc.gov* for those records that are required by 5 U.S.C. 552(a)(2) to be available by ''computer telecommunications.'' Records that the FOIA requires the Commission to make available for public inspection in an electronic format may be accessed through the e-FOIA Public Access Link at *https://www.cpsc.gov.*

(d) Subject to the requirements of Section 6 of the CPSA, the Commission will make available for public inspection in an electronic format copies of all records, regardless of form or format, that (1) have been released to any person under 5 U.S.C. 552(a)(3) and (2) that because of the nature of their subject matter, the Commission determines have become or are likely to become the subject of subsequent requests for substantially the same records or that have been requested three or more times.

■ 4. Amend § 1015.3 by:

■ a. Revising the section heading;

■ b. Revising the first sentence of paragraph (a);

■ c. Adding a sentence at the end of paragraph (b); and

■ d. Removing the word ''Secretary'' from paragraphs (d) and (e), wherever it appears, and adding, in its place, the word ''Secretariat''.

The revisions read, as follows:

§ 1015.3 Requests for records.

(a) A request for access to records of the Commission shall be in writing addressed to the Secretariat and shall be submitted through any of the following methods: The e-FOIA Public Access Link at *https://www.cpsc.gov;* email to *cpsc-foia@cpsc.gov;* mail to Consumer Product Safety Commission, 4330 East West Highway, Room 820, Bethesda, MD 20814; or facsimile to 301–504–0127. * * *

(b) * * * Before submitting their requests, requesters may contact the Commission's FOIA contact or FOIA Public Liaison to discuss the records they seek and to receive assistance in describing the records.

* * * * *

(d) If a requested record cannot be located from the information supplied, or is known to have been destroyed or otherwise disposed of, the requester shall be so notified by the Secretariat or delegate of the Secretariat.

(e) The Consumer Product Safety Commission uses a multitrack system to process requests under the Freedom of Information Act that is based on the amount of work and/or time involved in processing requests. Requests for records are processed in the order they are received within each track. Upon receipt of a request for records, the Secretariat or delegate of the Secretariat will determine which track is appropriate for the request. The Secretariat or delegate of the Secretariat may contact requesters whose requests do not appear to qualify for the fastest tracks and provide such requesters the opportunity to limit their requests so as to qualify for a faster track. Requesters who believe that their requests qualify for the fastest tracks and who wish to be notified if the Secretariat or delegate of the Secretariat disagrees may so indicate in the request and, where appropriate and feasible, will also be given an opportunity to limit their requests.

§ 1015.4 [Amended]

■ 5. Amend § 1015.4 by removing the word ''Secretary'' wherever it appears, and adding, in its place, the word ''Secretariat''.

■ 6. Amend § 1015.5 by:

■ a. Revising paragraph (a)

■ b. Removing the word ''Secretary'' in paragraphs (b), (b)(1), (d), and (d)(2) wherever it appears adding, in its place, the word ''Secretariat'';

■ c. Redesignating paragraphs (e) through (g), as paragraphs (f) through (h), respectively;

■ d. Add new paragraph (e);

■ e. Removing the word ''Secretary'' in redesignated paragraphs (f), (g), (g)(3), (g)(5), and (h) wherever it appears, and adding, in its place, the word ''Secretariat''; and

■ f. Revising redesignated paragraph (g)(2).

The revisions read, as follows:

§ 1015.5 Time limitation on responses to requests for records and requests for expedited processing.

(a) The Secretariat or delegate of the Secretariat shall respond to all written requests for records within twenty (20) working days (excepting Saturdays, Sundays, and legal public holidays). The time limitations on responses to requests for records submitted by mail shall begin to run at the time a request for records is received and date stamped by the Office of the Secretariat. The Office of the Secretariat shall date stamp the request the same day that it receives the request. The time limitations on responses to requests for records submitted electronically during working hours (8 a.m. to 4:30 p.m. EST) shall begin to run at the time the request was electronically received and the time limitations on responses submitted electronically during non-working hours will begin to run the next working day.

(b) The time for responding to requests for records may be extended by

the Secretariat at the initial stage or by the General Counsel of the Commission at the appellate stage up to an additional ten (10) working days under the following unusual circumstances:

(1) The need to search for and collect the requested records from field facilities or other establishments that are separate from the Office of the Secretariat.

* * * * *

(d) If the Secretariat at the initial stage or the General Counsel at the appellate stage determines that an extension of time greater than ten (10) working days is necessary to respond to a request satisfying the ''unusual circumstances'' specified in paragraph (b) of this section, the Secretariat or the General Counsel shall so notify the requester and give the requester the opportunity to:

(1) * * *

(2) Arrange with the Secretariat or the General Counsel an alternative time frame for processing the request or a modified request.

(e) If an extension of time greater than ten (10) working days is necessary, the Commission shall make available its FOIA Public Liaison for this purpose. A list of the Commission FOIA Public Liaisons is available at *https://www.cpsc.gov/Newsroom/FOIA.* The Commission will also notify requesters in writing to the availability of the Office of Government Information Services of the National Archives and Records Administration to provide dispute resolution services.

(f) The Secretariat or delegate of the Secretariat may aggregate and process as a single request requests by the same requester, or a group of requesters acting in concert, if the Secretariat or delegate reasonably believes that the requests actually constitute a single request which would otherwise satisfy the unusual circumstances specified in paragraph (b) of this section, and the requests involve clearly related matters.

(g) The Secretariat or delegate of the Secretariat will provide expedited processing of requests in cases where the requester demonstrates a compelling need for such processing.

(1) * * *

(2) Requesters for expedited processing must include in their requests, which may be submitted through any of the methods described in § 1015.3(a) of this part, a statement setting forth the basis for the claim that a ''compelling need'' exists for the requested information, certified by the requester to be true and correct to the best of his or her knowledge and belief.

(3) The Secretariat or delegate of the Secretariat will determine whether to grant a request for expedited processing and will notify the requester of such determination within ten (10) days of receipt of the request.

(4) * * *

(5) The Secretariat or delegate of the Secretariat will process as soon as practicable the documents responsive to a request for which expedited processing is granted.

(h) The Secretariat may be unable to comply with the time limits set forth in this § 1015.5 when disclosure of documents responsive to a request under this part is subject to the requirements of section 6(b) of the Consumer Product Safety Act, 15 U.S.C. 2055(b), and the regulations implementing that section, 16 CFR part 1101. The Secretariat or delegate of the Secretariat will notify requesters whose requests will be delayed for this reason.

■ 7. Revise § 1015.6 by:

■ a. Revising paragraph (a);

■ b. Removing the word ''Secretary'' from paragraphs (b), and (c) wherever it appears, and adding, in its place, the word ''Secretariat;''

■ c. Removing the number ''30'' in paragraph (b)(4), and adding, in its place, the number ''90''; and

■ d. Adding paragraph (b)(5).

The revisions read, as follows:

§ 1015.6 Responses: Form and content.

(a) When a requested record has been identified and is available for disclosure, the requester shall be supplied with a copy or notified as to where and when the record will be made available for public inspection in an electronic format. If the payment of fees is required the requester shall be advised by the Secretariat in writing of any applicable fees under § 1015.9 hereof. The requester will be notified of the right to seek assistance from the Commission's FOIA Public Liaison.

(b) A response denying a written request for a record shall be in writing signed by the Secretariat or delegate of the Secretariat and shall include:

* * * * *

(4) A statement that the denial may be appealed to the Commissioners of the Consumer Product Safety Commission. Any such appeal must be made within 90 calendar days of receipt of the denial by the requester.

(5) A statement that the requester has the right to seek dispute resolution services from the Commission's FOIA Public Liaison or the Office of Government Information Services.

(c) If no response is made within twenty (20) working days or any extension thereof, the requester can consider his or her administrative remedies exhausted and seek judicial relief in a United States District Court as specified in 5 U.S.C. 552(a)(4)(B). When it appears that no response can be made to the requester within the applicable time limit, the Secretariat or delegate of the Secretariat may ask the requester to forego judicial relief until a response can be made. The Secretariat or delegate of the Secretariat shall inform the requester of the reason for the delay, of the date on which a response may be expected and of his/her right to seek judicial review as specified in 5 U.S.C. 552(a)(4)(B).

■ 8. Amend § 1015.7 by:

■ a. Revising the section heading;

■ b. Revising paragraphs (a) and (b);

■ c. Removing the word ''Secretary'' in paragraphs (c) and (g) wherever it appears, and adding, in its place, the word ''Secretariat''; and

■ d. Revising paragraph (e).

The revisions read, as follows:

§ 1015.7 Appeals from initial denials; reconsideration by the Secretariat.

(a) When the Secretariat or delegate of the Secretariat has denied a request for records in whole or in part, the requester may, within 90 calendar days of its receipt, appeal the denial to the General Counsel of the Consumer Product Safety Commission, attention of the Secretariat. Appeals may be submitted through any of the following methods: The e-FOIA Public Access Link at *https://www.cpsc.gov;* email to *cpsc-foia@cpsc.gov;* mail to 4330 East West Highway, Room 820, Bethesda, MD 20814; or facsimile to 301–504–0127.

(b) The General Counsel, or the Secretariat upon reconsideration, will act upon an appeal within 20 working days of its receipt. The time limitations on an appeal submitted by mail shall begin to run at the time an appeal is received and date stamped by the Office of the Secretariat. The Office of the Secretariat will date stamp the request the same day that it receives the request. The time limitations on an appeal submitted electronically during working hours (8 a.m. to 4:30 p.m. EST) shall begin to run at the time the appeal was electronically received and the time limitations on responses electronically submitted during non-working hours will begin to run the next working day.

(c) After reviewing the appeal, the Secretariat will reconsider his/her initial denial. If the Secretariat upon reconsideration decides to release any or all of the information requested on appeal, an appeal as to the information released will be considered moot; and the Secretariat will so inform the requester and submitter of the information in accordance with

§§ 1015.6(a) and 1015.18(b). If the Secretariat decides to affirm the initial denial, in whole or in part, the General Counsel will decide the appeal within the 20-day time limit or any extension thereof in accordance with § 1015.5.

* * * * *

(e) The General Counsel's action on appeal shall be in writing, shall be signed by the General Counsel, and shall constitute final agency action. A denial in whole or in part of a request on appeal shall set forth the exemption relied upon; a brief explanation, consistent with the purpose of the exemption, of how the exemption applies to the records withheld; and the reasons for asserting it. The decision will inform the requester of the right to seek dispute resolution services from the Commission's FOIA Liaison or the Office of Government Information Services. A denial in whole or in part shall also inform the requester of his/her right to seek judicial review of the Commission's final determination in a United States district court, as specified in 5 U.S.C. 552(a)(4)(B).

* * * * *

(g) Copies of all appeals and copies of all actions on appeal shall be furnished to and maintained in a public file by the Secretariat.

■ 9. Amend § 1015.9 by:

■ a. Removing the word ''Secretary'' in paragraphs (a), (e)(9), (f)(4), (5) and (7), and adding, in its place, the word ''Secretariat'';

■ b. Revising paragraph (b), (c)(2) and (3);

■ c. Adding a sentence at the end of paragraph (e)(1);

■ d. Adding paragraph (f)(6);

■ e. Redesignating paragraph (f)(6) as paragraph (f)(7).

The revisions read, as follows:

§ 1015. 9 Fees for production of records.

(a) The Commission will provide, at no charge, certain routine information. For other Commission responses to information requests, the Secretariat shall determine and levy fees for duplication, search, review, and other services, in accordance with this section.

(b) Fees shall be paid to the Treasury of the United States according to the directions provided by the Commission.

* * * * *

(c)(2) *Search* includes all time spent looking for material that is responsive to a request, including page-by-page or line-by-line identification of material within documents and the reasonable efforts expended to locate and retrieve information from electronic records.

(3) *Duplication* refers to the process of making a copy of a document, including electronically, necessary to respond to a FOIA request. The Commission will honor the requester's preference for receiving a record in a particular format when it can readily reproduce it in the form or format requested.

* * * * *

(e)(1) * * * Where paper documents must be scanned in order to comply with a requester's preference to receive records in an electronic format, the requester must also pay the direct costs associated with scanning those materials.

(f)(6) Search fees shall be waived for all requests and duplication fees shall be waived for requests from educational institutions, non-commercial scientific institutions, and representatives of the news media if the Commission fails to comply with any time limit and notice under § 1015.5(b)–(d) and 5 U.S.C. 552(a)(6) other than those exceptions stated in 5 U.S.C. 552 (a)(4)(A)(viii)(ll). Those exceptions include:

(i) if the Commission has determined that unusual circumstances as defined in § 1015.5(b) apply and the Commission provided timely written notice to the requester as required by § 1015.5(e), then failure to comply with the time limit in § 1015.5(b)–(d) is excused for 10 additional days; or

(ii) if the Commission has determined that unusual circumstances as defined in § 1015.5(b) apply and more than 5,000 pages are necessary to respond to the request, and the Commission has provided timely written notice in accordance with § 1015.5(e) and the Commission has discussed with the requester via written mail, email, or telephone (or made not less than three good-faith efforts to do so) how the requester could effectively limit the scope of the request; or

(iii) if a court has determined that exceptional circumstances exist as defined in 5 U.S.C. 552(6)(C), then failure to comply with § 1015.6(b)–(d) and 5 U.S.C. 552(a)(6) shall be excused for the length of time provided by the court order.

(7) Any determination made by the Secretariat concerning fee waivers may be appealed by the requester to the Commission's General Counsel in the manner described at § 1015.7.

■ 10. Revise § 1015.10 as follows:

■ a. Adding a phrase at the end of the undesignated introductory paragraph;

■ b. Add paragraph (h) and (i).

The revisions read, as follows:

§ 1015.10 Commission report of actions to Congress.

On or before February 1 of each year, the Commission shall submit a report of its activities with regard to freedom of information requests during the preceding fiscal year to the Attorney General of the United States and to the Director of the Office of Government Information Services. This report shall include:

* * * * *

(h) The number of times the Commission denied a request for records under 5 U.S.C. 552(c).

(i) The number of records that were made available for public inspection in an electronic format under 5 U.S.C. 552(a)(2).

■ 11. Amend § 1015.11 by revising paragraphs (a) and (b) to read, as follows:

§ 1015.11 Disclosure of trade secrets to consultants and contractors; nondisclosure to advisory committees and other government agencies.

(a) In accordance with section 6(a)(2) of the CPSA, the Commission may disclose information which it has determined to be a trade secret or other matter referred to under 5 U.S.C. 552(b)(4) to Commission consultants and contractors for use only in their work for the Commission. Such persons are subject to the same restrictions with respect to disclosure of such information as any Commission employee.

(b) In accordance with section 6(a)(2) of the CPSA, the Commission is prohibited from disclosing information which it has determined to be a trade secret or other matter referred to under 5 U.S.C. 552(b)(4) to advisory committees, except when required in the official conduct of their business, or to other Federal agencies and state and local governments except when permitted by the provisions of section 29(f) of the CPSA.

■ 12. Amend § 1015.15 by:

■ a. Removing the words ''and the internal Commission procedure for withholding exempt records'' from paragraph (a); and

■ b. Revising paragraph (b) and (c).

The revisions read, as follows:

§ 1015.15 Purpose and scope.

(a) The regulations of this subpart provide information concerning the types of records which may be withheld from production and disclosure by the Consumer Product Safety Commission. These regulations also provide information on the method whereby persons submitting information to the Commission may request that the information be considered exempt from disclosure, and information concerning the Commission's treatment of documents submitted with a request that they be treated as exempt from disclosure.

(b) No identifiable record requested in accordance with the procedures contained in this part shall be withheld from disclosure unless it falls within one of the classes of records exempt under 5 U.S.C. 552(b). The Commission will make available, to the extent permitted by law, records authorized to be withheld under 5 U.S.C. 552(b) unless the Commission reasonably foresees that disclosure would harm an interest protected by the exemption or disclosure is prohibited by law or otherwise exempted from disclosure under 5 U.S.C. 552(b)(3). In this regard the Commission will not ordinarily release documents that provide legal advice to the Commission concerning pending or prospective litigation where the release of such documents would significantly interfere with the Commission's regulatory or enforcement proceedings.

(c) Draft documents that are agency records are subject to release upon request in accordance with this regulation. However, in order to avoid any misunderstanding of the preliminary nature of a draft document, each draft document released will be marked to indicate its tentative nature. Similarly, staff briefing packages, which have been completed but not yet transmitted to the Commission by the Office of the Secretariat are subject to release upon request in accordance with this regulation. Each briefing package or portion thereof released will be marked to indicate that it has not been transmitted to or acted upon by the Commission. In addition, briefing packages, or portions thereof, which the Secretariat upon the advice of the Office of the General Counsel has determined would be released upon request in accordance with this regulation, will be made available for public inspection in an electronic format through the Commission's Web site at *https://www.cpsc.gov* promptly after the briefing package has been transmitted to the Commissioners by the Office of the Secretariat. Such packages will be marked to indicate that they have not been acted upon by the Commission.

* * * * *

■ 13. Amend § 1015.16 by:

■ a. Revising paragraph (e); and

■ b. Removing from paragraph (f) the misspelled word ''consititute'' and adding, in its place, the word ''constitute''.

The revisions read, as follows:

§ 1015.16 Exemptions (5 U.S.C. 552(b)).

* * * * *

(e) Inter-agency or intra-agency memoranda or letters that would not be available by law to a party other than an agency in litigation with the agency provided that the deliberative process privilege shall not apply to records created 25 years or more before the date on which the records were requested.

(f) Personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

* * * * *

§ 1015.17 [Reserved]

■ 14. Remove and reserve § 1015.17.

§ 1015.20 Public availability of accident or investigation reports.

■ 15. Amend § 1015.20, by removing the period and the words ''No portion of'' from the first and second sentence of paragraph (a), and adding, in its place, ''unless'' and ''s'' to the word ''report'' to read as follows:

(a) Accident or investigation reports made by an officer, employee, or agent of the Commission are available to the public under the procedures set forth in subpart A of this part 1015 unless such reports are subject to the investigatory file exemption contained in the Freedom of Information Act (as restated in § 1015.16) except that portions identifying any injured person or any person treating such injured person will be deleted in accordance with section 25(c)(1) of the CPSA. * * *

Dated: December 21, 2016.

Todd A. Stevenson,

Secretariat, Consumer Product Safety Commission.

[FR Doc. 2016–31131 Filed 12–30–16; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF THE TREASURY

31 CFR Part 40

RIN 1505–AC54

Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance From the Department of the Treasury

AGENCY: Department of the Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would set out the Department of the Treasury (Treasury) rules for implementing section 504 of the Rehabilitation Act of 1973, as amended (section 504), for Treasury's programs offering Federal financial assistance. Section 504 prohibits discrimination on the basis of disability in programs or activities receiving Federal financial assistance. Section 504 and the section 504 coordination regulation (coordination regulation) require that all agencies that extend Federal financial assistance issue agency-specific regulations implementing section 504. Treasury recipients have been subject to section 504 since its effective date in 1973. Accordingly, today's proposed rule would not substantially change the existing duty of recipients of financial assistance from Treasury to refrain from discrimination on the basis of disability. This proposed rule fulfills the obligation of Treasury to issue agency-specific rules under the law, clarifies the responsibilities of recipients of financial assistance from Treasury under section 504, and describes the Treasury investigation and enforcement procedures to ensure compliance. The proposed regulation is consistent with the ADA Amendments Act of 2008 (ADA Amendments Act), which amended section 504.

DATES: Comments must be received on or before March 6, 2017.

ADDRESSES: Members of the public are invited to submit comments on all aspects of this proposed rule. Comments on this proposed rule should be sent to Mariam G. Harvey, Director, Office of Civil Rights and Diversity (OCRD), Department of Treasury, 1500 Pennsylvania Avenue NW., Washington, DC 20220. Comments may be submitted through *www.regulations.gov.* The Department encourages electronic submission of comments via *www.regulations.gov.* Brief comments (maximum five pages) may be submitted by facsimile machine (FAX) to (202) 622–0367. Receipt of submissions, whether online, by mail or FAX transmittal, will not be acknowledged; however, the sender may request confirmation that a submission has been received by telephoning OCRD at (202) 622–1160 (VOICE) or (202) 622–7104 (TTY/TDD).

In general, comments received will be posted to *Regulations.gov* without change, including any business or personal information provided. Please submit only information appropriate for public disclosure. Copies of this proposed rule in the alternative formats of large print and electronic file on computer disk are available upon request. To obtain the proposed rule in an alternative format, contact OCRD at the telephone and address listed above.

FOR FURTHER INFORMATION CONTACT: Lydia E. Aponte, Civil Rights Program Manager, OCRD, (202) 622–8335 (VOICE) or (202) 622–7104 (TTY/TDD).

SUPPLEMENTARY INFORMATION:

I. Background

This proposed rule implements section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), as amended, which provides that no otherwise qualified individual with a disability in the United States shall, ''solely by reason of his or her disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance or under any program or activity conducted by any Executive agency . . . .'' Here, the Department of the Treasury will be issuing section 504 federal financial assistance regulations for the first time. This proposed rule has been reviewed by DOJ in the exercise of its section 504 coordination authority under Executive Order 12250.

II. Overview of Proposed Rule

This proposed rule is designed to fulfill Treasury's statutory and regulatory obligations to issue regulations implementing the federal financial assistance requirements of section 504 that conform to and are consistent with the coordination regulation found at 28 CFR part 41. Treasury, as described below, is proposing language to set forth the 504 requirements for recipients of federal financial assistance that include addressing circumstances unique to Treasury or current applicable statutory requirements. The proposed rule sets forth section 504's prohibitions on discrimination based on disability in programs or activities receiving financial assistance from Treasury. It also elaborates on investigation, conciliation, and enforcement procedures. It clarifies that Treasury enforcement would be conducted by the Office of Civil Rights and Diversity (OCRD), part of the Office of the Assistant Secretary for Management. OCRD enforces all civil rights laws applicable to entities receiving financial assistance from Treasury. Treasury invites public comment on all aspects of this proposed rule and will take those comments into account before publishing a final rule.

Summary of Key Provisions

Subpart A—General

Subpart A provides the proposed rule's purpose, application, definitions, and enforcement mechanisms. The purpose of the proposed rule is to effectuate section 504 of the Rehabilitation Act of 1973 to prohibit discrimination on the basis of disability in programs or activities that receive financial assistance from the Department of the Treasury. These regulations will apply to all programs or activities that receive financial assistance from Treasury, such as awardees and grantees under various Community Development Financial Institution Fund programs and recipients of Treasury's Volunteer Income Tax Assistance Program.

Treasury has proposed incorporating by reference DOJ's updated regulation on the ADA Amendments Act regarding the meaning and interpretation of the definition of disability (see 28 CFR 35.108). The ADA Amendments Act of 2008 (the ADA Amendments Act or the Act) was signed into law on September 25, 2008, with a statutory effective date of January 1, 2009. Public Law 110–325, sec. 8, 122 Stat. 3553, 2559 (2008). The Act made important changes to the meaning and interpretation of the ADA definition of the term ''disability'' in order to effectuate the intent of Congress to restore the broad scope of the ADA by making it easier for an individual to establish that he or she has a disability within the meaning of the statute. The ADA Amendments Act also amended the Rehabilitation Act of 1973 to conform the section 504 definition of disability, at 29 U.S.C. 705(20)(B), to the ADA. Incorporating the changes to the meaning and interpretation of the definition of disability introduced by the ADA Amendments Act will promote greater consistency among federal agencies' section 504 regulations and reduce the potential for confusion for entities that are covered by section 504 and titles II (nondiscrimination in state or local government services) or III (nondiscrimination by public accommodations and commercial facilities) of the ADA. In addition, the proposed rule incorporates DOJ's Appendix which provides extensive guidance interpreting the definition of disability.

Treasury also incorporates a definition for auxiliary aids and services that is consistent with the ADA title II requirements for effective communication and includes updated examples of auxiliary aids and services from the DOJ title II regulations at 28 CFR part 35. Treasury's definitions are intended to promote more clarity and consistency with current applicable law and regulations.

Treasury proposes a substantive non-discrimination provision in § 40.4 to include requirements for recipient provision of effective communication with applicants, beneficiaries, members of the public, and companions with disabilities. This is consistent with the current application of section 504 and the DOJ title II regulations.

Subpart A also includes a provision, at § 40.4(j), requiring recipients to provide reasonable accommodations by making changes to policies, practices or procedures when necessary to avoid discrimination on the basis of disability, unless the covered entity can show that the accommodations would result in a fundamental alteration in the nature of its service, program, or activity or impose undue financial and administrative burdens. The obligation to modify policies, practices or procedures was first enunciated by the Supreme Court in *Southeastern Community College* v. *Davis,* 442 U.S. 397 (1979), which held that while section 504 prohibits the exclusion of an otherwise qualified individual with a disability from participation in a federally funded program solely by reason of the individual's disability, that person is not protected by section 504 if, in order to meet reasonable eligibility standards, the person needs program or policy modifications that would fundamentally alter the nature of the provider's program. Because the *Davis* Court analyzed the case in terms of the proper interpretation of the statutory term ''otherwise qualified,'' agency section 504 regulations promulgated immediately after *Davis* addressed the obligation to provide reasonable accommodations outside of the employment arena by defining ''qualified handicapped person,'' as one who meets the essential eligibility requirements of the program and who can achieve the purpose of the program or activity without modifications in the program or activity that the agency can demonstrate would result in a fundamental alteration in its nature. *See, e.g.,* 28 CFR 39.103 (the Department of Justice's section 504 federally conducted regulation).

Subsequently, in *Alexander* v. *Choate,* 469 U.S. 287 (1985), which addressed a section 504 challenge to a state policy reducing the annual number of days of inpatient hospital care covered by the state's Medicaid program, the Supreme Court implicitly acknowledged that the obligation to provide reasonable accommodations could be considered as an affirmative obligation, noting, ''the question of who is 'otherwise qualified' and what actions constitute 'discrimination' under the section would seem to be two sides of a single coin; the ultimate question is the extent to which a grantee is required to make reasonable modifications [accommodations] in its programs for the needs of the handicapped.'' *Alexander,* 469 U.S. at 300 n.19.

Alexander also introduced the concept of undue financial and

administrative burden as a limitation on the reasonable accommodation obligation. In responding to the petitioners' contention that *any* durational limitation on inpatient coverage in a state Medicaid plan is a violation of section 504, the court stated ''[i]t should be obvious that the administrative costs of implementing such a regime would be well beyond the accommodations that are required under *Davis.*'' *Alexander,* 469 U.S. at 308.

In the past decades, in keeping with these Supreme Court decisions, federal courts and federal agencies have regularly acknowledged federal agencies' affirmative obligation to ensure that recipients provide qualified individuals with disabilities reasonable accommodations in programs and activities unless the recipient can demonstrate that making these accommodations would fundamentally alter the program or activity or result in an undue financial and administrative burden. However, traditionally, agencies' section 504 regulations have lacked a specific provision implementing this requirement outside of the employment arena. The proposed incorporation of a reasonable accommodation provision is meant to fill this gap. The proposed rule also includes a prohibition on associational discrimination, at § 40.4(k), to ensure that persons who have a relationship with or are otherwise associated with individuals with disabilities are protected from discrimination.

This proposed rule contains requirements that recipients of Treasury assistance submit assurance of compliance with these regulations at § 40.5; that recipients with more than 50 employees designate at least one person to coordinate compliance with these regulations at § 40.6; and that recipients with more than 50 employees take appropriate initial and continuing steps to notify participants, beneficiaries, applicants and employees that they do not discriminate on the basis of disability in violation of section 504 and these proposed regulations at § 40.7.

Consistent with the requirements in the section 504 coordination regulation, § 40.8 of this proposed rule requires recipients to conduct self-evaluations, with the assistance of interested persons, including individuals with disabilities, of their compliance with section 504 within one year of the effective date of this regulation. Treasury recognizes the value of a self-evaluation process to obtain meaningful feedback from the community affected by this regulation and to promote effective and efficient implementation of section 504.

Subpart B—Employment Practices

Subpart B applies section 504's prohibition of discrimination on the basis of disability as it relates to the employment practices of recipients of Treasury financial assistance and recipient relationships with third parties. In particular, this regulation conforms to the Rehabilitation Act Amendments of 1992 (Pub. L. 102–569, sec 506), which amended the Rehabilitation Act to make the same employment standards set forth in title I of the ADA apply to employment discrimination under section 504. The proposed rule references the standards applied under title I of the ADA of 1990 (42 U.S.C. 12111 *et seq.*), and the Equal Employment Opportunity Commission's ADA title I regulation at 29 CFR 1630, as amended.

Subpart C—Program Accessibility

Subpart C applies section 504's prohibition of discrimination on the basis of disability as it relates to both existing facilities and newly-constructed facilities of recipients of financial assistance from Treasury. Recipients of financial assistance from Treasury must operate each service, program or activity so that the service, program, or activity, when viewed in its entirety, is readily accessible to and usable by individuals with disabilities. The Department has included a safe harbor for recipients who have not altered existing facilities on or after the effective date of this rule and that comply with the corresponding technical and scoping specifications for those elements in the Uniform Federal Accessibility Standards (UFAS), Appendix A to 41 CFR part 101–19.6, 49 FR 31528, app. A (Aug. 7, 1984). These facilities are not required to be modified to be brought into compliance with the requirements set forth in the 2010 ADA Standards for Accessible Design (the 2004 ADAAG (the requirements set forth in appendices B and D to 36 CFR part 1191 (2009)), and the requirements contained in 28 CFR 35.151). This will likely apply to recipients who previously complied with UFAS on their own or because of other regulatory requirements, such as titles II or III of the ADA.

If construction of a recipient's facility commences after the effective date of this regulation, the facility must be designed and constructed so that it is readily accessible to and usable by persons with disabilities. Generally, new construction and alterations by recipients that are private entities in which the last application for a building permit or permit extension is certified to be complete one year after publication of this rule as final in the **Federal Register** or if no permit is required, if the start of physical construction is one year from the publication of the final rule, must comply with the 2010 Standards as defined in this rule. New construction and alterations by recipients that are public entities that commence one year after the publication of this rule as final in the **Federal Register** must comply with the 2010 Standards.

Subparts D and E—Compliance, Investigations and Procedure for Effecting Compliance; and Hearings and Decisions

As required by section 504, Subparts D and E describe procedures for complaint processing, compliance, investigations, and enforcement consistent with the remedies, procedures and rights set forth in Title VI of the Civil Rights Act of 1964 (42. U.S. C.A. § 2000d). *See* 29 U.S.C. 794a.

III. Procedural Determinations

Executive Order 12067

The Equal Employment Opportunity Commission has reviewed this proposed rule pursuant to Executive Order 12067.

Executive Order 12866

This regulatory action is not a ''significant regulatory action'' under Executive Order 12866, ''Regulatory Planning and Review,'' 58 FR 51735 (October 4, 1993). Accordingly, this rule is not subject to review under the Executive Order by the Office of Information and Regulatory Affairs within the Office of Management and Budget.

Executive Order 13175

In accordance with Executive Order 13175, we have evaluated the potential effects of this rule on federally-recognized Indian tribes and have determined that the rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Unfunded Mandates Reform Act of 1995

The Department certifies that no actions were deemed necessary under the Unfunded Mandates Reform Act of 1995. Furthermore, these regulations will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and they will not significantly or uniquely affect small governments.

The Regulatory Flexibility Act

The Department, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* has reviewed these regulations and certifies 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 recipients of federal financial assistance have been subject to section 504 and the coordination regulation since their effective date in 1973. Accordingly, this proposed rule would not substantially change the existing duty of recipients of financial assistance from Treasury to refrain from discrimination on the basis of disability. This proposed rule would merely fulfill the obligation of the Department to issue agency-specific rules under the law; the rule clarifies the responsibilities of recipients of financial assistance from Treasury under section 504 and describes the Department's investigation and enforcement procedures to ensure compliance. In particular, this rule codifies requirements for a transition plan and self-evaluation as outlined in the coordination regulation (28 CFR part 41). The transition plan and self-evaluation demonstrate an entity's compliance with section 504 and are anticipated to have minimal economic burden. Further, the rule likely would apply only to entities receiving federal financial assistance from the Department, which likely would only include a small number of entities in each industry and therefore would not be expected have an impact on a substantial number of small entities in any industry.

Notwithstanding this certification, the Department welcomes comments on the impacts of this rule on small entities.

Executive Order 13132

These regulations will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, the Department has determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Paperwork Reduction Act

Under the Paperwork Reduction Act (44 U.S.C. chapter 35), 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 issued by the Office of Management and Budget (OMB). The information collections contained in this proposed rule will be submitted and approved by OMB in connection with information collections for the applicable programs listed below.

The information collections contained in this proposed rule are found in §§ 40.5 (assurances), 40.8 (self-evaluation), 40.203 (transition plan), and 40.300 (compliance information).

The OMB control numbers that will be revised include the following:

Bureau/Office	Program or activity	OMB control numbers
Departmental Offices, Office of Domestic Finance, Office of Financial Institutions.	Community Development Financial Institutions (CDFI) Fund—Financial Component.	1559–0021
Departmental Offices, Office of Domestic Finance, Office of Financial Institutions.	Community Development Financial Institutions (CDFI) Fund—Technical Assistance Component.	1559–0021
Departmental Offices, Office of Domestic Finance, Office of Financial Institutions.	Bank Enterprise Award Program	1559–0032, 1559–0005
Departmental Offices, Office of Domestic Finance, Office of Financial Institutions.	Native American Community Development Financial Institutions (CDFI) Assistance Program, Financial Assistance (FA) Awards.	1559–0021
Departmental Offices, Office of Domestic Finance, Office of Financial Institutions.	Native American Community Development Financial Institutions (CDFI) Assistance (NACA) Program, Technical Assistance Grants.	1559–0021
Departmental Offices, Office of Domestic Finance, Office of Financial Institutions.	Community Development Financial Institutions Fund, Capital Magnet Fund.	1559–0043
Departmental Offices, Office of Domestic Finance, Office of Small Business, Community Development, and Housing Policy.	State Small Business Credit Initiative	1505–0227
Internal Revenue Service	Tax Counseling for the Elderly Grant Program	1545–2222
Internal Revenue Service	Volunteer Income Tax Assistance Program	1545–2222
Internal Revenue Service	Volunteer Income Tax Assistance Grant Program	1545–2222
Internal Revenue Service	Low Income Taxpayer Clinic Grant Program	1545–1648
United States Mint	U.S. Commemorative Coin Programs	TBD
Departmental Offices, Treasury Executive Office for Asset Forfeiture.	Equitable sharing program (transfer of forfeited property to state and local law enforcement agencies).	1505–0152
Departmental Offices, Office of the Fiscal Assistant Secretary.	Grants under the RESTORE Act's Direct Component and Centers of Excellence program.	1505–0250

Comments on the collection of information should be sent to the Office of Management and Budget, Attention: Desk Officer for the Department of Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, or email to *OIRA_Submission@OMB.EOP.gov* with copies to the Department of Treasury at the addresses specified in the **ADDRESSES** section. Comments on the information collection should be submitted no later than March 6, 2017. Comments are specifically requested concerning:

(1) Whether the proposed information collection is necessary for the proper performance of agency functions, including whether the information will have practical utility;

(2) The accuracy of the estimated burden associated with the proposed collection of information, including the validity of the methodology and assumptions used (see below);

(3) How to enhance the quality, utility, and clarity of the information required to be maintained; and

(4) How to minimize the burden of complying with the proposed information collection, including the application of automated collection techniques or other forms of information technology.

List of Subjects in 31 CFR Part 40

Civil rights.

For the reasons stated in the preamble, the Department of the Treasury proposes to add part 40 to Title 31 of the Code of Federal Regulations to read as follows:

PART 40—NONDISCRIMINATION ON THE BASIS OF DISABILITY IN PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE FROM THE DEPARTMENT OF THE TREASURY

Subpart A—General Provisions

Sec.
40.1 Purpose, broad coverage and effective date.
40.2 Applicability.
40.3 Definitions.
40.4 Discrimination prohibited.
40.5 Assurances required.
40.6 Designation of responsible employee and adoption of grievance procedures.
40.7 Notice of nondiscrimination and accessible services.
40.8 Remedial action, voluntary action, and self-evaluation.
40.9 Effect of state or local law or other requirements.
40.10 Effect of compliance with regulations of other Federal agencies.

Subpart B—Employment Practices

40.101 Applicability.
40.102 Discrimination prohibited.

Subpart C—Program Accessibility

40.201 Applicability.
40.202 Discrimination prohibited.
40.203 Existing facilities.
40.204 New construction and alterations.

Subpart D—Compliance, Investigations and Procedure for Effecting Compliance

40.300 Compliance information.
40.301 Conduct of investigations.
40.302 Procedure for effecting compliance.

Subpart E—Hearings and Decisions and Notices

40.400 Hearings.
40.401 Decisions and notices.

Authority: 29 U.S.C. 701–796; 31 U.S.C. 321.

Subpart A—General Provisions

§ 40.1 Purpose, broad coverage, and effective date.

(a) *Purpose.* The purpose of this part is to implement section 504 of the Rehabilitation Act of 1973, as amended, which provides that no otherwise qualified individual with a disability in the United States shall solely by reason of his or her disability be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance from the Department of the Treasury.

(b) *Broad Coverage.* Consistent with the purpose of the ADA Amendments Act of 2008 of reinstating a broad scope of protection under the Americans with Disabilities Act and section 504, the definition of ''disability'' applicable to this part shall be construed broadly in favor of expansive coverage. The primary object of attention in cases brought under this part should be whether entities covered under section 504 have complied with their obligations and whether discrimination has occurred, not whether the individual meets the definition of disability. The question of whether an individual meets the definition of disability should not demand extensive analysis.

(c) *Effective date.* This part is effective on [30 days after publication of the final rule].

§ 40.2 Applicability.

This part applies to all programs or activities that receive Federal financial assistance provided by the Department of the Treasury after the effective date of this part, whether or not the assistance was approved before the effective date and whether or not a recipient's grant or award documents reference the obligation to comply with section 504.

§ 40.3 Definitions.

2004 ADAAG means the requirements set forth in appendices B and D to 36 CFR part 1191 (2009).

2010 Standards means the 2010 ADA Standards for Accessible Design, which consist of the 2004 ADAAG and the requirements contained in 28 CFR 35.151.

The *Act* means the Rehabilitation Act of 1973, Public Law 93–112, 87 Stat. 390 (1973), as amended. The Act appears at 29 U.S.C. 701–796.

Applicant means one who submits an application, request, or plan required to be approved by the designated Department official or by a primary recipient as a condition to becoming a recipient.

Auxiliary aids and services means services or devices that enable persons with sensory, manual, or speech disabilities to have an equal opportunity to participate in, and enjoy the benefits of, the recipient's programs or activities. Auxiliary aids and services include:

(1) Qualified interpreters on-site or through video remote interpreting (VRI) services; note takers; real-time computer-aided transcription services; written materials; exchange of written notes; telephone handset amplifiers; assistive listening devices; assistive listening systems; telephones compatible with hearing aids; closed caption decoders; open and closed captioning, including real-time captioning; voice, text, and video-based telecommunications products and systems, including text telephones (TTYs), videophones, and captioned telephones, or equally effective telecommunications devices; videotext displays; accessible electronic and information technology; or other effective methods of making aurally delivered information available to individuals who are deaf or hard of hearing;

(2) Qualified readers; taped texts; audio recordings; Brailled materials and displays; screen reader software; magnification software; optical readers; secondary auditory programs (SAP); large print materials; accessible electronic and information technology; or other effective methods of making visually delivered materials available to individuals who are blind or have low vision;

(3) Acquisition or modification of equipment or devices; and

(4) Other similar services and actions.

Current illegal use of drugs means illegal use of drugs that occurred recently enough to justify a reasonable belief that a person's drug use is current or that continuing use is a real and ongoing problem.

Department means the Department of the Treasury and includes each of its operating bureaus and other organizational units.

Direct threat means a significant risk to the health or safety of others that cannot be eliminated by a change to policies, practices or procedures, or by the provision of auxiliary aids or services, as provided in § 40.4(l) of this part.

Disability has the same meaning as that given in 28 CFR part 35.

Drug means a controlled substance as defined in schedules I through V of section 202 of the Controlled Substances Act (21 U.S.C. 812).

Facility means all or any portion of buildings, structures, sites, complexes, equipment, roads, walks, passageways, parking lots, rolling stock or other conveyances, including the site where the building, property, structure, or equipment is located, or other real or personal property or interest in such property.

Federal financial assistance means any grant, contract (other than a direct Federal procurement contract or a contract of insurance or guaranty), subgrant, contract under a grant, cooperative agreement, formula

allocation, loan, or any other arrangement by which the Department provides or otherwise makes available assistance in the form of:

(a) Funds;

(b) Services of Federal personnel;

(c) Real and personal property or any interest in such property, including:

(1) A sale, transfer, lease or use (other than on a casual or transient basis) of Federal property for less than fair market value, for reduced consideration or in recognition of the public nature of the recipient's program or activity; or

(2) Proceeds from a subsequent sale, transfer or lease of Federal property if the Federal share of its fair market value is not returned to the Federal government; or

(3) Any other thing of value by way of grant, loan, contract, or cooperative grant.

Historic preservation programs means programs conducted by recipients of Federal financial assistance that have preservation of historic properties as a primary purpose.

Historic properties means those buildings or facilities that are eligible for listing in the National Register of Historic Places, or such properties designated as historic under a statute of the appropriate state or local government body.

Illegal use of drugs means the use of one or more drugs, the possession or distribution of which is unlawful under the Controlled Substances Act (21 U.S.C. 812). The term illegal use of drugs does not include the use of a drug taken under supervision by a licensed health care professional, or other uses authorized by the Controlled Substances Act or other provisions of Federal law.

Individual with a disability means any person who has a disability. (The term individual with a disability does not include an individual who is currently engaging in the illegal use of drugs, when the recipient acts on the basis of such use.)

Primary recipient means any recipient that is authorized or required to extend Federal financial assistance to another recipient.

Program or activity means all of the operations of any entity described below, any part of which is extended Federal financial assistance:

(a)(1) A department, agency, special purpose district, or other instrumentality of a state or of a local government; or

(2) The entity of such state or local government that distributes Federal financial assistance and each such department or agency (and each other state or local government entity) that is the recipient of Federal financial assistance, in the case of assistance to a state or local government; or

(b)(1) A college, university, or other postsecondary institution, or a public system of higher education; or

(2) A local educational agency (as defined in 20 U.S.C. 7801), system of vocational education, or other school system; or

(c)(1) An entire corporation, partnership, or other private organization, or an entire sole proprietorship if—

(i) Assistance is extended to such corporation, partnership, private organization, or sole proprietorship as a whole; or

(ii) The corporation, partnership, private organization, or sole proprietorship is principally engaged in the business of providing education, health care, housing, social services, or parks and recreation; or

(2) The entire plant or other comparable, geographically separate physical facility to which Federal financial assistance is extended, in the case of any other corporation, partnership, private organization, or sole proprietorship that is the recipient of Federal financial assistance; or

(d) Any other entity which is established by two or more of the entities described in paragraphs (a), (b) or (c) of this paragraph.

Qualified individual with a disability means:

(a) With respect to any aid, benefit, or service, provided under a program or activity subject to this part, an individual with a disability who, with or without reasonable accommodations in rules, policies, or procedures, the removal of architectural, communication, or transportation barriers, or the provision of auxiliary aids or services, meets the essential eligibility requirements for participation in, or receipt from, that aid, benefit, or service; and

(b) With respect to employment, the definition given that term in the Equal Employment Opportunity Commission's regulation at 29 CFR part 1630, implementing title I of the Americans with Disabilities Act of 1990, which regulation is made applicable to this part by § 40.101 and § 40.102.

Qualified interpreter means an interpreter who, via a video remote interpreting (VRI) service or an on-site appearance, is able to interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary. Qualified interpreters include, for example, sign language interpreters, oral transliterators, and cued-language transliterators.

Qualified reader means a person who is able to read effectively, accurately, and impartially using any necessary specialized vocabulary.

Recipient means any state or its political subdivision, any instrumentality of a state or its political subdivision, any public or private agency, institution, organization, or other entity, or any person to which Federal financial assistance is extended directly or through another recipient, including any successor, assignee, or transferee of a recipient, but excluding the ultimate beneficiary of the assistance.

Secretary means the Secretary of the Treasury or any officer or employee of the Department to whom the Secretary has delegated or may delegate the authority to act under the regulations of this part.

Section 504 means section 504 of the Act, (Pub. L. 93–112, 87 Stat. 394 (29 U.S.C. 794), as amended.

Sub-recipient means an entity to which a primary recipient extends Federal financial assistance.

Ultimate beneficiary is one among a class of persons who are entitled to benefit from, or otherwise participate in, a program or activity receiving Federal financial assistance and to whom the protections of this part extend. The ultimate beneficiary class may be the general public or some narrower group of persons.

Video remote interpreting (VRI) service means an interpreting service that uses video conference technology over dedicated lines or wireless technology offering high-speed, wide-bandwidth video connection that delivers high-quality video images as provided in § 40.4(*i*)(4).

§ 40.4 Discrimination prohibited.

(a) *General.* No qualified individual shall, solely on the basis of disability, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any program or activity receiving assistance subject to this part.

(b) Discriminatory actions prohibited.

(1) A recipient may not, in providing any program or activity subject to this part, discriminate on the basis of disability, directly or through contractual, licensing, or other arrangements, on the basis of disability:

(i) Deny a qualified individual with a disability the opportunity accorded others to participate in or benefit from the aid, benefit, or service.

(ii) Afford a qualified individual with a disability an opportunity to participate in or benefit from the aid, benefit or

service that is not equal to that afforded to others;

(iii) Provide a qualified individual with a disability with an aid, benefit, or service that is not as effective in affording equal opportunity to obtain the same result, to gain the same benefit, or to reach the same level of achievement as that provided to others;

(iv) Deny a qualified individual with a disability an equal opportunity to participate in the program or activity by providing services to the program;

(v) Provide different or separate aids, benefits, or services to qualified individuals with disabilities or classes of qualified individuals with disabilities than is provided to others unless such action is necessary to provide qualified individuals with disabilities or classes of qualified individuals with disabilities with aids, benefits, or services that are as effective as that provided to others;

(vi) Deny a qualified individual with a disability an opportunity to participate as a member of a planning or advisory board;

(vii) Aid or perpetuate discrimination against a qualified individual with a disability by providing assistance to an agency, organization, or person that discriminates on the basis of disability in providing any aid, benefit, or service to beneficiaries of the recipient's program;

(viii) Permit the participation in the program or activity of agencies, organizations or persons which discriminate against individuals with disabilities who are beneficiaries in the recipient's program.

(ix) Intimidate or retaliate against any individual, with or without a disability, for the purpose of interfering with any right secured by section 504 or this part;

(x) Otherwise limit a qualified individual with a disability in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving the aid, benefit, or service;

(2) A recipient may not deny a qualified individual with a disability the opportunity to participate in any programs or activities that are not separate or different, despite the existence of permissibly separate or different programs or activities.

(3) A recipient may not, directly or through contractual, licensing, or other arrangements, utilize criteria or methods of administration that:

(i) have the effect of subjecting qualified individuals with disabilities to discrimination on the basis of disability;

(ii) have the purpose or effect of defeating or substantially impairing accomplishment of the objectives of the recipient's program or activity with respect to individuals with disabilities; or

(iii) perpetuate the discrimination of another recipient if both recipients are subject to common administrative control or are agencies of the same State.

(4) A recipient may not, in determining the site or a location of a facility, make selections—

(i) that have the purpose or effect of excluding individuals with disabilities from, denying them the benefits of, or otherwise subjecting them to discrimination on the basis of disability; or

(ii) that have the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of the program or activity with respect to individuals with disabilities.

(5) A recipient is prohibited from discriminating on the basis of disability in aid, benefits, or services in programs or activities operating without Federal financial assistance where such action would discriminate against individuals with disabilities who are beneficiaries or participants in any program or activity of the recipient receiving Federal financial assistance from this Department.

(6) An entity not otherwise receiving Federal financial assistance but using a facility provided with the aid of Federal financial assistance from this Department after the effective date of this part is prohibited from discriminating on the basis of disability.

(7) A recipient, in the selection of procurement contractors, may not use criteria that subject qualified individuals with disabilities to discrimination on the basis of disability.

(8) A recipient may not administer a licensing or certification program in a manner that subjects qualified individuals with disabilities to discrimination on the basis of disability, nor may a recipient establish requirements for the programs or activities of licensees or certified entities that subject qualified individuals with disabilities to discrimination on the basis of disability. The programs or activities of entities that are licensed or certified by a recipient are not, themselves, covered by this part unless those entities are also recipients of federal financial assistance from this Department.

(c) The exclusion of individuals without disabilities or specified classes of individuals with disabilities from aid, benefits, or services limited by Federal statute or executive order to individuals with disabilities or a different class of individuals with disabilities is not prohibited by this part.

(d) Nothing in this part prohibits a recipient from providing aid, benefits, or services to individuals with disabilities or to a particular class of individuals with disabilities beyond those required by this part.

(e) *Integrated Setting.* Recipients shall administer programs or activities in the most integrated setting appropriate to the needs of qualified individuals with disabilities.

(f) Nothing in this part shall be construed to require an individual with a disability to accept an accommodation, aid, service, opportunity, or benefit provided under section 504 or this part which such individual chooses not to accept.

(g) A recipient may not place a surcharge on a particular individual with a disability or any group of individuals with disabilities to cover the costs of measures, such as the provision of auxiliary aids, reasonable accommodations, or program accessibility, that are required to provide that individual or group with the nondiscriminatory treatment required by the Act or this part.

(h) Illegal Use of Drugs.

(1) *General.* Except as provided in subparagraph (3) of this section, this part does not prohibit discrimination against an individual based on that individual's current use of illegal drugs.

(2) A recipient shall not discriminate on the basis of illegal use of drugs against an individual who is not engaging in current illegal use of drugs and who—

(i) Has successfully completed a supervised drug rehabilitation program or has otherwise been rehabilitated successfully;

(ii) Is participating in a supervised rehabilitation program; or

(iii) Is erroneously regarded as engaging in such use.

(3) Health and drug rehabilitation services.

(i) A recipient shall not deny health services, or services provided in connection with drug rehabilitation, to an individual on the basis of that individual's current illegal use of drugs, if the individual is otherwise entitled to such services.

(ii) A drug rehabilitation or treatment program may deny participation to individuals who engage in illegal use of drugs while they are in the program.

(4) *Drug testing.*

(i) This part does not prohibit a recipient from adopting or administering reasonable policies or procedures, including but not limited to drug testing, designed to ensure that an individual who formerly engaged in the

illegal use of drugs is not now engaging in current illegal use of drugs.

(ii) Nothing in paragraph (4) of this section shall be construed to encourage, prohibit, restrict, or authorize the conducting of testing for the illegal use of drugs.

(i) Communications.

(1)(i) A recipient shall take appropriate steps to ensure that communications with applicants, participants, beneficiaries, members of the public, and companions with disabilities are as effective as communications with others.

(ii) For purposes of this section, ''companion'' means a family member, friend, or associate of an individual seeking access to a program or activity of a recipient, who, along with such individual, is an appropriate person with whom the recipient should communicate.

(2)(i) A recipient shall furnish appropriate auxiliary aids and services where necessary to afford qualified individuals with disabilities, an equal opportunity to participate in, and enjoy the benefits of, a service, program, or activity of a recipient.

(ii) The type of auxiliary aid or service necessary to ensure effective communication will vary in accordance with the method of communication used by the individual; the nature, length, and complexity of the communication involved; and the context in which the communication is taking place. In determining what types of auxiliary aids and services are necessary, a recipient entity shall give primary consideration to the requests of individuals with disabilities. In order to be effective, auxiliary aids and services must be provided in accessible formats, in a timely manner, and in such a way as to protect the privacy and independence of the individual with a disability.

(3)(i) A recipient shall not require an individual with a disability to bring another individual to interpret for him or her.

(ii) A recipient shall not rely on an adult accompanying an individual with a disability to interpret or facilitate communication except—

(A) In an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no interpreter available; or

(B) Where the individual with a disability specifically requests that the accompanying adult interpret or facilitate communication, the accompanying adult agrees to provide such assistance, and reliance on that adult for such assistance is appropriate under the circumstances.

(iii) A recipient shall not rely on a minor child to interpret or facilitate communication, except in an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no interpreter available.

(4) Video remote interpreting (VRI) services. A recipient that chooses to provide qualified interpreters via VRI services shall ensure that it provides—

(i) Real-time, full-motion video and audio over a dedicated high-speed, wide-bandwidth video connection or wireless connection that delivers high-quality video images that do not produce lags, choppy, blurry, or grainy images, or irregular pauses in communication;

(ii) A sharply delineated image that is large enough to display the interpreter's face, arms, hands, and fingers, and the participating individual's face, arms, hands, and fingers, and can be seen by the participating individual regardless of the individuals' body position.

(iii) A clear, audible transmission of voices; and

(iv) Adequate training to users of the technology and other involved individuals so that they may quickly and efficiently set up and operate the VRI.

(5) Where a recipient communicates by telephone with applicants, participants, beneficiaries and members of the public, text telephones (TTYs) or equally effective telecommunications systems shall be used to communicate with individuals who are deaf or hard of hearing or have speech impairments.

(6) When a recipient uses an automated-attendant system, including, but not limited to, voice mail and messaging, or an interactive voice response system, for receiving and directing incoming telephone calls, that system must provide effective real-time communication with individuals using auxiliary aids and services, including TTYs and all forms of FCC-approved telecommunications relay system, including Internet-based relay systems.

(7) A recipient shall respond to telephone calls from a telecommunications relay service established under title IV of the ADA in the same manner that it responds to other telephone calls.

(8) This section does not require the recipient to take any action that it can demonstrate would result in a fundamental alteration in the nature of a program or activity or in undue financial and administrative burdens. In those circumstances where the recipient believes that the proposed action would fundamentally alter the program or activity or would result in undue financial and administrative burdens, the recipient has the burden of proving that compliance with § 40.4(*i*) would result in such alteration or burdens. The decision that compliance would result in such alteration or burdens must be made by the head of the recipient agency or the agency head's designee after considering all of the recipient's resources available for use in the funding and operation of the conducted program or activity and must be accompanied by a written statement of the reasons for reaching that conclusion. If an action required to comply with this section would result in such an alteration or such burdens, the recipient shall take any other action that would not result in such an alteration or such burdens but would nevertheless ensure that, to the maximum extent possible, individuals with disabilities receive the benefits and services of the program or activity.

(j) *Reasonable accommodations.* (1) A recipient shall make reasonable accommodations in policies, practices, or procedures when such accommodations are necessary to avoid discrimination on the basis of disability, unless the recipient can demonstrate that making the accommodations would fundamentally alter the nature of the service, program, or activity or result in an undue financial and administrative burden. For purposes of this section, the term reasonable accommodation shall be interpreted in a manner consistent with the term ''reasonable modifications'' as set forth in the Americans with Disabilities Act Title II regulation at 28 CFR 35.130(b)(7), and not as it is defined or interpreted for the purposes of employment discrimination under Title I of the ADA (42 U.S.C. 12111–12112) and its implementing regulation at 29 CFR part 1630.

(2) A recipient is not required to provide a reasonable accommodation to an individual who meets the definition of disability solely under the ''regarded as'' prong of the definition of disability at § 40.3, definition of disability,

(k) *Prohibition on associational discrimination.* A recipient shall not exclude or otherwise deny aids, benefits, or services of its programs or activities to an individual because of that individual's relationship or association with an individual with a known disability.

(l) *Direct Threat.* (1) This part does not require a recipient to permit an individual to participate in or benefit from the services, programs, or activities of that recipient when that individual poses a direct threat to the health or safety of others.

(2) In determining whether an individual poses a direct threat to the health or safety of others, a recipient must make an individualized assessment, based on reasonable judgment that relies on current medical knowledge or on the best available objective evidence, to ascertain: The nature, duration, and severity of the risk; the probability that the potential injury will actually occur; and whether reasonable accommodations in policies, practices, or procedures or the provision of auxiliary aids or services will mitigate the risk.

(m) *Claims of no disability.* Nothing in this subpart shall provide the basis for a claim that an individual without a disability was subject to discrimination because of a lack of disability, including a claim that an individual with a disability was granted a reasonable accommodation that was denied to an individual without a disability.

§ 40.5 Assurances required.

(a) *Assurances.* Either at the application stage or the award stage, an applicant for federal financial assistance to which this part applies shall submit an assurance that the program or activity will be operated in compliance with this part.

(b) *Duration of obligation.* (1) In the case where the Federal financial assistance is to provide or is in the form of personal property, real property or an interest therein or structures thereon, the assurance shall obligate the recipient, or, in the case of a subsequent transfer, the transferee, for the period during which the property is used for a purpose for which the Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits, or for as long as the recipient retains ownership or possession of the property, whichever is longer. In all other cases the assurance shall obligate the recipient for the period during which federal financial assistance is extended to the program.

(2) In the case where Federal financial assistance is provided in the form of a transfer of real property, structures, or improvements thereon, or interest therein, from the Federal government, the instrument effecting or recording the transfer shall contain a covenant running with the land assuring nondiscrimination for the period during which the real property is used for a purpose for which the Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits. Where no transfer of property or interest therein from the Federal government is involved, but property is acquired or improved with Federal financial assistance, the recipient shall agree to include such covenant in any subsequent transfer of such property. When the property is obtained from the Federal government, such covenant may also include a condition coupled with a right to be reserved by the Department to revert title to the property in the event of a breach of the covenant where, in the discretion of the designated agency official, such a condition and right of reverter is appropriate to the statute under which the real property is obtained and to the nature of the grant and the grantee. In such event if a transferee of real property proposes to mortgage or otherwise encumber the real property as security for financing construction of new, or improvement of existing, facilities on such property for the purposes for which the property was transferred, the designated agency official may agree, upon request of the transferee and if necessary to accomplish such financing, and upon such conditions as the designated agency official deems appropriate, to subordinate such right of reversion to the lien of such mortgage or other encumbrance.

(c) *Continuing Federal financial assistance.* Every application by a state or a state agency for continuing Federal financial assistance to which this part applies shall as a condition to its approval and the extension of any Federal financial assistance pursuant to the application:

(1) Contain, be accompanied by, or be covered by a statement that the program is (or, in the case of a new program, will be) conducted in compliance with all requirements imposed by or pursuant to this part; and

(2) Provide, be accompanied by, or be covered by provision for such methods of administration for the program as are found by the designated agency official to give reasonable guarantee that the applicant and all recipients of Federal financial assistance under such program will comply with all requirements imposed by or pursuant to this part.

(d) *Assurance from institutions.* (1) In the case of any application for Federal financial assistance to an institution of higher education (including assistance for construction, for research, for special training projects, for student loans or for any other purpose), the assurance required by this section shall extend to admission practices and to all other practices relating to the treatment of students.

(2) The assurance required with respect to an institution of higher education, hospital, or any other institution, insofar as the assurance relates to the institution's practices with respect to admission or other treatment of individuals as students, patients, or clients of the institution or to the opportunity to participate in the provision of services or other benefits to such individuals, shall be applicable to the entire institution.

(e) *Form.* (1) The assurances required by paragraph (a) of this section, which may be included as part of a document that addresses other assurances or obligations, shall include that the applicant or recipient will comply with all applicable Federal statutes relating to nondiscrimination. This includes but is not limited to: Section 504 of the Rehabilitation Act of 1973, as amended.

(2) The designated agency official will specify the extent to which such assurances will be required of the applicant's or recipient's subgrantees, contractors, subcontractors, transferees, or successors in interest. Any such assurance shall include provisions which give the United States a right to seek its judicial enforcement.

§ 40.6 Designation of responsible employee and adoption of grievance procedures.

(a) *Designation of responsible employee.* A recipient that employs fifty or more persons shall designate at least one person to coordinate compliance with this part.

(b) *Adoption of grievance procedures.* A recipient that employs fifty or more persons shall adopt grievance procedures that incorporate appropriate due process standards (*e.g.* adequate notice, fair hearing) and provide for the prompt and equitable resolution of complaints alleging any action prohibited by this part except that such procedures need not be established with respect to complaints from applicants for employment. Any individual may file a complaint with the Department without having first used the recipient's grievance procedures.

(c) The Secretary may require any recipient with fewer than fifty employees to designate a responsible employee, comply with the requirements for providing notice of nondiscrimination, and adopt grievance procedures when the Secretary finds a violation of this part or finds that complying with these administrative requirements will not significantly impair the ability of the recipient to provide benefits or services.

§ 40.7 Notice of nondiscrimination and accessible services.

(a) A recipient employing fifty or more persons shall take appropriate

initial and continuing steps to notify participants, beneficiaries, applicants, and employees, including those who are blind or have low vision or deaf or hard of hearing, and unions or professional organizations holding collective bargaining or professional agreements with the recipient that it does not discriminate on the basis of disability in violation of section 504 and this part. The notification shall state, where appropriate, that the recipient does not discriminate in admission or access to, or participation in, or employment in, its programs or activities. The recipient shall also identify the responsible employee designated pursuant to § 40.6(a), where to file section 504 complaints with the Department, and where applicable, with the recipient, and identify the existence and location of accessible services, activities, and facilities. A recipient shall make the initial notification required by this paragraph within 90 days of the effective date of this part. Methods of initial and continuing notification may include but are not limited to the posting of notices, placement of notices in the recipient's publications, publication of notices on the recipient's Web site, publication in newspapers or magazines, radio announcements, and the use of other visual and aural media.

(b) If a recipient publishes or uses recruitment materials or publications containing general information that it makes available to participants, beneficiaries, applicants or employees, it shall include in those materials or publications a statement of the policy described in paragraph (a) of this section. A recipient may meet the requirement of this paragraph either by including appropriate inserts in existing materials and publications or by revising and reprinting the materials and publications.

§ 40.8 Remedial action, voluntary action, and self-evaluation.

(a) *Remedial action.* (1) If the Secretary finds that a recipient has discriminated against individuals on the basis of disability in violation of section 504 or this part, the recipient shall take such remedial action as the Secretary deems necessary to overcome the effects of the discrimination.

(2) Where a recipient is found to have discriminated against individuals on the basis of disability in violation of section 504 or this part and where another recipient exercises control over the recipient that has discriminated, the Secretary, where appropriate, may require either or both recipients to take remedial action.

(3) The Secretary may, where necessary to overcome the effects of discrimination in violation of section 504 or this part, require a recipient to take remedial action:

(i) With respect to individuals with disabilities who are no longer participants in the recipient's program or activity but who were participants in the program when such discrimination occurred;

(ii) With respect to individuals with disabilities who would have been participants in the program or activity had the discrimination not occurred, or;

(iii) With respect to individuals with disabilities presently in the program or activity, but not receiving full benefits or equal and integrated treatment within the program.

(b) *Voluntary action.* A recipient may take steps, in addition to any action that is required by this part, to increase the participation of qualified individuals with disabilities in the recipient's program or activity.

(c) *Self-evaluation.* (1) A recipient shall, within one year of the effective date of this part:

(i) Evaluate, with the assistance of interested persons, including individuals with disabilities or organizations representing individuals with disabilities, its current policies and practices and the effects thereof that do not or may not meet the requirements of this part.

(ii) Modify, after consultation with interested persons, including individuals with disabilities or organizations representing individuals with disabilities, any policies and practices that do not meet the requirements of this part; and

(iii) Take, after consultation with interested persons, including individuals with disabilities or organizations representing individuals with disabilities, appropriate remedial steps to eliminate the effects of any discrimination that resulted in adherence to these policies and practices.

(2) A recipient employing fifty or more persons shall, for at least three years following completion of the evaluation required under paragraph (c)(1) of this section, maintain on file, make available for public inspection, and provide to the Secretary upon request:

(i) A list of the interested persons consulted,

(ii) A description of areas examined and any problems identified, and

(iii) A description of any modifications made and of any remedial steps taken.

§ 40.9 Effect of state or local law or other requirements.

The obligation to comply with this part is not obviated or alleviated by the existence of any state or local law or other requirement that, on the basis of disability, imposes prohibitions or limits upon the eligibility of qualified individuals with disabilities to receive services or to participate in any program or activity.

§ 40.10 Effect of compliance with regulations of other Federal agencies.

A recipient that has designated a responsible official and established a grievance procedure, provided notice, completed a self-evaluation, or prepared a transition plan in the course of complying with regulations issued by other Federal agencies under section 504 or title II of the Americans with Disabilities Act will be in compliance with §§ 40.6, 40.7, 40.8(c), or 40.203(f), respectively, if all requirements of those sections have been met in regard to programs or activities assisted by this Department.

Subpart B—Employment Practices

§ 40.101 Applicability.

This part applies to all programs or activities that receive Federal financial assistance provided by the Department.

§ 40.102 Discrimination prohibited.

(a) *General.* No qualified individual with a disability shall, on the basis of disability, be subjected to discrimination in employment under any program or activity to which this part applies.

(b) *Employment discrimination standards.* The standards used to determine whether paragraph (a) of this section has been violated shall be the standards applied under Title I of the Americans with Disabilities Act of 1990 (42 U.S.C. 12111 *et seq.*) and, as such sections relate to employment, the provisions of sections 501 through 504 and 510 of the Americans with Disabilities Act of 1990 (42 U.S.C. 12201–12204 and 12210), as amended by the ADA Amendments Act of 2008 (Pub L. 110–325), as such standards are implemented in the Equal Employment Opportunity Commission's regulation at 29 CFR pt. 1630, as amended. The procedures to be used to determine whether paragraph (a) of this section has been violated shall be the procedures set forth in Subpart D of this part.

Subpart C—Program Accessibility

§ 40.201 Applicability.

This subpart applies to all programs or activities that receive Federal

financial assistance provided by the Department after the effective date of this part.

§ 40.202 Discrimination prohibited.

Recipients shall ensure that no qualified individuals with disabilities are denied the benefits of, excluded from participation in, or otherwise subjected to discrimination under any program or activity receiving assistance from this Department because a recipient's facilities are inaccessible to or unusable by individuals with disabilities.

§ 40.203 Existing facilities.

(a) *Accessibility.* A recipient shall operate each service, program or activity so that the service, program, or activity, when viewed in its entirety, is readily accessible to and usable by individuals with disabilities. This paragraph does not—

(1) Necessarily require a recipient to make each of its existing facilities or every part of an existing facility accessible to and usable by qualified individuals with disabilities;

(2) Require a recipient to take any action that would threaten or destroy the historically significant features of an historic property; or

(3) Require a recipient to take any action that it can demonstrate would result in a fundamental alteration in the nature of a service, program, or activity or in undue financial and administrative burdens. In those circumstances where personnel of the recipient believe that the proposed action would fundamentally alter the service, program, or activity or would result in undue financial and administrative burdens, a recipient has the burden of proving that compliance with § 40.203(a) of this part would result in such alteration or burdens. The decision that compliance would result in such alteration or burdens must be made by the director of the recipient entity or his or her designee after considering all resources available for use in the funding and operation of the service, program, or activity, and must be accompanied by a written statement of the reasons for reaching that conclusion. If an action would result in such an alteration or such burdens, a recipient shall take any other action that would not result in such an alteration or such burdens but would nevertheless ensure that individuals with disabilities receive the benefits or services provided by the recipient.

(b) *Methods.*

(1) A recipient may comply with the requirements of paragraph (a) of this section through such means as redesign of equipment, reassignment of classes or other services to accessible buildings, assignment of aides to beneficiaries, home visits, delivery of services at alternate accessible sites, alteration of existing facilities and construction of new facilities in conformance with the requirements of § 40.204, use of accessible rolling stock or other conveyances, or any other methods that result in making its services, programs or activities readily accessible to and usable by qualified individuals with a disabilities. A recipient is not required to make structural changes in existing facilities where other methods are effective in achieving compliance with paragraph (a) of this section. A recipient, in making alterations to existing buildings, shall meet the accessibility requirements of § 40.204. In choosing among available methods for meeting the requirements of paragraph (a) of this section, a recipient shall give priority to those methods that offer services, programs, and activities to qualified individuals with disabilities in the most integrated setting appropriate.

(2) Safe harbor. For the purposes of complying with this section, elements that have not been altered in existing facilities on or after [Effective date of the final rule], and that comply with the corresponding technical and scoping specifications for those elements in the Uniform Federal Accessibility Standards (UFAS), Appendix A to 41 CFR part 101–19.6, 49 FR 31528, app. A (Aug. 7, 1984) are not required to be modified to be brought into compliance with the requirements set forth in the 2010 Standards.

(c) *Small providers.* If a recipient with fewer than fifteen employees finds, after consultation with an individual with a disability seeking its services, that there is no method of complying with paragraph (a) of this section other than by making a significant alteration in its existing facilities, the recipient may, as an alternative, refer the individual with a disability to other providers of those services that are accessible at an equivalent cost to the beneficiary.

(d) *Historic preservation programs.* In meeting the requirements of § 40.203(a) in historic preservation programs, a recipient shall give priority to methods that provide physical access to individuals with disabilities. In cases where a physical alteration to a historic property is not required because of paragraph (a)(2) or (a)(3) of this section, alternative methods of achieving program accessibility include—

(1) Using audio-visual materials and devices to depict those portions of a historic property that cannot otherwise be made accessible;

(2) Assigning persons to guide individuals with disabilities into or through portions of historic properties that cannot otherwise be made accessible; or

(3) Adopting other innovative methods.

(e) *Time period.* A recipient shall comply with the requirements of paragraph (a) of this section within ninety days of the effective date of this part except that, where structural changes in facilities are necessary, such changes shall be made as expeditiously as possible and no later than within three years of the effective date of this part.

(f) *Transition plan.* In the event that structural changes to facilities are necessary to meet the requirement of paragraph (a) of this section, a recipient shall develop, within six months of the effective date of this part, a transition plan setting forth the steps necessary to complete such changes. The plan shall be developed with the assistance of interested persons, including individuals with disabilities or organizations representing individuals with disabilities. A copy of the transition plan shall be made available for public inspection. The plan shall, at a minimum:

(1) Identify physical obstacles in the recipient's facilities that limit the accessibility of its program or activity to individuals with disabilities;

(2) Describe in detail the methods that will be used to make the facilities accessible;

(3) Specify the schedule for taking the steps necessary to achieve full accessibility under paragraph (a) of this section and if the time period of the transition plan is longer than one year, identify steps that will be taken during each year of the transition period; and

(4) Identify the person responsible for implementation of the plan.

(g) *Notice of location of accessible facilities.*

(1) General. The recipient shall adopt and implement procedures to ensure that interested persons with disabilities, including persons with an intellectual disability, a learning disability, a vision or hearing disability or other disabilities, can obtain information as to the existence and location of services, activities, and facilities that are accessible to and usable by individuals with disabilities.

(2) Signs at primary entrances. The recipient shall provide signs at a primary entrance to each of its inaccessible facilities, directing users to an accessible facility or a location at

which they can obtain information about accessible facilities. The international symbol for accessibility shall be used at each accessible entrance of a facility.

§ 40.204 New construction and alterations.

(a) *Design and construction.* Each new facility or part of a facility constructed by, on behalf of, or for the use of a recipient shall be designed and constructed in such manner that the facility or part of the facility is readily accessible to and usable by individuals with disabilities, if the construction is commenced after the effective date of this part.

(b) *Alteration.* Each facility or part of a facility which is altered by, on behalf of, or for the use of a recipient after the effective date of this part in a manner that affects or could affect the usability of the facility or part of the facility shall to the maximum extent feasible be altered in such manner that the altered portion of the facility is readily accessible to and usable by individuals with disabilities.

(c) Accessibility standards and compliance dates.

(1) Applicable Accessibility Standard.

(i) New construction and alterations on or after the compliance dates specified in paragraph (2) must comply with the 2010 Standards.

(ii) New construction and alterations of buildings or facilities undertaken in compliance with the 2010 Standards shall comply with the scoping and technical requirements for a ''public building or facility'' in the 2010 Standards regardless of whether the recipient is a public or private entity.

(iii) Departures from particular requirements of the Standards by the use of other methods shall be permitted when it is clearly evident that equivalent access to the facility or part of the facility is thereby provided.

(2) Compliance Dates.

(i) *New construction and alterations by recipients that are private entities.* New construction and alterations in which the last application for a building permit or permit extension for such construction or alterations is certified to be complete by a state, county, or local government (or, in those jurisdictions where the government does not certify completion of applications, if the date when the last application for a building permit or permit extension is received by the state, county, or local government) is on or after [DATE ONE YEAR AFTER PUBLICATION OF THE FINAL RULE IN THE **Federal Register**], or if no permit is required, if the start of physical construction or alterations occurs on or after [DATE ONE YEAR FROM THE PUBLICATION OF THE FINAL RULE IN THE **Federal Register**], then such new construction and alterations shall comply with the 2010 Standards as defined in paragraph (1) of this section.

(ii) *New construction and alterations by recipients that are public entities.* If physical construction or alterations commence on or after [DATE ONE YEAR AFTER PUBLICATION OF THE FINAL RULE IN THE **Federal Register**], then such new construction and alterations shall comply with the 2010 Standards.

(3) For the purposes of this section, ceremonial groundbreaking or razing of structures prior to site preparation will not be considered to commence or start physical construction or alterations.

(4) *Compliance with the Architectural Barriers Act of 1968.* Nothing in this section or § 40.203 relieves recipients whose facilities are covered by the Architectural Barriers Act of 1968, as amended (42 U.S.C. 4151–4157), from their responsibility of complying with the requirements of that Act and any implementing regulations.

(5) This section does not require recipients to make building alterations that have little likelihood of being accomplished without removing or altering a load-bearing structural member.

Subpart D—Compliance, Investigations and Procedure for Effecting Compliance

§ 40.300 Compliance information.

(a) *Cooperation and assistance.* The Secretary shall to the fullest extent practicable seek the cooperation of recipients in obtaining compliance with this part and shall provide assistance and guidance to recipients to help them comply voluntarily with this part.

(b) *Compliance reports.* Each recipient shall keep such records and submit to the Secretary timely, complete, and accurate compliance reports at such times, and in such form and containing such information, as the Secretary may determine to be necessary to enable the Secretary to ascertain whether the recipient has complied or is complying with this part. In the case in which a primary recipient extends Federal financial assistance to any other recipient, such other recipient shall also submit such compliance reports to the primary recipient as may be necessary to enable the primary recipient to carry out its obligations under this part. In general, recipients should have available for the Secretary data showing the extent to which individuals with disabilities are beneficiaries of programs receiving Federal financial assistance.

(c) *Access to sources of information.* Each recipient shall permit access by the Secretary, during normal business hours, to such of its books, records, accounts, and other sources of information and its facilities as may be pertinent to ascertain compliance with this part. Where any information required of a recipient is in the exclusive possession of any other agency, institution, or person and this agency, institution, or person fails or refuses to furnish this information, the recipient shall so certify in its report and shall set forth what efforts it has made to obtain the information.

(d) *Information to beneficiaries and participants.* Each recipient shall make available to participants, beneficiaries, and other interested persons such information regarding the provisions of this part and its applicability to the program for which the recipient receives Federal financial assistance and make such information available to them in such manner as the Secretary finds necessary to apprise such persons of the protections against discrimination assured them by section 504 and this part.

§ 40.301 Conduct of investigations.

(a) *Periodic compliance reviews.* The Secretary shall from time to time review the practices of recipients to determine whether they are complying with this part.

(b) *Complaints.* Any person who believes that he or she, or any specific class of persons, has been subjected to discrimination prohibited by this part may by himself or herself, or by a representative, file with the Secretary a written complaint. A complaint must be filed not later than 180 days after the date of the alleged discrimination, unless the time for filing is extended by the Secretary.

(c) *Investigations.* The Secretary will make a prompt investigation whenever a compliance review, report, complaint, or any other information indicates a possible failure to comply with this part. The investigation will include, where appropriate, a review of the pertinent practices and policies of the recipient, the circumstances under which the possible noncompliance with this part occurred, and other factors relevant to a determination as to whether the recipient has failed to comply with this part.

(d) *Resolution of matters.*

(1) If an investigation pursuant to paragraph (c) of this section indicates a failure to comply with this part, the Secretary will so inform the recipient

and the matter will be resolved by informal means whenever possible. If it has been determined that the matter cannot be resolved by informal means, action will be taken as provided for in § 40.302.

(2) If an investigation does not warrant action pursuant to paragraph (d)(1) of this section, the Secretary will so inform the recipient and the complainant, if any, in writing.

(e) *Intimidatory or retaliatory acts prohibited.* No recipient or other person shall intimidate, threaten, coerce, or discriminate against any individual for the purpose of interfering with any right or privilege secured by section 504 or this part, or because the individual has made a complaint, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under this part. The identity of complainants shall be kept confidential except to the extent necessary to carry out the purposes of this part, including the conduct of any investigation, hearing, or judicial proceeding arising thereunder.

§ 40.302 Procedure for effecting compliance.

(a) *General.* If there appears to be a failure or threatened failure to comply with this part, and if the noncompliance or threatened noncompliance cannot be corrected by informal means, compliance with this part may be effected by the suspension or termination of or refusal to grant or to continue Federal financial assistance or by any other means authorized by law. Such other means may include, but are not limited to: (1) A referral to the Department of Justice with a recommendation that appropriate proceedings be brought to enforce any rights of the United States under any law of the United States, or any assurance or other contractual undertaking, and (2) Any applicable proceeding under state or local law.

(b) *Noncompliance with § 40.5.* If an applicant fails or refuses to furnish an assurance required under § 40.5 or otherwise fails or refuses to comply with a requirement imposed by or pursuant to that section, Federal financial assistance may be refused in accordance with the procedures of paragraph (c) of this section. The Department shall not be required to provide assistance in such a case during the pendency of the administrative proceedings under such paragraph. However, the Department shall continue assistance during the pendency of such proceedings where such assistance is due and payable pursuant to an application approved prior to the effective date of this part.

(c) *Termination of or refusal to grant or to continue Federal financial assistance.*

(1) No order suspending, terminating, or refusing to grant or continue Federal financial assistance shall become effective until:

(i) The Secretary has advised the applicant or recipient of the applicant's or recipient's failure to comply and has determined that compliance cannot be secured by voluntary means;

(ii) There has been an express finding on the record, after opportunity for hearing, of a failure by the applicant or recipient to comply with a requirement imposed by or pursuant to this part;

(iii) The action has been approved by the Secretary pursuant to § 40.401(e); and

(iv) The expiration of 30 days after the Secretary has filed with the committee of the House and the committee of the Senate having legislative jurisdiction over the program involved, a full written report of the circumstances and the grounds for such action.

(2) Any action to suspend or terminate or to refuse to grant or to continue Federal financial assistance shall be limited to the particular political entity, or part thereof, or other applicant or recipient as to whom such a finding has been made and shall be limited in its effect to the particular program, or part thereof, in which such noncompliance has been so found.

(d) *Other means authorized by law.* No action to effect compliance with section 504 by any other means authorized by law shall be taken by the Department until:

(1) The Secretary has determined that compliance cannot be secured by voluntary means;

(2) The recipient or other person has been notified of its failure to comply and of the action to be taken to effect compliance; and

(3) The expiration of at least 10 days from the mailing of such notice to the recipient or other person. During this period of at least 10 days, additional efforts shall be made to persuade the recipient or other person to comply with the regulation and to take such corrective action as may be appropriate.

Subpart E—Hearings and Decisions and Notices

§ 40.400 Hearings.

(a) *Opportunity for hearing.* Whenever an opportunity for a hearing is required by § 40.302(c), reasonable notice shall be given by registered or certified mail, return receipt requested, to the affected applicant or recipient. This notice shall advise the applicant or recipient of the action proposed to be taken, the specific provision under which the proposed action against it is to be taken, and the matters of fact or law asserted as the basis for this action, and either:

(1) Fix a date not less than 20 days after the date of such notice within which the applicant or recipient may request of the Secretary that the matter be scheduled for hearing; or

(2) Advise the applicant or recipient that the matter in question has been set down for hearing at a stated place and time. The time and place so fixed shall be reasonable and shall be subject to change for cause. The complainant, if any, shall be advised of the time and place of the hearing. An applicant or recipient may waive a hearing and submit written information and argument for the record. The failure of an applicant or recipient to request a hearing under this paragraph or to appear at a hearing for which a date has been set shall be deemed to be a waiver of the right to a hearing under § 40.301(c) and consent to the making of a decision on the basis of such information as is available.

(b) *Time and place of hearing.* Hearings shall be held at the offices of the Department component administering the program, at a time fixed by the Secretary, unless he or she determines that the convenience of the applicant or recipient or of the Department requires that another place be selected. Hearings shall be held before the Secretary, or at the Secretary's discretion, before a hearing examiner appointed in accordance with section 3105 of title 5, United States Code, or detailed under section 3344 of title 5, United States Code.

(c) *Right to counsel.* In all proceedings under this section, the applicant or recipient and the Department shall have the right to be represented by counsel.

(d) *Procedures, evidence, and record.* (1) The hearing, decision, and any administrative review thereof shall be conducted in conformity with sections 554 through 557 of title 5, United States Code, and in accordance with such rules of procedure as are proper (and not inconsistent with this section) relating to the conduct of the hearing, giving of notices subsequent to those provided for in paragraph (a) of this section, taking of testimony, exhibits, arguments and briefs, requests for findings, and other related matters. Both the Secretary and the applicant or recipient shall be entitled to introduce all relevant evidence on the issues as stated in the notice for hearing or as determined by

the officer conducting the hearing at the outset of or during the hearing.

(2) Technical rules of evidence do not apply to hearings conducted pursuant to this part, but rules or principles designed to assure production of the most credible evidence available and to subject testimony to test by cross-examination shall be applied where determined reasonably necessary by the officer conducting the hearing. The hearing officer may exclude irrelevant, immaterial, or unduly repetitious evidence. All documents and other evidence offered or taken for the record shall be open to examination by the parties and opportunity shall be given to refute facts and arguments advanced on either side of the issues. A transcript shall be made of the oral evidence except to the extent the substance thereof is stipulated for the record. All decisions shall be based upon the hearing record and written findings shall be made.

(e) *Consolidated or joint hearings.* In cases in which the same or related facts are asserted to constitute noncompliance with this part with respect to two or more Federal statutes, authorities, or other means by which Federal financial assistance is extended and to which this part applies, or noncompliance with this part and the regulations of one or more other Federal departments or agencies issued under section 504, the Secretary may, by agreement with such other departments or agencies, where applicable, provide for the conduct of consolidated or joint hearings, and for the application to such hearings of rules or procedures not inconsistent with this part. Final decisions in such cases, insofar as this regulation is concerned, shall be made in accordance with § 40.401.

§ 40.401 Decisions and notices.

(a) *Procedure on decisions by hearing examiner.* If the hearing is held by a hearing examiner, the hearing examiner shall either make an initial decision, if so authorized, or certify the entire record including his recommended findings and proposed decision to the Secretary for a final decision, and a copy of such initial decision or certification shall be mailed to the applicant or recipient. Where the initial decision is made by the hearing examiner the applicant or recipient may, within 30 days after the mailing of such notice of initial decision, file with the Secretary the applicant's or recipient's exceptions to the initial decision, with the reasons therefore. In the absence of exceptions, the Secretary may, on his or her own motion, within 45 days after the initial decision, serve on the applicant or recipient a notice that he or she will review the decision. Upon the filing of such exceptions or of notice of review, the Secretary shall review the initial decision and issue his or her own decision thereon including the reasons therefore. In the absence of either exceptions or a notice of review, the initial decision shall, subject to paragraph (e) of this section, constitute the final decision of the Secretary.

(b) *Decisions on record or review by the Secretary.* Whenever a record is certified to the Secretary for decision or he or she reviews the decision of a hearing examiner pursuant to paragraph (a) of this section, or whenever the Secretary conducts the hearing, the applicant or recipient shall be given reasonable opportunity to file with the Secretary briefs or other written statements of its contentions, and a written copy of the final decision of the Secretary shall be sent to the applicant or recipient and to the complainant, if any.

(c) *Decisions on record where a hearing is waived.* Whenever a hearing is waived pursuant to § 40.400, a decision shall be made by the Secretary on the record and a written copy of such decision shall be sent to the applicant or recipient, and to the complainant, if any.

(d) *Rulings required.* Each decision of a hearing examiner or the Secretary shall set forth his or her ruling on each finding, conclusion, or exception presented, and shall identify the requirement or requirements imposed by or pursuant to this part with which it is found that the applicant or recipient has failed to comply.

(e) *Approval by the Secretary.* Any final decision by an official of the Department, other than the Secretary personally, which provides for the suspension or termination of, or the refusal to grant or continue Federal financial assistance, or the imposition of any other sanction available under this part or section 504, shall promptly be transmitted to the Secretary personally, who may approve such decision, may vacate it, or remit or mitigate any sanction imposed.

(f) *Content of orders.* The final decision may provide for suspension or termination of, or refusal to grant or continue Federal financial assistance, in whole or in part, to which this regulation applies, and may contain such terms, conditions, and other provisions as are consistent with and will effectuate the purposes of section 504 and this part, including provisions designed to assure that no Federal financial assistance to which this regulation applies will thereafter be extended to the applicant or recipient determined by such decision to be in default in its performance of an assurance given by it pursuant to this part, or to have otherwise failed to comply with this part, unless and until it corrects its noncompliance and satisfies the Secretary that it will fully comply with this part.

(g) *Post termination proceedings.* (1) An applicant or recipient adversely affected by an order issued under paragraph (f) of this section shall be restored to full eligibility to receive Federal financial assistance if it satisfies the terms and conditions of that order for such eligibility or if it brings itself into compliance with this part and provides reasonable assurance that it will fully comply with this part.

(2) Any applicant or recipient adversely affected by an order entered pursuant to paragraph (f) of this section may at any time request the Secretary to restore fully its eligibility to receive Federal financial assistance. Any such request shall be supported by information showing that the applicant or recipient has met the requirements of paragraph (g)(1) of this section. If the Secretary determines that those requirements have been satisfied, he or she shall restore such eligibility.

(3) If the Secretary denies any such request, the applicant or recipient may submit a request for a hearing in writing, specifying why it believes such official to have been in error. It shall thereupon be given an expeditious hearing, with a decision on the record in accordance with rules or procedures issued by the Secretary. The applicant or recipient will be restored to such eligibility if it proves at such a hearing that it satisfied the requirements of paragraph (g)(1) of this section. While proceedings under this paragraph are pending, the sanctions imposed by the order issued under paragraph (f) of this section shall remain in effect.

Kody Kinsley,

Assistant Secretary for Management.

[FR Doc. 2016–31236 Filed 12–30–16; 8:45 am]

BILLING CODE 4810–25–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA–HQ–OPPT–2015–0810; FRL–9955–71]

Significant New Use Rule on Certain Chemical Substances; Reopening of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; reopening of comment period.

SUMMARY: EPA issued a proposed rule in the **Federal Register** of October 27, 2016 proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for three chemical substances which were the subject of premanufacture notices (PMNs). This document reopens the comment period for 60 days. A commenter requested additional time to submit written comments for the proposed rule. EPA believes that the request is reasonable and is therefore reopening the comment period in order to give all interested persons the opportunity to comment fully

DATES: Comments on the proposed rule published in the **Federal Register** of October 27, 2016 (81 FR 74755), identified by docket identification (ID) number EPA–HQ–OPPT–2015–0810, must be received on or before March 6, 2017.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2015–0810, 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 Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 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.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–9232; email address: *moss.kenneth@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION: This document reopens the public comment period established in the **Federal Register** document of October 27, 2016. In that document, EPA proposed SNURs under the TSCA for three chemical substances which were the subject of PMNs. EPA is hereby reopening the comment period for 60 days.

To submit comments, or access the docket, please follow the detailed instructions provided under **ADDRESSES**. If you have questions, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

Dated: December 5, 2016.

Maria J. Doa,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2016–29755 Filed 12–30–16; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register

Vol. 82, No. 1

Tuesday, January 3, 2017

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

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–831]

Fresh Garlic From the People's Republic of China: Initiation of Antidumping Duty New Shipper Review; 2015–2016

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

SUMMARY: The Department of Commerce (the Department) is initiating a new shipper review (NSR) with respect to Zhengzhou Yudi Shengjin Agricultural Trade Co. Ltd. (''Zhengzhou Yudi'') in the context of the antidumping duty order on Fresh Garlic from the People's Republic of China (PRC). The period of review (POR) is November 1, 2015, through October 31, 2016.

DATES: Effective January 3, 2017.

FOR FURTHER INFORMATION CONTACT: Chien-Min Yang, 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; telephone: (202) 482–5484.

SUPPLEMENTARY INFORMATION:

Background

The Department published the antidumping duty order on fresh garlic from the PRC in the **Federal Register** on November 16, 1994.[1] On November 15, 2016, the Department received a timely request for a NSR from Zhengzhou Yudi.[2] Zhengzhou Yudi certified that it is the exporter and producer of the fresh garlic upon which the request for a NSR is based.[3] Pursuant to section 751(a)(2)(B)(i)(I) of the Act and 19 CFR 351.214(b)(2)(i), Zhengzhou Yudi certified that it did not export fresh garlic for sale to the United States during the period of investigation (POI).[4] Moreover, pursuant to section 751(a)(2)(B)(i)(II) of the Act and 19 CFR 351.214(b)(2)(iii)(A), Zhengzhou Yudi certified that, since the investigation was initiated, it never has been affiliated with any exporter or producer who exported the subject merchandise to the United States during the POI, including those not individually examined during the investigation.[5] Further, as required by 19 CFR 351.214(b)(2)(iii)(B), it certified that its export activities are not controlled by the central government of the PRC.[6] Zhengzhou Yudi also certified it had no shipments of subject merchandise subsequent to the POR.[7]

In addition to the certifications described above, pursuant to 19 CFR 351.214(b)(2)(iv), Zhengzhou Yudi submitted documentation establishing the following: (1) The date of its first sale to an unaffiliated customer in the United States; (2) the date on which the fresh garlic was first entered; and (3) the volume of that shipment.[8]

The Department queried the database of U.S. Customs and Border Protection (CBP) in an attempt to confirm that the shipment reported by Zhengzhou Yudi had entered the United States for consumption and that liquidation had been properly suspended for antidumping duties. The information which the Department examined was consistent with that provided by Zhengzhou Yudi in its request.[9]

Period of Review

Pursuant to 19 CFR 351.214(c), an exporter or producer may request a NSR within one year of the date on which its subject merchandise was first entered. Moreover, 19 CFR 351.214(d)(1) states that if the request for the review is made during the twelve-month period ending with the end of the anniversary month, the Secretary will initiate a NSR in the calendar month immediately following the anniversary month. Further, 19 CFR 315.214(g)(1)(i)(A) states that if the NSR was initiated in the month immediately following the anniversary month, the POR will be twelve-month period immediately preceding the anniversary month. Zhengzhou Yudi made the request for a NSR, that included all documents and information required by the statute and regulations, within one year of the date on which its fresh garlic first entered. Its request was filed in November, which is the anniversary month of the order. Therefore, the POR is November 1, 2015, through October 31, 2016.[10]

Initiation of New Shipper Review

Pursuant to section 751(a)(2)(B) of the Act and 19 CFR 351.214(b), and the information on the record, the Department finds that Zhengzhou Yudi's request meets the threshold requirements for initiation of a NSR for shipments of fresh garlic from the PRC produced and exported by Zhengzhou Yudi, and, therefore, is initiating a NSR of Zhengzhou Yudi. Absent a determination that the new shipper review is extraordinarily complicated, the Department intends to issue the preliminary results within 180 days after the date on which this review is initiated and the final results within 90 days after the date on which we issue the preliminary results.[11] If the information supplied by Zhengzhou Yudi is found to be incorrect or insufficient during the course of this proceeding, the Department may rescind the review for Zhengzhou Yudi or apply facts available pursuant to section 776 of the Act, depending on the facts on the record.

It is the Department's usual practice in cases involving non-market economies to require that a company seeking to establish eligibility for an antidumping duty rate separate from the country-wide rate (*i.e.,* a separate rate) provide evidence of *de jure* and *de facto* absence of government control over the company's export activities.[12] Accordingly, the Department will issue questionnaires to Zhengzhou Yudi, which will include a section requesting

[1] *See Antidumping Duty Order: Fresh Garlic from the People's Republic of China,* 59 FR 59209 (November 16, 1994).

[2] *See* Zhengzhou Yudi's request for a NSR dated November 15, 2016.

[3] *Id.* at 1 and at Exhibit 1.

[4] *Id.* at Exhibit 1.

[5] *Id.*

[6] *Id.*

[7] *Id.* at page 3–4.

[8] *Id.* at Exhibit 2.

[9] *See* Memorandum to the File from Chien-Min Yang, ''New Shipper Review of the Antidumping Duty Order on Fresh Garlic from the People's Republic of China: Customs Entries from November 1, 2015, to October 31, 2016,'' dated December 16, 2016.

[10] *See* 19 CFR 351.214(g)(1)(i)(A).

[11] *See* section 751(a)(2)(B)(iv) of the Act.

[12] *See* Import Administration Policy Bulletin, Number: 05.1. (*http://ia.ita.doc.gov/policy/bull05-1.pdf*).

information with regard to its export activities for the purpose of establishing its eligibility for a separate rate. The review will proceed if the responses provide sufficient indication that Zhengzhou Yudi is not subject to either *de jure* or *de facto* government control with respect to its exports of fresh garlic from the PRC.

On February 24, 2016, the President signed into law the ''Trade Facilitation and Trade Enforcement Act of 2015,'' H.R. 644, which made several amendments to section 751(a)(2)(B) of the Act. We will conduct this new shipper review in accordance with section 751(a)(2)(B) of the Act, as amended by the Trade Facilitation and Trade Enforcement Act of 2015.[13]

Interested parties requiring access to proprietary information in this proceeding should submit applications for disclosure under administrative protective order in accordance with 19 CFR 351.305 and 351.306.

This initiation and notice are in accordance with section 751(a)(2)(B) of the Act and 19 CFR 351.214 and 351.221(c)(1)(i).

Dated: December 27, 2016.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2016–31794 Filed 12–30–16; 8:45 am]

BILLING CODE 3510–DS–P

[13] The Trade Facilitation and Trade Enforcement Act of 2015 removed from section 751(a)(2)(B) of the Act the provision directing the Department to instruct Customs and Border Protection to allow an importer the option of posting a bond or security in lieu of a cash deposit during the pendency of a new shipper review.

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–009]

Calcium Hypochlorite From the People's Republic of China: Preliminary Intent To Rescind the New Shipper Review of Haixing Jingmei Chemical Products Sales Co., Ltd.

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

SUMMARY: In response to a November 20, 2015, request from Haixing Jingmei Chemical Products Sales Co., Ltd. (''Jingmei''), and the producer of its merchandise, Haixing Eno Chemical Co., Ltd. (''Eno''), the Department of Commerce (''Department'') is conducting a new shipper review of Jingmei, regarding the countervailing duty order on calcium hypochlorite from the People's Republic of China (''PRC''). The period of review (''POR'') is May 27, 2014, through December 31, 2015. The Department preliminarily determines to rescind this review because we requested but were not provided sufficient information to determine whether, and conclude that, Jingmei's sale of subject merchandise to the United States was *bona fide.* Interested parties are invited to comment on this preliminary intent to rescind.

DATES: Effective January 3, 2017.

FOR FURTHER INFORMATION CONTACT: Elizabeth Lobaugh, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–7425.

SUPPLEMENTARY INFORMATION:

Background

On March 4, 2016, the Department published notice of initiation of a new shipper review of calcium hypochlorite from the PRC for the period May 27, 2014, through December 31, 2015.[1] On July 12, 2016, the Department extended the deadline for the preliminary results to December 27, 2016.[2]

Scope of the Order

The merchandise covered by the Order is calcium hypochlorite, regardless of form (*e.g.,* powder, tablet (compressed), crystalline (granular), or in liquid solution), whether or not blended with other materials, containing at least 10% available chlorine measured by actual weight. Calcium hypochlorite is currently classifiable under the subheading 2828.10.0000 of the Harmonized Tariff Schedule of the United States.[3]

Methodology

The Department is conducting this review in accordance with section 751(a)(2)(B) of the Tariff Act of 1930, as amended (''the Act'') and 19 CFR 351.214. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (''ACCESS''). ACCESS is available to registered users at *http://access.trade.gov* and in the Department's 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.

Preliminary Intent To Rescind Jingmei New Shipper Review

Section 751(a)(2)(B)(iv) of the Act requires that a countervailing duty rate determined in a new shipper review be determined based solely on bona fide sales. For the reasons detailed in the Preliminary Decision Memorandum and the *Bona Fide* Sales Analysis Memorandum,[4] the Department preliminarily finds that, as a result of Jingmei's customers' failure to provide necessary information, we cannot determine whether, and conclude that, Jingmei's sale under review is *bona fide.* As a result, the Department preliminarily intends to rescind the new shipper review of Jingmei.

Public Comment

Interested parties may submit written comments by no later than 30 days after the date of publication of these preliminary results of review.[5] Rebuttals, limited to issues raised in the written comments, may be filed by no

[1] *See Calcium Hypochlorite from the People's Republic of China: Initiation of Countervailing Duty New Shipper Review; 2014–2015,* 81 FR 11516 (March 4, 2016) (''*Initiation*'').

[2] *See* Memorandum to the File through James C. Doyle, Director, Office V, to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations ''Extension of Deadline for Preliminary Results of Countervailing Duty New Shipper Review; 2014–2015'' (November 5, 2015).

[3] *See* Memorandum to Paul Piquado, Assistant Secretary for Enforcement and Compliance, from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations ''Decision Memorandum for the Preliminary Results of the Countervailing Duty New Shipper Review of Calcium Hypochlorite from the People's Republic of China: Haixing Jingmei Chemical Products Sales Co., Ltd.'' dated concurrently with and hereby adopted by this notice (''Preliminary Decision Memorandum'') for a complete description of the Scope of the Order.

[4] *See* Memorandum to James Doyle, Director, Office V, Antidumping and Countervailing Duty Operations, through Catherine Bertrand, Program Manager, Office V, Antidumping and Countervailing Duty Operations, from Elizabeth Lobaugh, International Trade Analyst, titled ''*Bona Fide* Nature of the Sale in the Countervailing Duty New Shipper Review of Calcium Hypochlorite from the People's Republic of China: Haixing Jingmei Chemical Products Sales Co., Ltd.'' dated concurrently with this notice.

[5] *See* 19 CFR 351.309(c).

later than five days after the written comments are filed.[6]

Any interested party may request a hearing within 30 days of publication of this notice.[7] Hearing requests should contain the following information: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Oral presentations will be limited to issues raised in the briefs. If a request for a hearing is made, parties will be notified of the time and date for the hearing to be held at the U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230.[8]

The Department intends to issue the final results of this new shipper review, which will include the results of its analysis of issues raised in any such comments, not later than 90 days after the date these preliminary results of new shipper review are issued, pursuant to section 751(a)(2)(B)(iii)) of the Act.

Assessment Rates

Upon completion of the final results, pursuant to 19 CFR 351.212(b), the Department will determine, and the U.S. Customs and Border Protection (''CBP'') shall assess, countervailing duties on all appropriate entries. If we proceed to a final rescission of the new shipper review, the assessment rate to which Jingmei's entries will be subject will not be affected by this review. If we do not proceed to a final rescission of the new shipper review, pursuant to 19 CFR 351.212(b)(2), we will calculate a countervailing duty rate. We intend to instruct CBP to assess countervailing duties on all appropriate entries covered by this review if any countervailing duty rate calculated in the final results of this review is above *de minimis*.[9]

Cash Deposit Requirements

Effective upon publication of the final rescission or the final results of this new shipper review, we will instruct CBP to discontinue the option of posting a bond or security in lieu of a cash deposit for entries of subject merchandise by Jingmei. If the Department proceeds to a final rescission of the new shipper review, the cash deposit rate will continue to be the all-others rate. If we issue final results of the new shipper review for Jingmei, we will instruct CBP to collect cash deposits, effective upon the publication of the final results, at the rates established therein.

The Department is issuing and publishing these results in accordance with sections 751(a)(2)(B) and 777(i)(l) of the Act, and 19 CFR 351.214 and 19 CFR 351.221(b)(4).

Dated: December 27, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Discussion of the Methodology
V. Recommendation

[FR Doc. 2016–31793 Filed 12–30–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Five-Year (''Sunset'') Reviews

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

SUMMARY: In accordance with section 751(c) of the Tariff Act of 1930, as amended (''the Act''), the Department of Commerce (''the Department'') is automatically initiating the five-year reviews (''Sunset Reviews'') of the antidumping and countervailing duty (''AD/CVD'') order(s) listed below. The International Trade Commission (''the Commission'') is publishing concurrently with this notice its notice of *Institution of Five-Year Review* which covers the same order(s).

DATES: Effective January 1, 2017.

FOR FURTHER INFORMATION CONTACT: The Department official identified in the *Initiation of Review* section below at AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230. For information from the Commission contact Mary Messer, Office of Investigations, U.S. International Trade Commission at (202) 205–3193.

SUPPLEMENTARY INFORMATION:

Background

The Department's procedures for the conduct of Sunset Reviews are set forth in its *Procedures for Conducting Five-Year (''Sunset'') Reviews of Antidumping and Countervailing Duty Orders,* 63 FR 13516 (March 20, 1998) and 70 FR 62061 (October 28, 2005). Guidance on methodological or analytical issues relevant to the Department's conduct of Sunset Reviews is set forth in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8101 (February 14, 2012).

Initiation of Review

In accordance with 19 CFR 351.218(c), we are initiating Sunset Reviews of the following antidumping and countervailing duty order(s):

DOC Case No.	ITC Case No.	Country	Product	Department Contact
A-570-835	731-TA-703	PRC	Furfuryl Alcohol (4th Review)	David Goldberger (202) 482-4136
A-583-803	731-TA-410	Taiwan	Light-Walled Rectangular Welded Carbon Steel Pipe and Tube (4th Review)	David Goldberger (202) 482-4136

[6] *See* 19 CFR 351.309(d).
[7] *See* 19 CFR 351.310(c).
[8] *See* 19 CFR 351.310(d).
[9] *See* 19 CFR 351.106(c)(2).

Filing Information

As a courtesy, we are making information related to sunset proceedings, including copies of the pertinent statute and Department's regulations, the Department's schedule for Sunset Reviews, a listing of past revocations and continuations, and current service lists, available to the public on the Department's Web site at the following address: ''*http://enforcement.trade.gov/sunset/.*'' All submissions in these Sunset Reviews must be filed in accordance with the Department's regulations regarding format, translation, and service of documents. These rules, including electronic filing requirements via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (''ACCESS''), can be found at 19 CFR 351.303.[1]

This notice serves as a reminder that any party submitting factual information in an AD/CVD proceeding must certify to the accuracy and completeness of that information.[2] Parties are hereby reminded that revised certification requirements are in effect for company/government officials as well as their representatives in these segments.[3] The formats for the revised certifications are provided at the end of the *Final Rule.* The Department intends to reject factual submissions if the submitting party does not comply with the revised certification requirements.

On April 10, 2013, the Department modified two regulations related to AD/CVD proceedings: The definition of factual information (19 CFR 351.102(b)(21)), and the time limits for the submission of factual information (19 CFR 351.301).[4] Parties are advised to review the final rule, available at *http://enforcement.trade.gov/frn/2013/1304frn/2013-08227.txt,* prior to submitting factual information in these segments. To the extent that other regulations govern the submission of factual information in a segment (such as 19 CFR 351.218), these time limits will continue to be applied. Parties are also advised to review the final rule concerning the extension of time limits for submissions in AD/CVD proceedings, available at *http://enforcement.trade.gov/frn/2013/1309frn/2013-22853.txt,* prior to submitting factual information in these segments.[5]

Letters of Appearance and Administrative Protective Orders

Pursuant to 19 CFR 351.103(d), the Department will maintain and make available a public service list for these proceedings. Parties wishing to participate in any of these five-year reviews must file letters of appearance as discussed at 19 CFR 351.103(d). To facilitate the timely preparation of the public service list, it is requested that those seeking recognition as interested parties to a proceeding submit an entry of appearance within 10 days of the publication of the Notice of Initiation.

Because deadlines in Sunset Reviews can be very short, we urge interested parties who want access to proprietary information under administrative protective order (''APO'') to file an APO application immediately following publication in the **Federal Register** of this notice of initiation. The Department's regulations on submission of proprietary information and eligibility to receive access to business proprietary information under APO can be found at 19 CFR 351.304–306.

Information Required from Interested Parties

Domestic interested parties, as defined in section 771(9)(C), (D), (E), (F), and (G) of the Act and 19 CFR 351.102(b), wishing to participate in a Sunset Review must respond not later than 15 days after the date of publication in the **Federal Register** of this notice of initiation by filing a notice of intent to participate. The required contents of the notice of intent to participate are set forth at 19 CFR 351.218(d)(1)(ii). In accordance with the Department's regulations, if we do not receive a notice of intent to participate from at least one domestic interested party by the 15-day deadline, the Department will automatically revoke the order without further review.[6]

If we receive an order-specific notice of intent to participate from a domestic interested party, the Department's regulations provide that *all parties* wishing to participate in a Sunset Review must file complete substantive responses not later than 30 days after the date of publication in the **Federal Register** of this notice of initiation. The required contents of a substantive response, on an order-specific basis, are set forth at 19 CFR 351.218(d)(3). Note that certain information requirements differ for respondent and domestic parties. Also, note that the Department's information requirements are distinct from the Commission's information requirements. Consult the Department's regulations for information regarding the Department's conduct of Sunset Reviews. Consult the Department's regulations at 19 CFR part 351 for definitions of terms and for other general information concerning antidumping and countervailing duty proceedings at the Department.

This notice of initiation is being published in accordance with section 751(c) of the Act and 19 CFR 351.218(c).

Dated: December 27, 2016.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2016–31844 Filed 12–30–16; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See also Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

[2] *See* section 782(b) of the Act.

[3] *See Certification of Factual Information To Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (''*Final Rule*'') (amending 19 CFR 351.303(g)).

[4] *See Definition of Factual Information and Time Limits for Submission of Factual Information: Final Rule,* 78 FR 21246 (April 10, 2013).

[5] *See Extension of Time Limits,* 78 FR 57790 (September 20, 2013).

[6] *See* 19 CFR 351.218(d)(1)(iii).

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Request for Nominations for Members To Serve on National Institute of Standards and Technology Federal Advisory Committees

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice.

SUMMARY: The National Institute of Standards and Technology (NIST) invites and requests nomination of individuals for appointment to nine existing Federal Advisory Committees: Board of Overseers of the Malcolm Baldrige National Quality Award, Judges Panel of the Malcolm Baldrige National Quality Award, Information Security and Privacy Advisory Board, Manufacturing Extension Partnership Advisory Board, National Construction Safety Team Advisory Committee, Advisory Committee on Earthquake Hazards Reduction, National Advisory Committee on Windstorm Impact Reduction, NIST Smart Grid Advisory Committee, and Visiting Committee on Advanced Technology. NIST will consider nominations received in response to this notice for appointment to the Committees, in addition to nominations already received. Registered Federal lobbyists may not serve on NIST Federal Advisory Committees.

DATES: Nominations for all committees will be accepted on an ongoing basis and will be considered as and when vacancies arise.

ADDRESSES: Please submit nominations to Robert Fangmeyer, Director, Baldrige Performance Excellence Program, NIST, 100 Bureau Drive, Mail Stop 1020, Gaithersburg, MD 20899–1020. Nominations may also be submitted via fax to 301–975–4967. Additional information regarding the Committee, including its charter, current membership list, and executive summary, may be found at *http://www.nist.gov/baldrige/community/overseers.cfm.*

FOR FURTHER INFORMATION CONTACT: Robert Fangmeyer, Director, Baldrige Performance Excellence Program and Designated Federal Officer, NIST, 100 Bureau Drive, Mail Stop 1020, Gaithersburg, MD 20899–1020; telephone 301–975–4781; fax 301–975–4967; or via email at *robert.fangmeyer@nist.gov.*

SUPPLEMENTARY INFORMATION:

Board of Overseers of the Malcolm Baldrige National Quality Award

Committee Information

The Board of Overseers of the Malcolm Baldrige National Quality Award (Board) was established in accordance with 15 U.S.C. 3711a(d)(2)(B), pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App.

Objectives and Duties

1. The Board shall review the work of the private sector contractor(s), which assists the Director of NIST in administering the Malcolm Baldrige National Quality Award (Award). The Board will make such suggestions for the improvement of the Award process as it deems necessary.

2. The Board shall make an annual report on the results of Award activities to the Director of NIST, along with its recommendations for the improvement of the Award process.

3. The Board will function solely as an advisory committee under the Federal Advisory Committee Act, as amended, 5 U.S.C. App.

4. The Board will report to the Director of NIST.

Membership

1. The Board will consist of approximately 12 members selected on a clear, standardized basis, in accordance with applicable Department of Commerce guidance, and for their preeminence in the field of organizational performance excellence. There will be a balanced representation from U.S. service, manufacturing, nonprofit, education, and health care industries. The Board will include members familiar with the quality improvement operations and competitiveness issues of manufacturing companies, service companies, small businesses, health care providers, and educational institutions. Members will also be chosen who have broad experience in for-profit and nonprofit areas.

2. Board members will be appointed by the Secretary of Commerce for three-year terms and will serve at the discretion of the Secretary. All terms will commence on March 1 and end on February 28 of the appropriate years.

Miscellaneous

1. Members of the Board shall serve without compensation, but may, upon request, be reimbursed travel expenses, including per diem, as authorized by 5 U.S.C. 5701 *et seq.*

2. The Board will meet annually, except that additional meetings may be called as deemed necessary by the NIST Director or by the Chairperson. Meetings are usually one day in duration. Historically, the Board has met twice per year.

3. Board meetings are open to the public. Board members do not have access to classified or proprietary information in connection with their Board duties.

Nomination Information

1. Nominations are sought from the private and public sector as described above.

2. Nominees should have established records of distinguished service and shall be familiar with the quality improvement operations and competitiveness issues of manufacturing companies, service companies, small businesses, educational institutions, health care providers, and nonprofit organizations. The category (field of eminence) for which the candidate is qualified should be specified in the nomination letter. Nominations for a particular category should come from organizations or individuals within that category. A summary of the candidate's qualifications should be included with the nomination, including (where applicable) current or former service on Federal advisory boards and Federal employment. In addition, each nomination letter should state that the person agrees to the nomination, acknowledges the responsibilities of serving on the Board, and will actively participate in good faith in the tasks of the Board. Besides participation at meetings, it is desired that members be able to devote the equivalent of seven days between meetings to either developing or researching topics of potential interest, and so forth, in furtherance of their Board duties.

3. The Department of Commerce is committed to equal opportunity in the workplace and seeks a broad-based and diverse Board membership.

Judges Panel of the Malcolm Baldrige National Quality Award

ADDRESSES: Please submit nominations to Robert Fangmeyer, Director, Baldrige Performance Excellence Program, NIST, 100 Bureau Drive Mail Stop 1020, Gaithersburg, MD 20899–1020. Nominations may also be submitted via fax to 301–975–4967. Additional information regarding the Committee, including its charter, current membership list, and executive summary, may be found at *http://patapsco.nist.gov/BoardofExam/Examiners_Judge2.cfm.*

FOR FURTHER INFORMATION CONTACT: Robert Fangmeyer, Director, Baldrige Performance Excellence Program and Designated Federal Officer, NIST, 100 Bureau Drive, Mail Stop 1020, Gaithersburg, MD 20899–1020; telephone 301–975–4781; fax 301–975–4967; or via email at *robert.fangmeyer@nist.gov.*

Committee Information

The Judges Panel of the Malcolm Baldrige National Quality Award (Panel) was established in accordance with 15 U.S.C. 3711a(d)(1) and the Federal Advisory Committee Act, as amended, 5 U.S.C. App.

Objectives and Duties

1. The Panel will ensure the integrity of the Malcolm Baldrige National Quality Award (Award) selection process. Based on a review of results of examiners' scoring of written applications, Panel members will vote on which applicants merit site visits by examiners to verify the accuracy of quality improvements claimed by applicants. The Panel will also review recommendations from site visits, and recommend Award recipients.

2. The Panel will ensure that individual judges will not participate in the review of applicants as to which they have any potential conflict of interest.

3. The Panel will function solely as an advisory body, and will comply with the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. App.

4. The Panel will report to the Director of NIST.

Membership

1. The Panel will consist of approximately 9 and not more than 12, members selected on a clear, standardized basis, in accordance with applicable Department of Commerce guidance. There will be a balanced representation from U.S. service, manufacturing, nonprofit, education, and health care industries. The Panel will include members familiar with the quality improvement operations and competitiveness issues of manufacturing companies, service companies, small businesses, health care providers, and educational institutions. Members will also be chosen who have broad experience in for-profit and nonprofit areas.

2. Panel members will be appointed by the Secretary of Commerce for three-year terms and will serve at the discretion of the Secretary. All terms will commence on March 1 and end on February 28 of the appropriate year.

Miscellaneous

1. Members of the Panel shall serve without compensation, but may, upon request, be reimbursed travel expenses, including per diem, as authorized by 5 U.S.C. 5701 *et seq.*

2. The Panel will meet three times per year. Additional meetings may be called as deemed necessary by the NIST Director or by the Chairperson. Meetings are usually one to four days in duration. In addition, each Judge must attend an annual three-day Examiner training course.

3. When approved by the Department of Commerce Chief Financial Officer and Assistant Secretary for Administration, Panel meetings are closed or partially closed to the public.

Nomination Information

1. Nominations are sought from all U.S. service and manufacturing industries, education, health care, and nonprofits as described above.

2. Nominees should have established records of distinguished service and shall be familiar with the quality improvement operations and competitiveness issues of manufacturing companies, service companies, small businesses, health care providers, educational institutions, and nonprofit organizations. The category (field of eminence) for which the candidate is qualified should be specified in the nomination letter. Nominations for a particular category should come from organizations or individuals within that category. A summary of the candidate's qualifications should be included with the nomination, including (where applicable) current or former service on federal advisory boards and federal employment. In addition, each nomination letter should state that the person agrees to the nomination, acknowledges the responsibilities of serving on the Panel, and will actively participate in good faith in the tasks of the Panel. Besides participation at meetings, it is desired that members be either developing or researching topics of potential interest, reading Baldrige applications, and so forth, in furtherance of their Panel duties.

3. The Department of Commerce is committed to equal opportunity in the workplace and seeks a broad-based and diverse Panel membership.

Information Security and Privacy Advisory Board (ISPAB)

ADDRESSES: Please submit nominations to Matt Scholl, NIST, 100 Bureau Drive, Mail Stop 8930, Gaithersburg, MD 20899–8930. Nominations may also be submitted via fax to 301–975–8670, Attn: ISPAB Nominations. Additional information regarding the ISPAB, including its charter and current membership list, may be found on its electronic home page at *http://csrc.nist.gov/groups/SMA/ispab/index.html.*

FOR FURTHER INFORMATION CONTACT: Matt Scholl, ISPAB Designated Federal Officer (DFO), NIST, 100 Bureau Drive, Mail Stop 8930, Gaithersburg, MD 20899–8930; telephone 301–975–2941; fax: 301–975–8670; or via email at *matthew.scholl@nist.gov.*

Committee Information

The ISPAB (Committee or Board) was originally chartered as the Computer System Security and Privacy Advisory Board by the Department of Commerce pursuant to the Computer Security Act of 1987 (Pub. L. 100–235). The E-Government Act of 2002 (Pub. L. 107–347, Title III), amended Section 21 of the National Institute of Standards and Technology Act (15 U.S.C. 278g–4), including changing the Committee's name, and the charter was amended accordingly.

Objectives and Duties

1. The Board will identify emerging managerial, technical, administrative, and physical safeguard issues relative to information security and privacy.

2. The Board will advise NIST, the Secretary of Homeland Security, and the Director of the Office of Management and Budget (OMB) on information security and privacy issues pertaining to Federal Government information systems, including thorough review of proposed standards and guidelines developed by NIST.

3. The Board shall report to the Director of NIST.

4. The Board reports annually to the Secretary of Commerce, the Secretary of Homeland Security, the Director of OMB, the Director of the National Security Agency, and the appropriate committees of the Congress.

5. The Board will function solely as an advisory body, in accordance with the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. App.

Membership

1. The Director of NIST will appoint the Chairperson and the members of the ISPAB, and members serve at the discretion of the NIST Director. Members will be selected on a clear, standardized basis, in accordance with applicable Department of Commerce guidance.

2. The ISPAB will consist of a total of 12 members and a Chairperson.

- The Board will include four members from outside the Federal Government who are eminent in the information technology industry, at least one of whom is representative of small or medium sized companies in such industries.
- The Board will include four members from outside the Federal Government who are eminent in the fields of information technology, or related disciplines, but who are not employed by or representative of a producer of information technology.
- The Board will include four members from the Federal Government who have information system management experience, including experience in information security and privacy, at least one of whom shall be from the National Security Agency.

Miscellaneous

1. Members of the Board, other than full-time employees of the Federal government, will not be compensated for their services, but will, upon request, be allowed travel expenses pursuant to 5 U.S.C. 5701 *et seq.,* while otherwise performing duties at the request of the Board Chairperson, while away from their homes or a regular place of business.

2. Meetings of the ISPAB are usually two to three days in duration and are usually held quarterly. ISPAB meetings are open to the public, including the press. Members do not have access to classified or proprietary information in connection with their ISPAB duties.

Nomination Information

1. Nominations are being accepted in all three categories described above.

2. Nominees should have specific experience related to information security or privacy issues, particularly as they pertain to Federal information technology. Letters of nomination should include the category of membership for which the candidate is applying and a summary of the candidate's qualifications for that specific category. Also include (where applicable) current or former service on Federal advisory boards and any Federal employment. Each nomination letter should state that the person agrees to the nomination, acknowledges the responsibilities of serving on the ISPAB, and that they will actively participate in good faith in the tasks of the ISPAB.

3. Besides participation at meetings, it is desired that members be able to devote a minimum of two days between meetings to developing draft issue papers, researching topics of potential interest, and so forth in furtherance of their ISPAB duties.

4. Selection of ISPAB members will not be limited to individuals who are nominated. Nominations that are received and meet the requirements will be kept on file to be reviewed as ISPAB vacancies occur.

5. The Department of Commerce is committed to equal opportunity in the workplace and seeks a broad-based and diverse ISPAB membership.

Manufacturing Extension Partnership (MEP) Advisory Board

ADDRESSES: Please submit nominations to Ms. Cheryl Gendron, NIST, 100 Bureau Drive, Mail Stop 4800, Gaithersburg, MD 20899–4800. Nominations may also be submitted via fax to 301–963–6556, or via email at *Cheryl.Gendron@nist.gov.* Additional information regarding MEP, including its charter may be found on its electronic home page at *http://www.nist.gov/mep/advisory-board.cfm.*

FOR FURTHER INFORMATION CONTACT: Ms. Cheryl Gendron, NIST, 100 Bureau Drive, Mail Stop 4800, Gaithersburg, MD 20899–4800; telephone 301–975–4919, fax 301–963–6556; or via email at *Cheryl.Gendron@nist.gov.*

Committee Information

The MEP Advisory Board (Board) is authorized under Section 3003(d) of the America COMPETES Act (P.L. 110–69); codified at 15 U.S.C. 278k(e), as amended, in accordance with the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. App.

Objectives and Duties

1. The Board will provide advice on MEP programs, plans, and policies.

2. The Board will assess the soundness of MEP plans and strategies.

3. The Board will assess current performance against MEP program plans.

4. The Board will function solely in an advisory capacity, and in accordance with the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. App.

5. The Board shall transmit through the Director of NIST an annual report to the Secretary of the Department of Commerce for transmittal to Congress within 30 days after the submission to Congress of the President's annual budget request each year. The report shall address the status of the MEP program and comment on the relevant sections of the programmatic planning document and updates thereto transmitted to Congress by the Director under 15 U.S.C. 278i(c) and (d).

Membership

1. The Board shall consist of 10 members, broadly representative of stakeholders, appointed by the Director of NIST. At least 2 members shall be employed by or on an advisory board for the MEP Centers, and at least 5 other members shall be from U.S. small businesses in the manufacturing sector. No member shall be an employee of the Federal Government.

2. The Director of NIST shall appoint the members of the Board. Members shall be selected on a clear, standardized basis, in accordance with applicable Department of Commerce guidance. Board members serve at the discretion of the Director of NIST.

3. The term of office of each member of the Board shall be three years, except that vacancy appointments shall be for the remainder of the unexpired term of the vacancy. Any person who has completed two consecutive full terms of service on the Board shall thereafter be ineligible for appointment during the one-year period following the expiration of the second term.

Miscellaneous

1. Members of the Board will not be compensated for their services but will, upon request, be allowed travel and per diem expenses as authorized by 5 U.S.C. 5701 *et seq.,* while attending meetings of the Board or subcommittees thereof, or while otherwise performing duties at the request of the Chair, while away from their homes or regular places of business.

2. The Board will meet at least three times a year. Additional meetings may be called by the Director of NIST or the Designated Federal Officer (DFO) or his or her designee.

3. Committee meetings are open to the public.

Nomination Information

1. Nominations are being accepted in all categories described above.

2. Nominees should have specific experience related to manufacturing and industrial extension services. Letters of nomination should include the category of membership for which the candidate is applying and a summary of the candidate's qualifications for that specific category. Each nomination letter should state that the person agrees to the nomination and acknowledges the responsibilities of serving on the MEP Advisory Board.

3. Selection of MEP Advisory Board members will not be limited to individuals who are nominated. Nominations that are received and meet the requirements will be kept on file to be reviewed as Board vacancies occur.

4. The Department of Commerce is committed to equal opportunity in the workplace and seeks a broad-based and diverse MEP Advisory Board membership.

National Construction Safety Team (NCST) Advisory Committee

ADDRESSES: Please submit nominations to Benjamin Davis, NIST, 100 Bureau Drive, Mail Stop 8615, Gaithersburg, MD 20899–8604. Additional information regarding the NCST, including its charter may be found on its electronic home page at *https://www.nist.gov/el/disaster-resilience/disaster-and-failure-studies/national-construction-safety-team-ncst/advisory.*

FOR FURTHER INFORMATION CONTACT: Judith Mitrani-Reiser, Director, Disaster and Failure Studies Program, NIST, 100 Bureau Drive, Mail Stop 8615, Gaithersburg, MD 20899–8604, telephone 301–975–0684; or via email at *judith.mitrani-reiser@nist.gov.*

Committee Information

The NCST Advisory Committee (Committee) was established in accordance with the National Construction Safety Team Act, Pub. L. 107–231 and the Federal Advisory Committee Act, as amended, 5 U.S.C. App.

Objectives and Duties

1. The Committee shall advise the Director of NIST on carrying out the National Construction Safety Team Act (Act), review the procedures developed under section 2(c)(1) of the Act, and

review the reports issued under section 8 of the Act.

2. The Committee functions solely as an advisory body, in accordance with the provisions of the Federal Advisory Committee Act.

3. The Committee shall report to the Director of NIST.

4. On January 1 of each year, the Committee shall transmit to the Committee on Science, Space, and Technology of the House of Representatives and to the Committee on Commerce, Science, and Transportation of the Senate a report that includes: (1) An evaluation of National Construction Safety Team (Team) activities, along with recommendations to improve the operation and effectiveness of Teams, and (2) an assessment of the implementation of the recommendations of Teams and of the Committee.

Membership

1. The Committee shall consist of no less than 4 nor more than 12 members. Members shall reflect the wide diversity of technical disciplines and competencies involved in the National Construction Safety Teams investigations. Members shall be selected on the basis of established records of distinguished service in their professional community and their knowledge of issues affecting the National Construction Safety Teams.

2. The Director of the NIST shall appoint the members of the Committee, and they will be selected on a clear, standardized basis, in accordance with applicable Department of Commerce guidance.

Miscellaneous

1. Members of the Committee shall not be compensated for their services but may, upon request, be allowed travel and per diem expenses in accordance with 5 U.S.C. 5703.

2. Members of the Committee shall serve as Special Government Employees (SGEs), will be subject to the ethics standards applicable to SGEs, and are required to file an annual Executive Branch Confidential Financial Disclosure Report.

3. The Committee shall meet at least once per year. Additional meetings may be called whenever requested by the NIST Director or the Designated Federal Officer (DFO); such meetings may be in the form of telephone conference calls and/or videoconferences.

Nomination Information

1. Nominations are sought from industry and other communities having an interest in the National Construction Safety Teams investigations.

2. Nominees should have established records of distinguished service. The field of expertise that the candidate represents should be specified in the nomination letter. Nominations for a particular field should come from organizations or individuals within that field. A summary of the candidate's qualifications should be included with the nomination, including (where applicable) current or former service on federal advisory boards and federal employment. In addition, each nomination letter should state that the nominee agrees to the nomination, acknowledges the responsibilities of serving on the Committee, and will actively participate in good faith in the tasks of the Committee.

3. The Department of Commerce is committed to equal opportunity in the workplace and seeks a broad-based and diverse Committee membership.

Advisory Committee on Earthquake Hazards Reduction (ACEHR)

ADDRESSES: Please submit nominations to Tina Faecke, Management and Program Analyst, National Earthquake Hazards Reduction Program, NIST, 100 Bureau Drive, Mail Stop 8604, Gaithersburg, MD 20899–8604. Nominations may also be submitted via fax to 301–975–4032 or email at *tina.faecke@nist.gov.* Additional information regarding the ACEHR, including its charter and executive summary may be found on its electronic home page at *http://www.nehrp.gov.*

FOR FURTHER INFORMATION CONTACT: Steven McCabe, Acting Director, National Earthquake Hazards Reduction Program, NIST, 100 Bureau Drive, Mail Stop 8604, Gaithersburg, MD 20899–8604, telephone 301–975–8549, fax 301–975–4032; or via email at *steven.mccabe@nist.gov.*

Committee Information

The Advisory Committee on Earthquake Hazards Reduction (Committee) was established in accordance with the National Earthquake Hazards Reduction Program Reauthorization Act of 2004, Pub. L. 108–360 and the Federal Advisory Committee Act, as amended, 5 U.S.C. App.

Objectives and Duties

1. The Committee will act in the public interest to assess trends and developments in the science and engineering of earthquake hazards reduction, effectiveness of the National Earthquake Hazards Reduction Program (Program) in carrying out the activities under section (a)(2) of the Earthquake Hazards Reduction Act of 1977, as amended (42 U.S.C. 7704(a)(2)), the need to revise the Program, the management, coordination, implementation, and activities of the Program.

2. The Committee will function solely as an advisory body, in accordance with the provisions of the Federal Advisory Committee Act.

3. The Committee shall report to the Director of NIST.

4. The Committee shall report to the Director of NIST at least once every two years on its findings of the assessments and its recommendations for ways to improve the Program. In developing recommendations, the Committee shall consider the recommendations of the United States Geological Survey (USGS) Scientific Earthquake Studies Advisory Committee (SESAC).

Membership

1. The Committee shall consist of not fewer than 11, nor more than 17 members. Members shall reflect the wide diversity of technical disciplines, competencies, and communities involved in earthquake hazards reduction. Members shall be selected on the basis of established records of distinguished service in their professional community and their knowledge of issues affecting the National Earthquake Hazards Reduction Program.

2. The Director of NIST shall appoint the members of the Committee. Members shall be selected on a clear, standardized basis, in accordance with applicable Department of Commerce guidance.

3. The term of office of each member of the Committee shall be three years, except that vacancy appointments shall be for the remainder of the unexpired term of the vacancy and that members shall have staggered terms such that the Committee will have approximately one-third new or reappointed members each year.

Miscellaneous

1. Members of the Committee shall not be compensated for their services, but may, upon request, be allowed travel and per diem expenses in accordance with 5 U.S.C. 5701 *et seq.,* while attending meetings of the Committee or subcommittees thereof, or while otherwise performing duties at the request of the Chair, while away from their homes or regular places of business.

2. Members of the Committee shall serve as Special Government Employees

(SGEs) and will be subject to the ethics standards applicable to SGEs, and are required to file an annual Executive Branch Confidential Financial Disclosure Report.

3. The Committee members shall meet face-to-face at least once per year. Additional meetings may be called whenever requested by the NIST Director or the Chair; such meetings may be in the form of telephone conference calls and/or videoconferences.

4. Committee meetings are open to the public.

Nomination Information

1. Members will be drawn from industry and other communities having an interest in the National Earthquake Hazards Reduction Program, such as, but not limited to, research and academic institutions, industry standards development organizations, state and local government, and financial communities, who are qualified to provide advice on earthquake hazards reduction and represent all related scientific, architectural, and engineering disciplines.

2. Any person who has completed two consecutive full terms of service on the Committee shall be ineligible for appointment for a third term during the two-year period following the expiration of the second term.

3. Nominees should have established records of distinguished service. The field of expertise that the candidate represents should be specified in the nomination letter. Nominations for a particular field should come from organizations or individuals within that field. A summary of the candidate's qualifications should be included with the nomination, including (where applicable) current or former service on federal advisory boards and federal employment. In addition, each nomination letter should state that the nominee agrees to the nomination, acknowledges the responsibilities of serving on the Committee, and will actively participate in good faith in the tasks of the Committee.

4. The Department of Commerce is committed to equal opportunity in the workplace and seeks a broad based and diverse Committee membership.

National Advisory Committee on Windstorm Impact Reduction (NACWIR)

ADDRESSES: Please submit nominations to Stephen Potts, NIST, 100 Bureau Drive, Mail Stop 8611, Gaithersburg, MD 20899–8611. Additional information regarding the NACWIR, including its charter may be found on its electronic home page at *https://www.nist.gov/el/mssd/nwirp/national-advisory-committee-windstorm-impact-reduction-project.*

FOR FURTHER INFORMATION CONTACT: Marc Levitan, Director, National Windstorm Impact Reduction Program, NIST, 100 Bureau Drive, Mail Stop 8611, Gaithersburg, MD 20899–8611, telephone 301–975–5340; or via email at *marc.levitan@nist.gov.*

Committee Information

The NACWIR (Committee) was established in accordance with the requirements of the National Windstorm Impact Act of 2004, Public Law 108–360, Title II, codified at 42 U.S.C. 15701–15707, as amended by the National Windstorm Reduction Act Reauthorization of 2015, Public Law 114–52 and the Federal Advisory Committee Act, as amended, 5 U.S.C. App.

Objectives and Duties

1. The Committee shall offer assessments and recommendations on the trends and developments in the natural, engineering, and social sciences and practices of windstorm impact mitigation; the priorities of the Strategic Plan for the National Windstorm Impact Reduction Program (Program); the coordination of the Program; the effectiveness of the Program in meeting its purposes under section 204 (42 U.S.C. 15707) of the National Windstorm Impact Reduction Act of 2004, as amended; and any revisions to the Program which may be necessary.

2. The Committee functions solely as an advisory body, in accordance with the provisions of the Federal Advisory Committee Act.

3. The Committee shall report to the Director of NIST.

4. The Committee will develop and submit reports on the assessments for ways to improve the Program at least once every two years.

Membership

1. The Committee shall consist of not fewer than 7 nor more than 15 members. The term of office of each member of the Committee shall terminate on September 30, 2017.

2. Members shall reflect the wide diversity of technical disciplines, competencies, and communities involved in windstorm impact reduction.

3. Members shall be selected on the basis of established records of distinguished service in their professional community and their knowledge of issues affecting the Program.

4. The Director of the NIST shall appoint the members of the Committee, and they will be selected on a clear, standardized basis, in accordance with applicable Department of Commerce guidance.

Miscellaneous

1. Members of the Committee shall not be compensated for their services but may, upon request, be allowed travel and per diem expenses in accordance with 5 U.S.C. 5701 *et seq.,* while attending meetings of the Committee or subcommittees thereof, or while otherwise performing duties at the request of the Chair, while away from their homes or regular places of business.

2. Members of the Committee shall serve as Special Government Employees (SGEs), will be subject to the ethics standards applicable to SGEs, and are required to file an annual Executive Branch Confidential Financial Disclosure Report. No member shall be an employee of the Federal Government.

3. The Committee shall meet in at least one face-to-face meeting per year. Additional meetings may be called whenever requested by the NIST Director or the Chair; such meetings may be in the form of telephone conference calls and/or videoconferences.

Nomination Information

1. Nominations are sought from research and academic institutions, industry and other communities who are qualified to provide advise on windstorm impact hazards reduction and represent related scientific, architectural, and engineering disciplines.

2. Nominees should have established records of distinguished service. The field of expertise that the candidate represents should be specified in the nomination letter. Nominations for a particular field should come from organizations or individuals within that field. A summary of the candidate's qualifications should be included with the nomination, including (where applicable) current or former service on Federal advisory boards and Federal employment. In addition, each nomination letter should state that the nominee agrees to the nomination, acknowledges the responsibilities of serving on the Committee, and will actively participate in good faith in the tasks of the Committee.

3. The Department of Commerce is committed to equal opportunity in the

workplace and seeks a broad-based and diverse Committee membership.

NIST Smart Grid Advisory Committee

ADDRESSES: Please submit nominations to Mr. Cuong Nguyen, Smart Grid and Cyber-Physical Systems Program Office, NIST, 100 Bureau Drive, Mail Stop 8200, Gaithersburg, MD 20899–8200. Nominations may also be submitted via email to *cuong.nguyen@nist.gov.* Information about the NIST Smart Grid Advisory Committee may be found at *http://www.nist.gov/smartgrid/committee.cfm.*

FOR FURTHER INFORMATION CONTACT: Mr. Cuong Nguyen, Smart Grid and Cyber-Physical Systems Program Office, NIST, 100 Bureau Drive, Mail Stop 8200, Gaithersburg, MD 20899–8200; telephone 301–975–2254, fax 301–948–5668; or via email at *cuong.nguyen@nist.gov.*

Committee Information

The NIST Smart Grid Advisory Committee (Committee) was established in accordance with the Federal Advisory Committee Act, as amended, 5 U.S.C. App and with the concurrence of the General Services Administration.

Objectives and Duties

1. The Committee shall advise the Director of NIST in carrying out duties authorized by section 1305 of the Energy Independence and Security Act of 2007 (Pub. L. 110–140).

2. The Committee duties are solely advisory in nature in accordance with the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. App.

3. The Committee shall report to the Director of NIST.

4. The Committee shall provide input to NIST on the Smart Grid Standards, Priorities, and Gaps, on the overall direction, status and health of the Smart Grid implementation by the Smart Grid industry including identification of issues and needs, on Smart Grid Interoperability Panel activities and on the direction of research and standards activities.

5. Upon request of the Director of NIST, the Committee will prepare reports on issues affecting Smart Grid activities.

Membership

1. The Committee shall consist of no less than 9 and no more than 15 members. Members shall be selected on the basis of established records of distinguished service in their professional community and their knowledge of issues affecting Smart Grid deployment and operations. Members shall reflect the wide diversity of technical disciplines and competencies involved in the Smart Grid deployment and operations and will come from a cross section of organizations.

2. The Director of NIST shall appoint the members of the Committee, and they will be selected on a clear, standardized basis, in accordance with applicable Department of Commerce guidance.

Miscellaneous

1. Members of the Committee shall not be compensated for their service, but will, upon request, be allowed travel and per diem expenses, in accordance with 5 U.S.C. 5701 *et seq.,* while attending meetings of the Committee or subcommittees thereof, or while otherwise performing duties at the request of the Chair, while away from their homes or regular places of business.

2. The Committee shall meet approximately two times per year at the call of the Designated Federal Officer (DFO). Additional meetings may be called by the DFO whenever one-third or more of the members so request it in writing or whenever the Director of NIST requests a meeting.

Nomination Information

1. Nominations are sought from all fields involved in issues affecting the Smart Grid.

2. Nominees should have established records of distinguished service. The field of expertise that the candidate represents should be specified in the nomination letter. Nominations for a particular field should come from organizations or individuals within that field. A summary of the candidate's qualifications should be included with the nomination, including (where applicable) current or former service on Federal advisory boards and Federal employment. In addition, each nomination letter should state that the person agrees to the nomination, acknowledges the responsibilities of serving on the Committee, and will actively participate in good faith in the tasks of the Committee. The Department of Commerce is committed to equal opportunity in the workplace and seeks a broad-based and diverse Committee membership.

Visiting Committee on Advanced Technology (VCAT)

ADDRESSES: Please submit nominations to Stephanie Shaw, Designated Federal Officer, VCAT, NIST, 100 Bureau Drive, Mail Stop 1060, Gaithersburg, MD 20899–1060. Nominations may also be submitted via fax to 301–216–0529 or via email at *stephanie.shaw@nist.gov.* Additional information regarding the VCAT, including its charter, current membership list, and past reports may be found on its electronic homepage at *http://www.nist.gov/director/vcat/.*

FOR FURTHER INFORMATION CONTACT: Stephanie Shaw, Designated Federal Officer, VCAT, NIST, 100 Bureau Drive, Mail Stop 1060, Gaithersburg, MD 20899–1060, telephone 301–975–2667, fax 301–216–0529; or via email at *stephanie.shaw@nist.gov.*

Committee Information

The VCAT (Committee) was established in accordance with 15 U.S.C. 278 and the Federal Advisory Committee Act, as amended, 5 U.S.C. App.

Objectives and Duties

1. The Committee shall review and make recommendations regarding general policy for NIST, its organization, its budget, and its programs, within the framework of applicable national policies as set forth by the President and the Congress.

2. The Committee will function solely as an advisory body, in accordance with the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. App.

3. The Committee shall report to the Director of NIST.

4. The Committee shall provide an annual report, through the Director of NIST, to the Secretary of Commerce for submission to the Congress not later than 30 days after the submittal to Congress of the President's annual budget request in each year. Such report shall deal essentially, though not necessarily exclusively, with policy issues or matters which affect NIST, or with which the Committee in its official role as the private sector policy adviser of NIST is concerned. Each such report shall identify areas of research and research techniques of NIST of potential importance to the long-term competitiveness of United States industry, in which NIST possesses special competence, which could be used to assist United States enterprises and United States industrial joint research and development ventures. Such report also shall comment on the programmatic planning document and updates thereto submitted to Congress by the Director under subsections (c) and (d) of section 278i of the NIST Act. The Committee shall submit to the Secretary and the Congress such additional reports on specific policy matters as it deems appropriate.

Membership

1. The Committee shall consist of 15 members appointed by the Director of NIST, at least ten of whom shall be from United States industry. Members shall be selected solely on the basis of established records of distinguished service; shall provide representation of a cross-section of traditional and emerging United States industries; and shall be eminent in fields such as business, research, new product development, engineering, labor, education, management consulting, environment, and international relations. No employee of the Federal Government shall serve as a member of the Committee.

2. The Director of NIST shall appoint the members of the Committee. Members shall be selected on a clear, standardized basis, in accordance with applicable Department of Commerce guidance.

3. The term of office of each member of the Committee shall be three years, except that vacancy appointments shall be for the remainder of the unexpired term of the vacancy.

Miscellaneous

1. Members of the Committee will not be compensated for their services, but will, upon request, be allowed travel expenses in accordance with 5 U.S.C. 5701 *et seq.,* while attending meetings of the Committee or of its subcommittees, or while otherwise performing duties at the request of the chairperson, while away from their homes or a regular place of business.

2. Members of the Committee shall serve as Special Government Employees (SGEs) and will be subject to the ethics standards applicable to SGEs. As SGEs, the members are required to file an annual Executive Branch Confidential Financial Disclosure Report.

3. Meetings of the VCAT usually take place at the NIST headquarters in Gaithersburg, Maryland. Meetings are usually two days in duration and are held at least twice each year.

4. Generally, Committee meetings are open to the public.

Nomination Information

1. Nominations are sought from all fields described above.

2. Nominees should have established records of distinguished service and shall be eminent in fields such as business, research, new product development, engineering, labor, education, management consulting, environment and international relations. The category (field of eminence) for which the candidate is qualified should be specified in the nomination letter. Nominations for a particular category should come from organizations or individuals within that category. A summary of the candidate's qualifications should be included with the nomination, including (where applicable) current or former service on Federal advisory boards and Federal employment. In addition, each nomination letter should state that the candidate agrees to the nomination, acknowledges the responsibilities of serving on the VCAT, and will actively participate in good faith in the tasks of the VCAT.

3. The Department of Commerce is committed to equal opportunity in the workplace and seeks a broad-based and diverse VCAT membership.

Kevin Kimball,

NIST Chief of Staff.

[FR Doc. 2016–31835 Filed 12–30–16; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Visiting Committee on Advanced Technology

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Visiting Committee on Advanced Technology (VCAT or Committee), National Institute of Standards and Technology (NIST), will meet in an open session on Wednesday, February 8, 2017 from 8:30 a.m. to 5:30 p.m. Eastern Time and Thursday, February 9, 2017 from 8:30 a.m. to 12:00 p.m. Eastern Time. The VCAT is composed of fifteen members appointed by the NIST Director who are eminent in such fields as business, research, new product development, engineering, labor, education, management consulting, environment, and international relations.

DATES: The VCAT will meet on Wednesday, February 8, 2017, from 8:30 a.m. to 5:30 p.m. Eastern Time and Thursday, February 9, 2017, from 8:30 a.m. to 12:00 p.m. Eastern Time.

ADDRESSES: The meeting will be held in the Portrait Room, Administration Building, at NIST, 100 Bureau Drive, Gaithersburg, Maryland, 20899. Please note admittance instructions under the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Stephanie Shaw, VCAT, NIST, 100 Bureau Drive, Mail Stop 1060, Gaithersburg, Maryland 20899–1060, telephone number 301–975–2667. Ms. Shaw's email address is *stephanie.shaw@nist.gov*.

SUPPLEMENTARY INFORMATION:

Authority: 15 U.S.C. 278 and the Federal Advisory Committee Act, as amended, 5 U.S.C. App.

The purpose of this meeting is for the VCAT to review and make recommendations regarding general policy for NIST, its organization, its budget, and its programs within the framework of applicable national policies as set forth by the President and the Congress. The agenda will include a discussion on NIST's values and how those values are critical to NIST's mission delivery. NIST's major scientific accomplishments, impacts on industry, and likely upcoming challenges will also be discussed. The Committee also will present its initial observations, findings, and recommendations for the 2016 VCAT Annual Report. The agenda may change to accommodate Committee business. The final agenda will be posted on the NIST Web site at *http://www.nist.gov/director/vcat/agenda.cfm*.

Individuals and representatives of organizations who would like to offer comments and suggestions related to the Committee's affairs are invited to request a place on the agenda. Approximately one-half hour will be reserved for public comments and speaking times will be assigned on a first-come, first-serve basis. The amount of time per speaker will be determined by the number of requests received, but is likely to be about 3 minutes each. The exact time for public comments will be included in the final agenda that will be posted on the NIST Web site at *http://www.nist.gov/director/vcat/agenda.cfm*. Questions from the public will not be considered during this period. Speakers who wish to expand upon their oral statements, those who had wished to speak but could not be accommodated on the agenda, and those who were unable to attend in person are invited to submit written statements to VCAT, NIST, 100 Bureau Drive, MS 1060, Gaithersburg, Maryland, 20899, via fax at 301–216–0529 or electronically by email to *stephanie.shaw@nist.gov*.

All visitors to the NIST site are required to pre-register to be admitted. Please submit your name, time of arrival, email address and phone number to Serena Martinez by 5:00 p.m. Eastern Time, Monday, January 30, 2017. Non-U.S. citizens must submit additional information; please contact Mrs. Martinez. Mrs. Martinez's email

address is *serena.martinez@nist.gov* and her phone number is 301–975–2661. For participants attending in person, please note that federal agencies, including NIST, can only accept a state-issued driver's license or identification card for access to federal facilities if such license or identification card is issued by a state that is compliant with the REAL ID Act of 2005 (Pub. L. 109–13), or by a state that has an extension for REAL ID compliance. NIST currently accepts other forms of federal-issued identification in lieu of a state-issued driver's license. For detailed information please contact Mrs. Martinez at 301–975–2661 or visit: *http://nist.gov/public_affairs/visitor/*.

Kevin Kimball,

NIST Chief of Staff.

[FR Doc. 2016–31836 Filed 12–30–16; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; West Coast Region U.S.—Canada Albacore Treaty Reporting System.

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 March 6, 2017.

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 Shannon Penna, National Marine Fisheries Service (NMFS), West Coast Region (WCR) Long Beach Office, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802, (562) 980–4238 or *shannon.penna@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for an extension of a current information collection *West Coast Region U.S.—Canada Albacore Treaty Reporting System.*

The National Marine Fisheries Service (NMFS), West Coast Region, manages the United States (U.S.)—Canada Albacore Tuna Treaty of 1981 (Treaty). Owners of vessels that fish from U.S. West Coast ports for albacore tuna *(Thunnus alalunga)* are required to notify the NMFS West Coast Region of their desire to be on the list of vessels provided to Canada each year indicating vessels eligible to fish for albacore tuna in waters under the jurisdiction of Canada. Additionally, vessel operators are required to report in advance their intention to fish in Canadian waters prior to crossing the maritime border, as well as to mark their fishing vessels to facilitate enforcement of the effort limits under the Treaty. Vessel operators are also required to maintain and submit a logbook of all catch and fishing effort. The regulations implementing the reporting and vessel marking requirements under the Treaty are at 50 CFR part 300.172–300.176.

The estimated burden below includes hours to complete the logbook requirement, although it is assumed that most if not all of the respondents already complete the required logbook under the mandatory West Coast Highly Migratory Species Fishery Management Plan (HMS FMP), OMB Control No. 0648–0223. Duplicate reporting under the Treaty and HMS FMP is not required. Most years, there will be much less fishing (and thus less reporting) under the Treaty than the level on which the estimate is based.

II. Method of Collection

Requests to be placed on the vessel eligibility list may be made in writing via mail, fax, email, telephone, or through online registration if available. Communications to comply with 'hail in' and 'hail out' requirements are made via ship to shore radio or via telephone and are compiled in an electronic database by Fisheries and Oceans Canada. Summaries of hail reports are provided to NMFS on a periodic basis. Vessel marking requirements entail painting the letter 'U' immediately after the U.S. Coast Guard documentation identification number or state registration number already on the vessel. Logbooks are maintained in pre-printed paper format and submitted via mail.

III. Data

OMB Control Number: 0648–0492.

Form Number(s): None.

Type of Review: Regular submission (extension of a current information collection).

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 120.

Estimated Time Per Response: 5 minutes for the request to be placed on the eligible list per year; 5 minutes for required vessel markings; 15 minutes for logbook entries; 10 minutes for each set of two hail reports for border crossings per year.

Estimated Total Annual Burden Hours: 240.

Estimated Total Annual Cost to Public: $1881.

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: December 27, 2016.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2016–31762 Filed 12–30–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF079

Marine Mammals; File No. 20666

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Randall Davis, Ph.D., Texas A&M University, Department of Marine Biology, 5007 Avenue U, Galveston, TX

77551, has applied in due form for a permit to conduct scientific research on harbor seals (*Phoca vitulina*).

DATES: Written, telefaxed, or email comments must be received on or before February 2, 2017.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the ''Features'' box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 20666 from the list of available applications.

These documents are also available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov.* Please include the File No. 20666 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Jennifer Skidmore or Sara Young, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216).

The applicant proposes to conduct physiology research on up to 5 harbor seals (over the life of the project) at the Texas A&M Institute of Preclinical Studies in College Station, TX. Animals will be transported from the Moody Gardens Aquarium in Galveston, TX, or other cooperating public display facilities to be determined. The object is to simultaneous measure heart rate and complete regional blood flow to tissues and organs during rest, and voluntary dives with and without exercise. Blood flow will be measured using stable isotopes and heart rate will be measured with an ECG recorder. One mortality over the life of the project is requested. The requested duration of the permit is 5 years.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: December 27, 2016.

Julia Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2016–31781 Filed 12–30–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF124

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The Scientific and Statistical Committee (SSC) of the Mid-Atlantic Fishery Management Council (Council) will hold a meeting.

DATES: The meeting will be held on Wednesday, January 25, beginning at 9 a.m. and conclude by 4 p.m.. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meeting will at the Royal Sonesta Harbor Court, 550 Light Street, Baltimore, MD 21202; telephone: (410) 234–0550.

Council address: Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331 or on their Web site at *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to receive a report of the results of a stock assessment recently completed for black sea bass and to make ABC recommendations to the Council for the species for the period 2017–19. In addition, the Council may request re-specification of the ABC recommendations for the previous years which were made based on *ad hoc* data poor methods, to evaluate fishery performance relative to catch limits developed using those methods. If time permits, the report of the CV Subcommittee of the SSC will be discussed.

Dated: December 28, 2016.

Jeffrey N. Lonergan,

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

[FR Doc. 2016–31806 Filed 12–30–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF127

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The North Pacific Fishery Management Council (Council) Bering Sea Fishery Ecosystem Plan Team (BS FEP) will meet January 19–20, 2017, in Seattle, WA.

DATES: The meeting will be held on Thursday, January 19, 2017 through Friday, January 20, 2017, from 9 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at the Alaska Fishery Science Center NMML Room 2011, 7600 Sand Point Way NE., Building 4, Seattle, WA 98115.

Council address: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501–2252; telephone: (907) 271–2809.

FOR FURTHER INFORMATION CONTACT: Diana Evans, Council staff; telephone: (907) 271–2809.

SUPPLEMENTARY INFORMATION:

Agenda

Thursday, January 19, 2017 through Friday, January 20, 2017

The BS FEP agenda will include: (a) FEP tasks, (b) discuss FEP objectives and work products, (c) outreach plan, and (d) potential action modules. The Agenda is subject to change, and the latest version will be posted at *http://www.npfmc.org/.*

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Shannon Gleason at (907) 271–2809 at least 7 working days prior to the meeting date.

Dated: December 28, 2016.

Jeffrey N. Lonergan,

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

[FR Doc. 2016–31817 Filed 12–30–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF126

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The North Pacific Fishery Management Council (Council) Crab Plan Team (CPT) will meet January 17 through January 19, 2017, in Seattle, WA.

DATES: The meeting will be held on Tuesday, January 17, 2017 through Wednesday, January 18, 2017, from 9 a.m. to 5 p.m., and on Thursday, January 19, 2017, from 9 a.m. to 4 p.m.

ADDRESSES: The meeting will be held at the Mountaineers Program Center, Cascade Room, 7700 Sand Point Way NE., Seattle, WA 98115.

Council address: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501–2252; telephone: (907) 271–2809.

FOR FURTHER INFORMATION CONTACT: Diana Stram, Council staff; telephone: (907) 271–2809.

SUPPLEMENTARY INFORMATION:

Agenda

Tuesday, January 17, 2017 through Thursday, January 19, 2017

The CPT will review and make recommendations on Norton Sound Red King Crab final assessment OFL/ABC stock prioritization, Aleutian Islands Golden King Crab, model scenarios for final assessment, Tanner Crab modeling, Bristol Bay Red King Crab—GMACs model, Bering Sea Fishery Research Foundation survey issues, dynamic B application and discussion.

The Agenda is subject to change, and the latest version will be posted at *http://www.npfmc.org/.*

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Shannon Gleason at (907) 271–2809 at least 7 working days prior to the meeting date.

Dated: December 28, 2016.

Jeffrey N. Lonergan,

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

[FR Doc. 2016–31816 Filed 12–30–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF123

New England Fishery Management Council; Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Ecosystem-Based Fishery Management (EBFM) Committee to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Monday, January 23, 2017, at 10 a.m.

ADDRESSES: The meeting will be held at the Sheraton Harborside Hotel, 250 Market Street, Portsmouth, NH 03801; telephone: (603) 431–2300.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Committee will receive a report on the application of Georges Bank Operating Models, *i.e.* examples and description of how they could be used to support a Management Strategy Evaluation, from the Ecosystem-Based Fishery Management Plan Development Team. The committee will also discuss progress toward development of an example Fishery Ecosystem Plan for Georges Bank. Other business will be discussed if time permits.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: December 28, 2016.

Jeffrey N. Lonergan,

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

[FR Doc. 2016–31805 Filed 12–30–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Personnel Development To Improve Services and Results for Children With Disabilities—Interdisciplinary Preparation in Special Education, Early Intervention, and Related Services for Personnel Serving Children With Disabilities Who Have High-Intensity Needs

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

Overview Information

Personnel Development To Improve Services and Results for Children With Disabilities—Interdisciplinary Preparation in Special Education, Early Intervention, and Related Services for Personnel Serving Children With Disabilities Who Have High-Intensity Needs.

Notice inviting applications for a new award for fiscal year (FY) 2017.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.325K.

DATES:

Applications Available: January 3, 2017.

Deadline for Transmittal of Applications: March 6, 2017.

Deadline for Intergovernmental Review: May 3, 2017.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purposes of this program are to (1) help address State-identified needs for personnel preparation in special education, early

intervention, related services, and regular education to work with children, including infants and toddlers, with disabilities; and (2) ensure that those personnel have the necessary skills and knowledge, derived from practices that have been determined through scientifically based research and experience, to be successful in serving those children.

Priority: In accordance with 34 CFR 75.105(b)(2)(v), this priority is from allowable activities specified in the statute (see sections 662 and 681 of the Individuals with Disabilities Education Act (IDEA)).

Absolute Priority: For FY 2017 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet this priority.

This priority is: Interdisciplinary Preparation in Special Education, Early Intervention, and Related Services for Personnel Serving Children With Disabilities Who Have High-Intensity Needs.

Background: The purpose of this priority is to increase the number and improve the quality of personnel who are fully credentialed to serve children, including infants and toddlers, with disabilities who have high-intensity needs,[1] especially in areas of chronic personnel shortage. The priority will fund high-quality interdisciplinary [2] projects that prepare special education, early intervention, and related services personnel at the master's, specialist, or clinical doctoral levels for professional practice in classrooms and school settings.

State demand for fully credentialed special education, early intervention, and related services personnel to serve infants, toddlers, children, and youth with disabilities exceeds the available supply, particularly in high-need schools [3] (Boe, deBettencourt, Rosenberg, Sindelar, & Leko, 2013). These shortages can negatively affect the quality of services provided to infants, toddlers, children, and youth with disabilities and their families (Boe et al., 2013).

The need for personnel with the knowledge and skills to serve children with disabilities who have high-intensity needs is even greater because specialized or advanced preparation is required to collaboratively design and support focused instruction and intensive individualized intervention(s) that address the needs of these children (Boe et al., 2013; Browder, Wood, Thompson, & Ribuffo, 2014; McLeskey & Brownell, 2015). Although children with disabilities who have high-intensity needs may require the combined expertise of numerous professionals (including special education, early intervention, and related services providers), it is often difficult for personnel from varied professional backgrounds to work together because they lack shared information, understanding, and experience.

Interdisciplinary approaches to personnel preparation provide scholars with experience working and learning in team environments similar to those in which they are likely to work once employed (Smith, 2010). For example, under the IDEA, personnel serving children with disabilities will work on interdisciplinary teams with parent(s), general and special education teachers, early intervention, and related service providers with the expertise convened to design, implement, and evaluate intervention plans based on the unique learning and developmental needs of each individual child. To enable personnel to provide efficient, high-quality integrated services, personnel preparation programs need to embed content, practices, and clinical experience into preservice training that will match the interdisciplinary team-based approaches in which graduates are likely to work. This priority aims to fund interdisciplinary projects that will provide such preparation.

Priority: The purpose of this priority is to increase the number and improve the quality of personnel who are fully credentialed to serve children, including infants and toddlers, with disabilities who have high-intensity needs—especially in areas of chronic personnel shortage. The priority will fund high-quality interdisciplinary projects that prepare special education, early intervention, and related services personnel at the master's, specialist, or clinical doctoral levels for professional practice in classrooms and school settings.

An applicant must propose an interdisciplinary project in special education, early intervention, or related services. An interdisciplinary project is a project that delivers core content through shared coursework, group assignments, and coordinated clinical experiences as part of master's, specialist, or clinical doctoral degree programs for scholars [4] across two or more disciplines and that leads to licensure, endorsement, or certification. Not all degree-program requirements (*e.g.,* courses, seminars, and clinical experiences) must be shared across disciplines, but the project must: (a) Identify the competencies needed to address the individualized needs of children with disabilities who have high-intensity needs using an interdisciplinary approach to service delivery; and (b) outline how the project will build capacity in those areas through shared coursework, group assignments, and coordinated clinical experiences for scholars supported by the proposed project. Projects may include individuals who are in degree programs (*e.g.,* general education) that are cooperating with, but not funded by, the applicant's proposed project in the interdisciplinary coursework, group assignments, coordinated field experiences, and other opportunities funded by the project (*e.g.,* speaker series, monthly seminars) if doing so does not diminish the benefit for project-funded scholars (*e.g.,* by reducing funds available for scholar support or limiting opportunities for scholars to participate in project activities).

Note: Personnel preparation programs that prepare individuals to be educational interpreters for the deaf at the bachelor's degree level can qualify under this priority without an interdisciplinary partner.

Note: The first year of the project period and up to $100,000 of Federal funds may be used for program planning. Planning activities during the first year could include outlining shared coursework, group assignments, or coordinated clinical

[1] For the purposes of this priority, ''high-intensity needs'' refers to a complex array of disabilities (*e.g.,* multiple disabilities, significant cognitive disabilities, significant physical disabilities, significant sensory disabilities, significant autism, significant emotional disabilities, significant learning disabilities, including dyslexia) or needs of children with these disabilities requiring intensive, individualized intervention(s) (*i.e.,* that are specifically designed to address persistent learning or behavior difficulties, implemented with greater frequency and for an extended duration than is commonly available in a typical classroom or early intervention setting, or which requires personnel to have knowledge and skills in identifying and implementing multiple interventions supported by evidence).

[2] For the purposes of this priority, ''interdisciplinary'' refers to preparing two or more disciplines together through shared coursework, group assignments, and coordinated field experiences.

[3] For the purposes of this priority, the term ''high-need school'' refers to a public elementary or secondary school that is a ''high-poverty'' or ''low-performing'' school as defined in footnotes 6 and 7, respectively.

[4] For the purposes of this priority, the term ''scholar'' means an individual who is pursuing a degree, license, endorsement, or certification related to special education, related services, or early intervention services and who receives scholarship assistance under section 662 of IDEA (see 34 CFR 304.3(g)). Individuals pursuing degrees in general education do not qualify as ''scholars'' eligible for scholarship assistance.

experiences designed to: (a) Build the knowledge, skills, and competencies that personnel from each discipline participating in the project will need to work collaboratively with other general and special education teachers, early intervention, and related services providers to design and deliver the focused instruction and intense individualized intervention(s) needed to address the individualized needs of children with disabilities who have high-intensity needs and (b) enhance the competency of beginning practitioners with master's, specialist, or clinical doctoral degrees in special education, early intervention, or related services to collaborate on interdisciplinary teams.

To be considered for funding under this absolute priority, all program applicants must meet the application requirements contained in the priority. All projects funded under this absolute priority also must meet the programmatic and administrative requirements specified in the priority.

The requirements of this priority are as follows:

(a) Demonstrate, in the narrative section of the application under ''Significance of the Project,'' how—

(1) The project addresses national, State, regional, or district shortages of personnel who are fully qualified to serve children with disabilities, ages birth through 21, who have high-intensity needs. To address this requirement, the applicant must—

(i) Present data on the effectiveness of each special education, early intervention, or related services personnel preparation program participating in the project in areas such as: The average amount of time it takes for scholars to complete the program; the percentage of program graduates who receive a license, endorsement, or certification related to special education, related services, or early intervention services; the percentage of program graduates finding employment related to their preparation after graduation; the effectiveness of program graduates in providing special education, early intervention, or related services, which could include data on the learning and developmental outcomes of children with disabilities they serve; the percentage of program graduates who maintain employment for two or more years in the area for which they were prepared and who are fully qualified under IDEA; and the percentage of graduates and their employers who report that program graduates received adequate preparation to provide high quality special education, early intervention, or related services; and

(ii) If available, present data on the effectiveness of interdisciplinary approaches to the preparation of special education, early intervention, or related services personnel that involve the programs participating in the proposed project.

Note: Data on the effectiveness of a personnel preparation program should be no older than five years prior to the start date of the project proposed in the application. When reporting percentages, the denominator (*i.e.,* total number of scholars or program graduates) must be provided.

(2) The project will increase the number of personnel who demonstrate the competencies needed to provide (a) focused instruction, and (b) intense individualized intervention(s) in an interdisciplinary team-based approach to address the individualized needs of children with disabilities who have high-intensity needs, ages birth through 21, that result in improvements in learning or developmental outcomes (*e.g.,* academic, social, emotional, behavioral), or successful transition to postsecondary education and the workforce. To address this requirement, the applicant must—

(i) Identify the competencies [5] that special education, early intervention, or related services personnel need in order to ensure delivery of (a) focused instruction, and (b) intense individualized intervention(s) in an interdisciplinary team-based approach that will: Lead to improved learning and developmental outcomes; ensure access to and progress in academic achievement standards or alternate academic achievements standards, as appropriate; lead to successful transition to college and career for children with disabilities, including children with disabilities who have high-intensity needs; and maximize the use of effective technology to deliver instruction, interventions, and services;

(ii) Identify the competencies needed by members of interdisciplinary teams that will result in improved outcomes for children with disabilities who have high-intensity needs;

(iii) Identify the competencies that personnel need to support inclusion of children with disabilities in the least restrictive and natural environments to the maximum extent appropriate by intentionally promoting participation in learning and social activities to foster development, learning, academic achievement, friendships with peers, and sense of belonging; and

(iv) Provide a conceptual framework for the proposed interdisciplinary personnel preparation project, including any empirical support that will promote the acquisition of the identified competencies (see paragraph (a)(2)(i) of the requirements for this priority) needed by special education, early intervention, or related services personnel, and how these competencies relate to the proposed project.

(b) Demonstrate, in the narrative section of the application under ''Quality of Project Services,'' how—

(1) The project will conduct its planning activities, if the first year of the project period is used for planning.

(2) The project will recruit and retain high-quality scholars into the bachelor's (if training educational interpreters for the deaf), master's, specialist, or clinical doctoral degree programs participating in the project and ensure equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. To meet this requirement, the applicant must—

(i) Describe criteria the applicant will use to identify high-quality applicants for admission into the degree programs participating in the project;

(ii) Describe the recruitment strategies the applicant will use to attract high-quality applicants and any specific recruitment strategies targeting high-quality applicants from traditionally underrepresented groups, including individuals with disabilities; and

(iii) Describe the approach, including mentoring, monitoring, and accommodations, the applicant will use to support scholars to complete their respective degree programs.

(3) The project reflects current practices supported by evidence and is designed to prepare scholars in the identified competencies. To address this requirement, the applicant must—

(i) Describe how the project will incorporate current practices supported by evidence (including relevant research citations) that improve outcomes for children with disabilities who have high-intensity needs into (a) the required coursework and clinical experiences for each personnel preparation program participating in the project; and (b) the shared coursework, group assignments, and coordinated clinical experiences required for the

[5] For the purposes of this priority, the term ''competencies'' means what a person knows and can do: The knowledge, skills, and dispositions necessary to effectively function in a role (National Professional Development Center on Inclusion, 2011). These competencies should ensure that personnel are able to use challenging academic standards, child achievement and functional standards, and assessments to improve instructional practices, services, learning and developmental outcomes (*e.g.,* academic, social, emotional, behavioral), and college- and career-readiness of children with disabilities.

interdisciplinary portions of the project; and

(ii) Describe how the project will use professional development practices supported by evidence for adult learners to instruct scholars.

(4) The project is of sufficient quality, intensity, and duration to prepare scholars in the identified competencies. To address this requirement, the applicant must describe how—

(i) The components of (a) each personnel preparation program participating in the project; and (b) the shared coursework, group assignments, and coordinated clinical experiences required for the interdisciplinary portions of the proposed project will support scholars' acquisition and enhancement of the identified competencies;

(ii) The components of (a) each personnel preparation program participating in the project and (b) the shared coursework, group assignments, and coordinated clinical experiences required for the interdisciplinary portions of the proposed project will be integrated to allow scholars to use their knowledge and skills in designing, implementing, and evaluating practices supported by evidence to address the learning and developmental needs of children with disabilities who have high-intensity needs in collaboration with other team members;

(iii) Scholars will be provided with ongoing guidance and feedback during training; and

(iv) The proposed project will provide ongoing induction opportunities and mentoring support to graduates of each personnel preparation program participating in the project.

(5) The project will collaborate with appropriate partners, including—

(i) High-need schools, which are high-poverty schools,[6] low-performing schools,[7] or publicly funded preschool programs, including Head Start programs and programs serving children eligible for services under IDEA Part C and Part B, section 619, that are located within the geographic boundaries of a high-need LEA. The purpose of these partnerships is to provide clinical practice for scholars aimed at developing the identified competencies as members of interdisciplinary teams; and

Note: A State that received ESEA flexibility was not required to identify schools in corrective action or restructuring under section 1116 of the ESEA; rather, the State identified priority and focus schools. Moreover, with the enactment of the Every Student Succeeds Act (ESSA), no State, beginning in the 2017–2018 school year, will identify schools in corrective action or restructuring under section 1116 of the ESEA or identify schools as priority and focus schools under ESEA flexibility. Therefore, consistent with section 5(e)(2) of the ESSA, the U.S. Department of Education (Department) will allow applicants to consider the following schools as low-performing schools: (1) Elementary and secondary schools identified, at the time of submission of an application under this competition, as in need of corrective action or restructuring under the ESEA, as amended by NCLB; (2) elementary and secondary schools identified, at the time of submission of an application under this competition, as a priority or focus school by a State under ESEA flexibility; and (3) secondary schools (both middle and high schools) in a State that are, at the time of submission of an application under this competition, equally as low-achieving as the Title I schools above and are eligible for, but do not receive, Title I funds.

(ii) Other programs on campus or at partnering universities for the purpose of sharing resources, supporting program development and delivery, and addressing personnel shortages.

(6) The project will use technology, as appropriate, to promote scholar learning and professional practice, enhance the efficiency of the project, collaborate with partners, and facilitate ongoing mentoring and support for scholars.

(7) The project will ensure that scholars understand how to use technology to support student learning; and

(8) The project will align with and use resources, as appropriate, available through technical assistance centers, which may include centers funded by the Department.

Note: Use our "Find a Center" at *www.osepideasthatwork.org* for information about the Office of Special Education Programs (OSEP) funded national centers.

(c) Demonstrate, in the narrative section of the application under "Quality of Project Evaluation," how—

(1) The applicant will use comprehensive and appropriate methodologies to evaluate how well the goals or objectives of the proposed project have been met, including the project processes and outcomes.

(2) The applicant will collect, analyze, and use data related to specific and measurable goals, objectives, and outcomes of the project. To address this requirement, the applicant must describe—

(i) How scholar competencies and other project processes and outcomes will be measured for formative evaluation purposes, including proposed instruments, data collection methods, and possible analyses; and

(ii) How data on the quality of services provided by proposed project graduates, including data on the learning and developmental outcomes (*e.g.,* academic, social, emotional, behavioral, meeting college- and career-ready standards) and on growth toward these outcomes of the children with disabilities who have high-intensity needs that the project graduates serve, will be collected and analyzed.

Note: Following the completion of the project period, grantees are encouraged to engage in ongoing data collection activities.

(3) The methods of evaluation will produce quantitative and qualitative data for objective performance measures that are related to the outcomes of the proposed project.

(4) The methods of evaluation will provide performance feedback and allow for periodic assessment of progress towards meeting the project outcomes. To address this requirement, the applicant must describe how—

(i) Results of the evaluation will be used as a basis for improving the proposed project to prepare special education, early intervention, or related services personnel to provide (a) focused instruction, and (b) intense individualized intervention(s) in an interdisciplinary team-based approach to improve outcomes of children with disabilities who have high-intensity needs; and

(ii) The grantee will report the evaluation results to OSEP in its annual and final performance reports.

(d) Demonstrate, in the narrative under "Project Assurances," or appendices, as applicable, that the following program requirements are met. The applicant must—

(1) Include, in the application as Appendix B, brief syllabi for required courses, seminars, and field experiences of the degree programs participating in the project, such as—

[6] For the purposes of this priority, the term "high-poverty school" means a school that is in the highest two quartiles of schools served by a local educational agency, based on the percentage of enrolled students from low-income families as defined in section 1113(a)(5) of the Elementary and Secondary Education Act of 1965, as amended (ESEA).

[7] For the purpose of this priority, the term "low-performing school" means a school receiving assistance through Title I of the ESEA that, at the time of submission of an application under this competition, is (1) identified as a school in need of corrective action or restructuring under section 1116 of the ESEA, as amended by the No Child Left Behind Act of 2001 (NCLB); or (2) identified as a priority or focus school in a State that implemented ESEA flexibility. The inclusion of these schools as "low-performing schools" reflects the fact that the 2016–2017 school year is a year of transition between requirements of the ESEA as amended by NCLB and the ESEA as amended by the Every Student Succeeds Act.

(i) Syllabi for shared courses, seminars, and coordinated clinical experiences; and

(ii) Proposed syllabi for new courses.

(2) Ensure that a comprehensive set of completed syllabi, including syllabi created or revised as part of a project planning year, are submitted to OSEP by the end of Year 1 of the grant.

(3) Ensure scholars will not be selected based on race, ethnicity, or national origin. Per the Supreme Court's decision in *Adarand Constructors, Inc.* v. *Pena,* 515 U.S. 200 (1995), the Department does not allow the selection of individuals on the basis of race, ethnicity, or national origin. For this reason, grantees must ensure that any discussion of the recruitment of scholars based on race, ethnicity, or national origin distinguishes between increasing the pool of applicants and actually selecting scholars.

(4) Ensure that the project will meet all requirements for grantees in disbursing scholarships as outlined in 34 CFR 304.22. Failure by a grantee to properly meet these requirements would be a violation of the grant award that could result in sanctions, including the grantee being liable for returning any misused funds to the Department. Specifically, before disbursement of scholarship assistance to an individual, a grantee must—

(a) Ensure that the scholar—

(1) Is a citizen or national of the United States;

(2) Is a permanent resident of—

(i) Puerto Rico, the United States Virgin Islands, Guam, American Samoa, or the Commonwealth of the Northern Mariana Islands; or

(ii) The Republic of the Marshall Islands, the Federated States of Micronesia, or the Republic of Palau during the period in which these entities are eligible to receive an award under the Personnel Development to Improve Services and Results for Children with Disabilities program; or

(3) Provides evidence from the U.S. Department of Homeland Security that the individual is—

(i) A lawful permanent resident of the United States; or

(ii) In the United States for other than a temporary purpose with the intention of becoming a citizen or permanent resident;

(b) Limit the cost of attendance portion of the scholarship assistance (as discussed in 34 CFR 304.21(a)) to the amount by which the individual's cost of attendance at the institution exceeds the amount of grant assistance the scholar is to receive for the same academic year under title IV of the HEA; and

(c) Obtain a Certification of Eligibility for Federal Assistance from each scholar, as prescribed in 34 CFR 75.60, 75.61, and 75.62.

(5) Ensure that the project will meet all requirements in 34 CFR 304.23, particularly those related to informing all scholarship recipients of their service obligation commitment. Failure by a grantee to properly meet these requirements would be a violation of the grant award that could result in sanctions, including the grantee being liable for returning any misused funds to the Department. Specifically, the grantee must prepare, and ensure that each scholarship recipient signs, the following two documents:

(i) A Pre-Scholarship Agreement prior to the scholar receiving a scholarship for an eligible program (Office of Management and Budget (OMB) Control Number 1820–0686); and

(ii) An Exit Certification immediately upon the scholar leaving, completing, or otherwise exiting that program (OMB Control Number 1820–0686).

(6) Ensure that prior approval from the OSEP project officer will be obtained before admitting additional scholars beyond the number of scholars proposed in the application and before transferring a scholar to another OSEP-funded grant.

(7) Ensure that the project will meet the statutory requirements in section 662(e) through 662(h) of IDEA.

(8) Ensure that at least 65 percent of the total requested budget over the five years will be used for scholar support. Applicants proposing to use Year 1 for program development may budget for less than 65 percent of the total requested budget over the five years for scholar support; instead 65 percent of the total award minus funds allocated for program development will be used to calculate the value of required scholar support.

(9) Ensure that the institution of higher education (IHE) will not require scholars enrolled in the program to work (*e.g.,* as graduate assistants) as a condition of receiving support (*e.g.,* tuition, stipends) from the proposed project, unless the work is specifically related to the acquisition of scholars' competencies and the requirements for completion of their personnel preparation program. This prohibition on work as a condition of receiving support does not apply to the service obligation requirements in section 662(h) of IDEA.

(10) Ensure that the budget includes attendance of the project director at a three-day project directors' meeting in Washington, DC, during each year of the project.

(11) Ensure that the project director, key personnel, and scholars will actively participate in the cross-project collaboration, advanced trainings, and cross-site learning opportunities (*e.g.,* webinars, briefings) organized by OSEP. This partnership will be used to build capacity of participants, increase the impact of funding, and innovative and interdisciplinary service delivery models across projects.

(12) Ensure that if the project maintains a Web site, relevant information and documents are in a format that meets government or industry-recognized standards for accessibility.

(13) Ensure that annual data will be submitted on each scholar who receives grant support (OMB Control Number 1820–0686). The primary purposes of the data collection are to track the service obligation fulfillment of scholars who receive funds from OSEP grants and to collect data for program performance measure reporting under the Government Performance and Results Act of 1993 (GPRA). Applicants are encouraged to visit the Personnel Development Program Data Collection System (DCS) Web site at *https://pdp.ed.gov/osep* for further information about this data collection requirement. Typically, data collection begins in January of each year, and grantees are notified by email about the data collection period for their grant, although grantees may submit data as needed, year round. This data collection must be submitted electronically by the grantee and does not supplant the annual grant performance report required of each grantee for continuation funding (see 34 CFR 75.590). Data collection includes the submission of a signed, completed Pre-Scholarship Agreement and Exit Certification for each scholar funded under an OSEP grant (see paragraph (4) of this section, subparagraphs (i) and (ii)).

Focus Areas: Within this absolute priority, the Secretary intends to support interdisciplinary projects under the following two focus areas: (A) Preparing Personnel to Serve Infants, Toddlers, and Preschool-Age Children with Disabilities who have High-Intensity Needs; and (B) Preparing Personnel to Serve School-Age Children with Disabilities who have High-Intensity Needs.

Note: Interdisciplinary projects are encouraged for personnel preparation programs serving educational interpreters, but are not required.

Note: Applicants must identify the specific focus area (*i.e.,* A or B) under which they are

applying as part of the competition title on the application cover sheet (SF form 424, line 4). Applicants may not submit the same proposal under more than one focus area.

Focus Area A: Preparing Personnel To Serve Infants, Toddlers, and Preschool-Age Children With Disabilities Who Have High-Intensity Needs. OSEP intends to fund nine awards under this focus area. For the purpose of Focus Area A, early intervention personnel are those who are prepared to provide services to infants and toddlers with disabilities ages birth to three, and early childhood personnel are those who are prepared to provide services to children with disabilities ages three through five (and in States where the age range is other than ages three through five, we will defer to the State's certification for early childhood). In States where certification in early intervention is combined with certification in early childhood, applicants may propose a combined early intervention and early childhood personnel preparation project under this focus area. For purposes of this focus area, interdisciplinary projects are projects that deliver core content through shared coursework, group assignments, and coordinated clinical experiences shared across disciplines for: (a) Early intervention providers or early childhood special educators and related services personnel who serve infants, toddlers, and preschool-age children with disabilities who have high-intensity needs; or (b) projects preparing only related services personnel to serve infants, toddlers, and preschool-age children with disabilities who have high-intensity needs.

Note: In Focus Area A, OSEP intends to fund in FY 2017 at least three high-quality applications from Minority-Serving IHEs,[8] including a minimum of one Historically Black College or University (HBCU) and, as a result, may fund applications out of rank order.

Focus Area B: Preparing Personnel To Serve School-Age Children With Disabilities Who Have High-Intensity Needs. OSEP intends to fund 27 awards under this focus area. For the purpose of Focus Area B, personnel who serve children with disabilities who have high-intensity needs are special education teachers or related services providers prepared to serve school-age children with disabilities who have high-intensity needs. For purposes of this focus area, interdisciplinary projects are: (a) Projects that deliver core content through shared coursework, group assignments, and coordinated clinical experiences shared across disciplines for special education teachers and related services personnel who serve school-age children with disabilities who have high-intensity needs; or (b) projects preparing only related services personnel to serve school-age children with disabilities who have high-intensity needs.

Note: In Focus Area B, OSEP intends to fund in FY 2017 at least eight high-quality applications from Minority-Serving IHEs including a minimum of two HBCUs and, as a result, may fund applications out of rank order.

Note: A project funded under Focus Area A or B may budget for less than the 65 percent required for scholar support in Year 1 if the first year of the proposed project will be used for planning new or improved coursework, group assignments, or coordinated clinical experience needed to support interdisciplinary preparation for special education, early intervention, or related services personnel serving children with disabilities who have high-intensity needs, and the applicant can provide sufficient justification for a designation less than this required percentage. Sufficient justification for proposing less than 65 percent of the budget for scholar support in Year 1 would include support for activities, such as—

(1) Program improvement to develop and deliver shared coursework, group assignments, and coordinated clinical experience needed to support interdisciplinary preparation for personnel across two or more master's, specialist or clinical doctorate degree programs (*e.g.,* hiring of a new faculty member or consultant to assist in course development, providing professional development and training for faculty and clinical supervisors, negotiating agreements with schools to serve as sites for coordinated clinical experience). In the initial project year, scholar support would not be required. The project must demonstrate that the newly established coursework and coordinated clinical experience is approved and ready for implementation in order to receive continuation funds in Year 2.

(2) Building capacity (*e.g.,* hiring of a clinical practice supervisor, providing professional development and training for faculty) or purchasing needed resources (*e.g.,* additional teaching supplies or specialized equipment to enhance instruction).

Note: Applicants proposing projects to develop, expand, or add a new area of emphasis to special education, early intervention, or related services programs must provide, in their applications, information on how these new areas will be sustained once Federal funding ends.

References

Boe, E.E., deBettencourt, L., Dewey, J.F., Rosenberg, M.S., Sindelar, P.T., & Leko, C.D. (2013). Variability in demand for special education teachers: Indicators, explanations, and impacts. *Exceptionality, 21,* 103–125.

Browder, D.M., Wood, L., Thompson, J., & Ribuffo, C. (2014). *Evidence-based practices for students with severe disabilities* (Document No. IC–3). Retrieved from University of Florida, Collaboration for Effective Educator, Development, Accountability, and Reform Center Web site: *http://ceedar.education.ufl.edu/tool/innovation-configurations/.*

Individuals with Disabilities Education Act, 20 U.S.C. 1400, *et seq.* (2004).

McLeskey, J., & Brownell, M. (2015). *High-leverage practices and teacher preparation in special education* (Document No. PR–1). Retrieved from University of Florida, Collaboration for Effective Educator, Development, Accountability, and Reform Center Web site: *http://ceedar.education.ufl.edu/wp-content/uploads/2016/05/High-Leverage-Practices-and-Teacher-Preparation-in-Special-Education.pdf.*

National Professional Development Center on Inclusion. (August, 2011). *Competencies for early childhood educators in the context of inclusion: Issues and guidance for States.* Chapel Hill, NC: The University of North Carolina, FPG Child Development Institute, Author.

Smith, J. (2010). An interdisciplinary approach to preparing early intervention professionals: A university and community collaborative initiative. *Teacher Education and Special Education,* 33(2), 131–142.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (APA) (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed priorities. Section 681(d) of IDEA, however, makes the public comment requirements of the APA inapplicable to the priority in this notice.

Program Authority: 20 U.S.C. 1462 and 1481.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The regulations for this program in 34 CFR part 304.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

[8] For the purposes of this priority, the term ''Minority-Serving IHEs'' refers to IHEs with a minority enrollment of 50 percent or more, which may include Historically Black Colleges and Universities, Tribal Colleges, and Predominantly Hispanic Serving Colleges and Universities.

Note: The regulations in 34 CFR part 86 apply to IHEs only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: The Administration has requested $83,700,000 for the Personnel Development to Improve Services and Results for Children with Disabilities program for FY 2017, of which we intend to use an estimated $9,000,000 for this competition. The actual level of funding, if any, depends on final congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for this program.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2018 from the list of unfunded applicants from this competition.

Estimated Range of Awards: See chart.

Estimated Average Size of Awards: See chart.

Maximum Award: See chart.

Estimated Number of Awards: See chart.

Project Period: See chart.

PERSONNEL DEVELOPMENT TO IMPROVE SERVICES AND RESULTS FOR CHILDREN WITH DISABILITIES (84.325K) APPLICATION NOTICE FOR FISCAL YEAR 2017

CFDA number and name	Applications available	Deadline for transmittal of applications	Deadline for intergovernmental review	Estimated range of awards	Estimated average size of awards	Maximum award for each budget period of 12 months	Estimated number of awards	Project period	Contact person
84.325K Interdisciplinary Preparation in Special Education, Early Intervention, and Related Services for Personnel Serving Children with Disabilities who have High-Intensity Needs.	January 3, 2017.	March 6, 2017.	May 3, 2017						
Focus Area A: Preparing Personnel to Serve Infants, Toddlers, and Preschool-Age Children with Disabilities who have High-Intensity Needs.	.....	.....	.....	$200,000–$250,000	$250,000	* $250,000	9	Up to 60 mos.	Focus Area A or Minority Serving Institutions: Dawn Ellis, 202–245–6417, *dawn.ellis@ed.gov*, Potomac Center Plaza, Room 5137.
Focus Area B: Preparing Personnel to Serve School-Age Children with Disabilities who have High-Intensity Needs.	.....	.....	.....	$200,000–$250,000	$250,000	* $250,000	27	Up to 60 mos.	Focus Area B: Maryann McDermott, 202–245–7439, *maryann.mcdermott@ed.gov*, Potomac Center Plaza, Room 5144. or Sarah Allen, 202–245–7875, *sarah.allen@ed.gov*, Potomac Center Plaza, Room 5144.

* We will reject any application that proposes a budget exceeding the maximum award for a single budget period of 12 months.

Note: The Department is not bound by any estimates in this notice.

Evaluation Period: In August 2013, the Department amended the EDGAR to authorize the award of an evaluation period after the end of the approved project period. 34 CFR 75.250 allows for an evaluation period for the sole purpose of data collection, analysis, and reporting. The full text of this regulation is included in the application package.

Under 34 CFR 75.250(b) the Secretary has the authority to make data collection/analysis awards. By the terms of that section, the awards can only go to current grantees, may only be used for data collection, analysis and reporting and do not have to go through a formal competitive process.

III. Eligibility Information

1. *Eligible Applicants:* IHEs, private nonprofit organizations.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

3. *Eligible Subgrantees:* (a) Under 34 CFR 75.708(b) and (c) a grantee may award subgrants—to directly carry out project activities described in its application—to the following types of entities: IHEs and private nonprofit organizations suitable to carry out the activities proposed in the application.

(b) The grantee may award subgrants to entities it has identified in an approved application.

4. *Other General Requirements:*

(a) Recipients of funding under this competition must make positive efforts to employ and advance in employment qualified individuals with disabilities (see section 606 of IDEA).

(b) Each applicant for, and recipient of, funding must, with respect to the aspects of their proposed project, involve individuals with disabilities, or parents of individuals with disabilities ages birth through 26, in planning, implementing, and evaluating the project (see section 682(a)(1)(A) of IDEA).

IV. Application and Submission Information

1. *Address to Request Application Package:* You can obtain an application

package via the Internet or from the Education Publications Center (ED Pubs). To obtain a copy via the Internet, use the following address: *www.ed.gov/fund/grant/apply/grantapps/index.html.* To obtain a copy from ED Pubs, write, fax, or call the following: ED Pubs, U.S. Department of Education, P.O. Box 22207, Alexandria, VA 22304. Telephone, toll free: 1–877–433–7827. FAX: (703) 605–6794. If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: *www.EDPubs.gov* or at its email address: *edpubs@inet.ed.gov*.

If you request an application from ED Pubs, be sure to identify this competition as follows: CFDA number 84.325K.

Individuals with disabilities can obtain a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) by contacting the person or team listed under *Accessible Format* in section VIII of this notice.

2. *Content and Form of Application Submission:* Requirements concerning the content and form of an application, together with the forms you must submit, are in the application package for this competition.

Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. You must limit Part III to no more than 50 pages, using the following standards:

- A ''page'' is 8.5'' x 11'', on one side only, with 1'' margins at the top, bottom, and both sides.
- Double-space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, reference citations, and captions, as well as all text in charts, tables, figures, graphs, and screen shots.
- Use a font that is 12 point or larger.
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial. An application submitted in any other font (including Times Roman or Arial Narrow) will not be accepted.

The page limit and double-spacing requirements do not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the abstract (follow the guidance provided in the application package for completing the abstract), the table of contents, the list of priority requirements, the resumes, the reference list, the letters of support, or the appendices. However, the page limit and double-spacing requirements do apply to all of Part III, the application narrative, including all text in charts, tables, figures, graphs, and screen shots.

We will reject your application if you exceed the page limit in the application narrative section, or if you apply standards other than those specified in this notice and the application package.

3. *Submission Dates and Times:*

Applications Available: January 3, 2017.

Deadline for Transmittal of Applications: March 6, 2017.

Applications for grants under this competition must be submitted electronically using the *Grants.gov* Apply site (*Grants.gov*). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to *Other Submission Requirements* in section IV of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review: May 3, 2017.

4. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and System for Award Management:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the System for Award Management (SAM), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet at the following Web site: *http://fedgov.dnb.com/webform.* A DUNS number can be created within one to two business days.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow two to five weeks for your TIN to become active.

The SAM registration process can take approximately seven business days, but may take upwards of several weeks, depending on the completeness and accuracy of the data you enter into the SAM database. Thus, if you think you might want to apply for Federal financial assistance under a program administered by the Department, please allow sufficient time to obtain and register your DUNS number and TIN. We strongly recommend that you register early.

Note: Once your SAM registration is active, it may be 24 to 48 hours before you can access the information in, and submit an application through, *Grants.gov.*

If you are currently registered with SAM, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your registration annually. This may take three or more business days.

Information about SAM is available at *www.SAM.gov.* To further assist you with obtaining and registering your DUNS number and TIN in SAM or updating your existing SAM account, we have prepared a *SAM.gov* Tip Sheet, which you can find at: *www2.ed.gov/fund/grant/apply/sam-faqs.html.*

In addition, if you are submitting your application via *Grants.gov*, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with *Grants.gov* as an AOR. Details on these steps are outlined at the following *Grants.gov* Web page: *www.grants.gov/web/grants/register.html.*

7. *Other Submission Requirements:* Applications for grants under this

competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. *Electronic Submission of Applications.*

Applications for grants under the Interdisciplinary Preparation in Special Education, Early Intervention, and Related Services for Personnel Serving Children with Disabilities who have High-Intensity Needs competition, CFDA number 84.325K, must be submitted electronically using the Governmentwide *Grants.gov* Apply site at *www.Grants.gov.* Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not email an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement *and* submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

You may access the electronic grant application for the Interdisciplinary Preparation in Special Education, Early Intervention, and Related Services for Personnel Serving Children with Disabilities who have High-Intensity Needs competition at *www.Grants.gov*. You must search for the downloadable application package for this competition by the CFDA number. Do not include the CFDA number's alpha suffix in your search (*e.g.,* search for 84.325, not 84.325K).

Please note the following:

- When you enter the *Grants.gov* site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- Applications received by *Grants.gov* are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the *Grants.gov* system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the *Grants.gov* system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from *Grants.gov*, we will notify you if we are rejecting your application because it was date and time stamped by the *Grants.gov* system after 4:30:00 p.m., Washington, DC time, on the application deadline date.
- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through *Grants.gov*.
- You should review and follow the Education Submission Procedures for submitting an application through *Grants.gov* that are included in the application package for this competition to ensure that you submit your application in a timely manner to the *Grants.gov* system. You can also find the Education Submission Procedures pertaining to *Grants.gov* under News and Events on the Department's G5 system home page at *www.G5.gov.* In addition, for specific guidance and procedures for submitting an application through *Grants.gov*, please refer to the *Grants.gov* Web site at: *www.grants.gov/web/grants/applicants/apply-for-grants.html.*
- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.
- You must submit all documents electronically, including all information you typically provide on the following forms: The Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.
- You must upload any narrative sections and all other attachments to your application as files in a read-only, non-modifiable Portable Document Format (PDF). Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, non-modifiable PDF (*e.g.,* Word, Excel, WordPerfect, etc.) or submit a password-protected file, we will not review that material. Please note that this could result in your application not being considered for funding because the material in question—for example, the application narrative—is critical to a meaningful review of your proposal. For that reason it is important to allow yourself adequate time to upload all material as PDF files. The Department will not convert material from other formats to PDF. Additional, detailed information on how to attach files is in the application instructions.
- Your electronic application must comply with any page-limit requirements described in this notice.
- After you electronically submit your application, you will receive from *Grants.gov* an automatic notification of receipt that contains a *Grants.gov* tracking number. This notification indicates receipt by *Grants.gov* only, not receipt by the Department. *Grants.gov* will also notify you automatically by email if your application met all the *Grants.gov* validation requirements or if there were any errors (such as submission of your application by someone other than a registered Authorized Organization Representative, or inclusion of an attachment with a file name that contains special characters). You will be given an opportunity to correct any errors and resubmit, but you must still meet the deadline for submission of applications.

Once your application is successfully validated by *Grants.gov*, the Department will retrieve your application from *Grants.gov* and send you an email with a unique PR/Award number for your application.

These emails do not mean that your application is without any disqualifying errors. While your application may have been successfully validated by *Grants.gov*, it must also meet the Department's application requirements as specified in this notice and in the application instructions. Disqualifying errors could include, for instance, failure to upload attachments in a read-only, non-modifiable PDF; failure to submit a required part of the application; or failure to meet applicant eligibility requirements. It is your responsibility to ensure that your submitted application has met all of the Department's requirements.

- We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues With the Grants.gov System: If you are experiencing problems submitting your application through *Grants.gov*, please contact the *Grants.gov* Support Desk, toll free, at 1–800–518–4726. You must obtain a *Grants.gov* Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the *Grants.gov* system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with *Grants.gov*, along with the *Grants.gov* Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the *Grants.gov* system and that the problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. We will contact you after we determine whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the *Grants.gov* system. We will not grant you an extension if you failed to fully register to submit your application to *Grants.gov* before the application deadline date and time or if the technical problem you experienced is unrelated to the *Grants.gov* system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the *Grants.gov* system because—

- You do not have access to the Internet; or
- You do not have the capacity to upload large documents to the *Grants.gov* system;

and

- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevents you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Maryann McDermott, U.S. Department of Education, 400 Maryland Avenue SW., Room 5144, Potomac Center Plaza, Washington, DC 20202–5108. FAX: (202) 245–7439.

Your paper application must be submitted in accordance with the mail or hand-delivery instructions described in this notice.

b. *Submission of Paper Applications by Mail.*

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.325K), LBJ Basement Level 1, 400 Maryland Avenue SW., Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

We will not consider applications postmarked after the application deadline date.

c. *Submission of Paper Applications by Hand Delivery.*

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.325DK), 550 12th Street SW., Room 7039, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210 and are listed in the application package.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Additional Review and Selection Process Factors:* In the past, the Department has had difficulty finding peer reviewers for certain competitions because so many individuals who are eligible to serve as peer reviewers have conflicts of interest. The standing panel requirements under section 682(b) of IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected

for funding within specific groups. This procedure will make it easier for the Department to find peer reviewers by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of interest. It also will increase the quality, independence, and fairness of the review process, while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications.

4. *Risk Assessment and Special Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose special conditions and, in appropriate circumstances, high risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

5. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $150,000), under 2 CFR 200.205(a)(2), we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through SAM. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

4. *Performance Measures:* Under GPRA, the Department has established a set of performance measures, including long-term measures, that are designed to yield information on various aspects of the effectiveness and quality of the Personnel Development to Improve Services and Results for Children with Disabilities program. These measures include: (1) The percentage of preparation programs that incorporate scientifically or evidence-based practices into their curricula; (2) the percentage of scholars completing preparation programs who are knowledgeable and skilled in evidence-based practices for children with disabilities; (3) the percentage of scholars who exit preparation programs prior to completion due to poor academic performance; (4) the percentage of scholars completing preparation programs who are working in the area(s) in which they were prepared upon program completion; and (5) the Federal cost per scholar who completed the preparation program.

In addition, the Department will gather information on the following outcome measures: (1) The percentage of scholars who completed the preparation program and are employed in high-need districts; (2) the percentage of scholars who completed the preparation program and are employed in the field of special education for at least two years; and (3) the percentage of scholars who completed the preparation program and who are rated effective by their employers.

Grantees may be asked to participate in assessing and providing information on these aspects of program quality.

5. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Maryann McDermott, U.S. Department of Education, 400 Maryland Avenue SW., Room 5144, Potomac Center Plaza, Washington, DC 20202–5108. Telephone: (202) 245–7439.

If you use a TDD or a TTY, call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) by contacting the Management Support Services Team, U.S. Department of Education, 400 Maryland Avenue SW., Room 5113, Potomac Center Plaza, Washington, DC 20202–2500. Telephone: (202) 245–7363. If you use a

TDD or a TTY, call the FRS, toll free, at 1–800–877–8339.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or PDF. To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: December 28, 2016.

Sue Swenson,

Deputy Assistant Secretary, delegated the authority to perform the functions and duties of the Assistant Secretary.

[FR Doc. 2016–31838 Filed 12–30–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2016–ICCD–0115]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Lender's Request for Payment of Interest and Special Allowance—LaRS

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before February 2, 2017.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2016–ICCD–0115. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 224–84, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Lender's Request for Payment of Interest and Special Allowance—LaRS.

OMB Control Number: 1845–0013.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: Private Sector.

Total Estimated Number of Annual Responses: 7,350.

Total Estimated Number of Annual Burden Hours: 14,333.

Abstract: The Department of Education (the Department) is submitting the Lender's Interest and Special Allowance Request & Report, ED Form 799 for approval. The information collected on the ED Form 799 is needed to pay interest and special allowance to holders of Federal Family Education Loans, for internal financial reporting, budgetary projections, and for audit and lender reviews by the Department, Servicers, External Auditors and General Accounting Office (GAO).

The legal authority for collecting this information is Title IV, Part B of the Higher Education Act of 1965, as amended by the Higher Education Reconciliation Act of 2005 (''the HERA''), (Pub. L. 109–171). The Department is requesting the continual approval for regulatory sections 682.304 and 682.414.

Dated: December 28, 2016.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016–31776 Filed 12–30–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

National Advisory Committee on Institutional Quality and Integrity

AGENCY: National Advisory Committee on Institutional Quality and Integrity, U.S. Department of Education.

ACTION: Notice of membership.

SUMMARY: This notice lists the members of the National Advisory Committee on Institutional Quality and Integrity (NACIQI). This notice is required under Section 114(e)(1) of the Higher Education Act of 1965, as amended (HEA).

SUPPLEMENTARY INFORMATION:

NACIQI's Statutory Authority and Functions

NACIQI is established under Section 114 of the HEA, and is composed of 18 members appointed—

(A) On the basis of the individuals' experience, integrity, impartiality, and good judgment;

(B) From among individuals who are representatives of, or knowledgeable concerning, education and training beyond secondary education, representing all sectors and types of institutions of higher education; and,

(C) On the basis of the individuals' technical qualifications, professional standing, and demonstrated knowledge in the fields of accreditation and administration of higher education.

NACIQI meets at least twice a year and advises the Secretary of Education with respect to:

- The establishment and enforcement of the standards of accrediting agencies or associations under subpart 2 of part G of Title IV of the HEA;

• The recognition of specific accrediting agencies or associations;
• The preparation and publication of the list of nationally recognized accrediting agencies and associations;
• The eligibility and certification process for institutions of higher education under Title IV of the HEA and part C of subchapter I of chapter 34 of Title 42, together with recommendations for improvements in such process;
• The relationship between (1) accreditation of institutions of higher education and the certification and eligibility of such institutions, and (2) State licensing responsibilities with respect to such institutions; and
• Any other advisory functions relating to accreditation and institutional eligibility that the Secretary of Education may prescribe by regulation.

ADDRESSES: U.S. Department of Education, Office of Postsecondary Education, 400 Maryland Ave. SW., Room 6W250, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: Jennifer Hong, Executive Director/Designated Federal Official, NACIQI, U.S. Department of Education, 400 Maryland Ave. SW., Room 6W250, Washington, DC 20202, telephone: (202) 453–7805, or email *Jennifer.Hong@ed.gov.*

What are the terms of office for the committee members?

The term of office of each member is six years. Any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member's predecessor was appointed shall be appointed for the remainder of such term.

Who are the current members of the committee?

The current members of the NACIQI are:

Members Appointed by the Secretary of Education With Terms Expiring September 30, 2019

• Simon J. Boehme (Student Member), Independent Consultant, San Francisco, California.
• Roberta L. Derlin, Ph.D., Associate Provost Emeritus, New Mexico State University, Albuquerque, New Mexico.
• John Etchemendy, Ph.D., Provost, Stanford University, Stanford, California.
• Susan D. Phillips, Ph.D., Former Provost and Vice President for Academic Affairs and Former Vice President for Strategic Partnerships, University at Albany/SUNY, Albany, New York.
• Frank H. Wu, J.D., Distinguished Professor, University of California Hastings College of Law, San Francisco, California.
• Federico Zaragoza, Ph.D., Vice Chancellor for Economic and Workforce Development, Alamo Colleges, San Antonio, Texas.

Members Appointed by the Speaker of the House of Representatives With Terms Expiring September 30, 2020

• Kathleen Sullivan Alioto, Ed.D., Strategic Advisor, Fundraiser, and Consultant, New York, New York, San Francisco, California, and Boston, Massachusetts.
• George T. French, Jr., Ph.D., President, Miles College, Fairfield, Alabama.
• Arthur E. Keiser, Ph.D., Chancellor and C.E.O., Keiser University, Fort Lauderdale, Florida.
• Arthur J. Rothkopf, J.D., President Emeritus, Lafayette College, Washington, DC.
• Ralph Wolff, J.D., Independent Policy Consultant, Oakland, California.
• Vacant.

Members Appointed by the President Pro Tempore of the Senate With Terms Expiring September 30, 2022

• Jill Derby, Ph.D., Senior Consultant, Association of Governing Boards of Universities and Colleges, Gardnerville, Nevada.
• Paul J. LeBlanc, Ph.D., President, Southern New Hampshire University, Manchester, New Hampshire.
• Anne D. Neal, J.D., Senior Fellow, American Council of Trustees and Alumni, Washington, DC.
• Richard F. O'Donnell, Founder and CEO, Skills Fund, Austin, Texas.
• Steven Van Ausdle, Ph.D., President Emeritus, Walla Walla Community College, Walla Walla, Washington.
• Vacant.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Authority: 20 U.S.C. 1011c.

John B. King, Jr.,
Secretary of Education.

[FR Doc. 2016–31400 Filed 12–30–16; 8:45 am]
BILLING CODE P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2016–ICCD–0116]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Student Assistance General Provisions—Satisfactory Academic Progress Policy

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before February 2, 2017.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2016–ICCD–0116. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 224–84, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an

opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Student Assistance General Provisions—Satisfactory Academic Progress Policy.

OMB Control Number: 1845–0108.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments; Individuals and Households; Private Sector.

Total Estimated Number of Annual Responses: 33,543,341.

Total Estimated Number of Annual Burden Hours: 1,470,256.

Abstract: The Department of Education (the Department) is making this request is for an extension of the current approval of the policies and procedures for determining satisfactory academic progress (SAP) as required in Section 484 of the Higher Education Act of 1965, as amended (HEA). These regulations identify the policies and procedures to ensure that students are making satisfactory academic progress in their program at a pace and a level to receive or continue to receive Title IV, HEA program funds. If there is lapse in progress, the policy must identify how the student will be notified and what steps are available to a student not making satisfactory academic progress toward the completion of their program, and under what conditions a student who is not making satisfactory academic progress may continue to receive Title IV, HEA program funds.

Dated: December 28, 2016.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016–31777 Filed 12–30–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Fusion Energy Sciences Advisory Committee (FESAC)

AGENCY: Office of Science, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Fusion Energy Sciences Advisory Committee. The Federal Advisory Committee Act requires that public notice of these meetings be announced in the **Federal Register**.

DATES: February 1, 2017 8:30 a.m. to 5:00 p.m., February 2, 2017 8:30 a.m. to 12:00 noon.

ADDRESSES: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

FOR FURTHER INFORMATION CONTACT: Edmund J. Synakowski, Designated Federal Officer, Office of Fusion Energy Sciences (FES), U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585–1290, Telephone: (301) 903–4941.

SUPPLEMENTARY INFORMATION:

Purpose of the Committee: To provide advice on a continuing basis to the Director, Office of Science of the Department of Energy, on the many complex scientific and technical issues that arise in the development and implementation of the fusion energy sciences program.

Tentative Agenda Items

- DOE/SC Perspective
- FES Perspective
- Update on the ITER Project
- Status of the NSTX–U Project
- Update on the Wendelstein 7–X Project
- Public Comment
- Adjourn

Note: Remote attendance of the FESAC meeting will be possible via Zoom. Instructions will be posted on the FESAC Web site *(http://science.energy.gov/fes/fesac/meetings/)* prior to the meeting and can also be obtained by contacting Dr. Samuel J. Barish by email *sam.barish@science.doe.gov* or by phone (301) 903–2917.

Public Participation: The meeting is open to the public. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. If you would like to make an oral statement regarding any of the items on the agenda, you should contact Dr. Samuel J. Barish by fax at (301) 903–1233 or email at *sam.barish@science.doe.gov.* Reasonable provision will be made to include the scheduled oral statements during the Public Comments time on the agenda. The Chairperson of the Committee will conduct the meeting to facilitate the orderly conduct of business. Public comment will follow the 10-minute rule.

Minutes: The minutes of the meeting will be available for public review and copying within 30 days on the Fusion Energy Sciences Advisory Committee Web site at *http://science.energy.gov/fes/fesac/.*

Issued at Washington, DC, on December 23, 2016.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2016–31804 Filed 12–30–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Oak Ridge Reservation

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Oak Ridge Reservation. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, January 11, 2017 6:00 p.m.

ADDRESSES: Department of Energy Information Center, Office of Science and Technical Information, 1 Science.gov Way, Oak Ridge, Tennessee 37831.

FOR FURTHER INFORMATION CONTACT: Melyssa P. Noe, Alternate Deputy Designated Federal Officer, U.S. Department of Energy, Oak Ridge Office of Environmental Management, P.O. Box 2001, EM–942, Oak Ridge, TN 37831. Phone (865) 241–3315; Fax (865) 241–6932; Email: *Melyssa.Noe@orem.doe.gov.* Or visit the Web site at *www.energy.gov/orssab.*

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

- Welcome and Announcements
- Comments from the Deputy Designated Federal Officer (DDFO)
- Comments from the DOE, Tennessee Department of Environment and Conservation, and Environmental Protection Agency Liaisons
- Public Comment Period
- Discussion: Ongoing Groundwater Efforts
- Additions/Approval of Agenda
- Motions/Approval of November 9, 2016 Meeting Minutes
- Status of Recommendations with DOE
- Committee Reports
- Alternate DDFO Report
- Adjourn

Public Participation: The EM SSAB, Oak Ridge, 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 Melyssa P. Noe at least seven days in advance of the meeting at the phone 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 the agenda item should contact Melyssa P. Noe 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 Melyssa P. Noe at the address and phone number listed above. Minutes will also be available at the following Web site: *www.energy.gov/orssab.*

Issued at Washington, DC, on December 23, 2016.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2016–31810 Filed 12–30–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Nevada

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Nevada. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, January 18, 2017 4:00 p.m.

ADDRESSES: Frank H. Rogers Science and Technology Building, 755 East Flamingo, Las Vegas, Nevada 89119.

FOR FURTHER INFORMATION CONTACT: Barbara Ulmer, Board Administrator, 232 Energy Way, M/S 167, North Las Vegas, Nevada 89030. Phone: (702) 630–0522; Fax (702) 295–2025 or Email: *NSSAB@nnsa.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.

Tentative Agenda

1. Briefing for Corrective Action Alternatives for Corrective Action Unit 576, Miscellaneous Radiological Site and Debris—Work Plan Item #1
2. Briefing for Internal Peer Review Process Improvement—Work Plan Item #6

Public Participation: The EM SSAB, Nevada, 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 Barbara Ulmer at least seven days in advance of the meeting at the phone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral presentations pertaining to agenda items should contact Barbara Ulmer at the telephone number listed above. The request 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 can do so during the 15 minutes allotted for public comments.

Minutes: Minutes will be available by writing to Barbara Ulmer at the address listed above or at the following Web site: *http://www.nnss.gov/NSSAB/pages/MM_FY17.html.*

Issued at Washington, DC, on December 23, 2016.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2016–31808 Filed 12–30–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Portsmouth

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), Portsmouth. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Thursday, January 12, 2017 6:00 p.m.

ADDRESSES: Ohio State University, Endeavor Center, 1862 Shyville Road, Piketon, Ohio 45661.

FOR FURTHER INFORMATION CONTACT: Greg Simonton, Alternate Deputy Designated Federal Officer, Department of Energy Portsmouth/Paducah Project Office, Post Office Box 700, Piketon, Ohio 45661, (740) 897–3737, *Greg.Simonton@lex.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.

Tentative Agenda

- Call to Order, Introductions, Review of Agenda
- Approval of November 2016 Minutes
- Deputy Designated Federal Officer's Comments
- Federal Coordinator's Comments
- Liaison's Comments
- Presentation
- Administrative Issues
- Subcommittee Updates
- Public Comments
- Final Comments from the Board
- Adjourn

Public Participation: The meeting is open to the public. The EM SSAB, Portsmouth, 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 Greg Simonton at least seven days in advance

of the meeting at the phone 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 Greg Simonton 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 Greg Simonton at the address and phone number listed above. Minutes will also be available at the following Web site: *http://www.ports-ssab.energy.gov/.*

Issued at Washington, DC, on December 23, 2016.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2016–31807 Filed 12–30–16; 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 meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Northern New Mexico. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, January 25, 2017 1:00 p.m.–5:15 p.m.

ADDRESSES: Ohkay Conference Center, Highway 68, 1 Mile North of Española, Ohkay Owingeh, New Mexico 87566.

FOR FURTHER INFORMATION CONTACT: Menice Santistevan, Northern New Mexico Citizens' Advisory Board (NNMCAB), 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.

Tentative Agenda

- Call to Order
- Welcome and Introductions
- Approval of Agenda and Meeting Minutes of November 15, 2016
- Old Business
  - Report from Chair
- New Business
- Update from Co-Deputy Designated Federal Officers and Executive Director
  - 2017 Meeting Schedule
- Update on Technical Area 21
- Break
- Presentation: EM Los Alamos Field Office Fiscal Year 2016 Accomplishments
- Public Comment Period
- Updates from EM Los Alamos Field Office and New Mexico Environment Department
- Wrap-Up Comments from NNMCAB Members
- Adjourn

Public Participation: The EM SSAB, Northern New Mexico, 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 Menice Santistevan at least seven days 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 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 December 23, 2016.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2016–31803 Filed 12–30–16; 8:45 am]

BILLING CODE 6405–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Savannah River Site

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Savannah River Site. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES:

Monday, January 23, 2017—1:00 p.m.–4:45 p.m.

Tuesday, January 24, 2017—8:30 a.m.–4:00 p.m.

ADDRESSES: Marriott, One Hotel Circle, Hilton Head Island, SC 29928

FOR FURTHER INFORMATION CONTACT: James Giusti, Office of External Affairs, Department of Energy, Savannah River Operations Office, P.O. Box A, Aiken, SC, 29802; Phone: (803) 952–7684.

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

Monday, January 23, 2017

Opening and Agenda Review
Combined Committees Session
Order of committees:
- Facilities Disposition & Site Remediation
- Strategic & Legacy Management
- Waste Management
- Nuclear Materials
- Administrative & Outreach

Public Comments
Adjourn

Tuesday, January 24, 2017

Opening, Minutes Approval, Chair Update, and Agenda Review
Agency Updates
Public Comments
Break
Administrative & Outreach Committee Update
- Voting for Committee Chairs
- Voting on Standard Operating Procedure
- Recognition of Outgoing Members

Facilities Disposition & Site Remediation Committee Update
Lunch Break
Strategic & Legacy Management Committee Update

Waste Management Committee Update
Public Comments
Break
Nuclear Materials Committee Update
Public Comments
Adjourn

Public Participation: The EM SSAB, Savannah River Site, 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 James Giusti at least seven days in advance of the meeting at the phone 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 James Giusti's office at the address or telephone 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 James Giusti at the address or phone number listed above. Minutes will also be available at the following Web site: *http://cab.srs.gov/srs-cab.html.*

Issued at Washington, DC, on December 23, 2016.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2016–31802 Filed 12–30–16; 8:45 am]

BILLING CODE 6450–01–P

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 requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Thursday, January 19, 2017 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/2017_meetings.htm.*

Issued at Washington, DC, on December 23, 2016.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2016–31809 Filed 12–30–16; 8:45 am]

BILLING CODE 6450–01–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: ER11–4267–009; ER10–2682–009; ER11–113–010; ER11–4268–009; ER11–4269–010; ER11–4270–009; ER11–4694–006; ER12–1680–007.

Applicants: Algonquin Energy Services Inc., Algonquin Power Windsor Locks LLC, Algonquin Tinker Gen Co., Algonquin Northern Maine Gen Co., Sandy Ridge Wind, LLC, Granite State Electric Company, Minonk Wind, LLC, GSG 6, LLC.

Description: Triennial Market Power Update for the Northeast Region and Notice of Change in Status of Algonquin Energy Services Inc., et al.

Filed Date: 12/22/16.

Accession Number: 20161222–5588, 20161222–5590, 20161223–5327.

Comments Due: 5 p.m. ET 2/21/17.

Docket Numbers: ER15–2013–004, ER15–2020–003.

Applicants: Talen Energy Marketing, LLC, Talen Montana, LLC.

Description: Triennial Market Rate Based Update for Northwest Region of Talen Energy Marketing, LLC, et. al.

Filed Date: 12/22/16.

Accession Number: 20161222–5586.

Comments Due: 5 p.m. ET 2/21/17.

Docket Numbers: ER17–654–000.

Applicants: Arlington Valley Solar Energy II, LLC.

Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 12/24/2016.

Filed Date: 12/23/16.

Accession Number: 20161223–5245.

Comments Due: 5 p.m. ET 1/13/17.

Docket Numbers: ER17–655–000.

Applicants: Bluegrass Generation Company, L.L.C.

Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 12/24/2016.

Filed Date: 12/23/16.

Accession Number: 20161223–5254.

Comments Due: 5 p.m. ET 1/13/17.

Docket Numbers: ER17–656–000.

Applicants: Carville Energy LLC.

Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 12/24/2016.

Filed Date: 12/23/16.
Accession Number: 20161223–5263.
Comments Due: 5 p.m. ET 1/13/17.

Docket Numbers: ER17–657–000.
Applicants: Centinela Solar Energy, LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 12/24/2016.
Filed Date: 12/23/16.
Accession Number: 20161223–5269.
Comments Due: 5 p.m. ET 1/13/17.

Docket Numbers: ER17–658–000.
Applicants: Cherokee County Cogeneration Partners, LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 12/24/2016.
Filed Date: 12/23/16.
Accession Number: 20161223–5272.
Comments Due: 5 p.m. ET 1/13/17.

Docket Numbers: ER17–659–000.
Applicants: Columbia Energy LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 12/24/2016.
Filed Date: 12/23/16.
Accession Number: 20161223–5273.
Comments Due: 5 p.m. ET 1/13/17.

Docket Numbers: ER17–660–000.
Applicants: Decatur Energy Center, LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 12/24/2016.
Filed Date: 12/23/16.
Accession Number: 20161223–5274.
Comments Due: 5 p.m. ET 1/13/17.

Docket Numbers: ER17–661–000.
Applicants: DeSoto County Generating Company, LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 12/24/2016.
Filed Date: 12/23/16.
Accession Number: 20161223–5275.
Comments Due: 5 p.m. ET 1/13/17.

Docket Numbers: ER17–662–000.
Applicants: Doswell Limited Partnership.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 12/24/2016.
Filed Date: 12/23/16.
Accession Number: 20161223–5282.
Comments Due: 5 p.m. ET 1/13/17.

Docket Numbers: ER17–663–000.
Applicants: Las Vegas Power Company, LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 12/24/2016.
Filed Date: 12/23/16.
Accession Number: 20161223–5283.
Comments Due: 5 p.m. ET 1/13/17.

Docket Numbers: ER17–664–000.
Applicants: LS Power Marketing, LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 12/24/2016.
Filed Date: 12/23/16.
Accession Number: 20161223–5284.
Comments Due: 5 p.m. ET 1/13/17.

Docket Numbers: ER17–665–000.
Applicants: LSP University Park, LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 12/24/2016.
Filed Date: 12/23/16.
Accession Number: 20161223–5287.
Comments Due: 5 p.m. ET 1/13/17.

Docket Numbers: ER17–666–000.
Applicants: Mobile Energy LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 12/24/2016.
Filed Date: 12/23/16.
Accession Number: 20161223–5292.
Comments Due: 5 p.m. ET 1/13/17.

Docket Numbers: ER17–667–000.
Applicants: Renaissance Power, L.L.C.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 12/24/2016.
Filed Date: 12/23/16.
Accession Number: 20161223–5295.
Comments Due: 5 p.m. ET 1/13/17.

Docket Numbers: ER17–668–000.
Applicants: Riverside Generating Company, L.L.C.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 12/24/2016.
Filed Date: 12/23/16.
Accession Number: 20161223–5299.
Comments Due: 5 p.m. ET 1/13/17.

Docket Numbers: ER17–669–000.
Applicants: Santa Rosa Energy Center, LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 12/24/2016.
Filed Date: 12/23/16.
Accession Number: 20161223–5305.
Comments Due: 5 p.m. ET 1/13/17.

Docket Numbers: ER17–670–000.
Applicants: Seneca Generation, LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 12/24/2016.
Filed Date: 12/23/16.
Accession Number: 20161223–5306.
Comments Due: 5 p.m. ET 1/13/17.

Docket Numbers: ER17–671–000.
Applicants: University Park Energy, LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 12/24/2016.
Filed Date: 12/23/16.
Accession Number: 20161223–5307.
Comments Due: 5 p.m. ET 1/13/17.

Docket Numbers: ER17–672–000.
Applicants: Wallingford Energy LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 12/24/2016.
Filed Date: 12/23/16.
Accession Number: 20161223–5308.
Comments Due: 5 p.m. ET 1/13/17.

Docket Numbers: ER17–673–000.
Applicants: West Deptford Energy, LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 12/24/2016.
Filed Date: 12/23/16.
Accession Number: 20161223–5309.
Comments Due: 5 p.m. ET 1/13/17.

Docket Numbers: ER17–674–000.
Applicants: RRI Energy Services, LLC.
Description: Tariff Cancellation: Notice of Termination for FERC Electric Tariff, Original Volume No. 2 to be effective 12/23/2016.
Filed Date: 12/23/16.
Accession Number: 20161223–5313.
Comments Due: 5 p.m. ET 1/13/17.

Docket Numbers: ER17–675–000.
Applicants: Duke Energy Carolinas, LLC.
Description: § 205(d) Rate Filing: Amendment to SCPSA and CEPCI NITSA and Metering Agreements to be effective 1/1/2017.
Filed Date: 12/27/16.
Accession Number: 20161227–5035.
Comments Due: 5 p.m. ET 1/17/17.

Docket Numbers: ER17–676–000.
Applicants: Midcontinent Independent System Operator, Inc. Wolverine Power Supply Cooperative, Inc., Norton Rose Fulbright US LLP.
Description: § 205(d) Rate Filing: 2016–12–27_SA 2989 Wolverine-Spartan Renewable GIOA to be effective 12/30/2016.
Filed Date: 12/27/16.
Accession Number: 20161227–5038.
Comments Due: 5 p.m. ET 1/17/17.

Docket Numbers: ER17–677–000.
Applicants: Midcontinent Independent System Operator, Inc., Norton Rose Fulbright US LLP, Wolverine Power Supply Cooperative, Inc.
Description: § 205(d) Rate Filing: 2016–12–27_SA 2990 Wolverine-Spartan Renewable WDS to be effective 12/30/2016.
Filed Date: 12/27/16.
Accession Number: 20161227–5043.
Comments Due: 5 p.m. ET 1/17/17.

Docket Numbers: ER17–678–000.
Applicants: Midcontinent Independent System Operator, Inc., American Transmission Systems, Incorporated.
Description: § 205(d) Rate Filing: 2016–12–27_SA 2923 ATC-Quilt Block Wind Farm E&P (J395) Notice of Termination to be effective 12/28/2016.

Filed Date: 12/27/16.
Accession Number: 20161227–5049.
Comments Due: 5 p.m. ET 1/17/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: December 27, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–31840 Filed 12–30–16; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2015–0021; FRL–9956–39]

Pesticide Product Registrations; Receipt of Applications for New Active Ingredients

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received applications to register pesticide products containing active ingredients not included in any currently registered pesticide products. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before February 2, 2017.

ADDRESSES: Submit your comments, identified by the Docket Identification (ID) Number and the File Symbol of interest as shown in the body of this document, 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 Confidential Business Information (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.*

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *BPPDFRNotices@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).

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

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, EPA seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. Registration Applications

EPA has received applications to register pesticide products containing active ingredients not included in any currently registered pesticide products. Pursuant to the provisions of FIFRA section 3(c)(4) (7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by EPA on these applications. For actions being evaluated under EPA's public participation process for registration actions, there will be an additional opportunity for public comment on the proposed decisions. Please see EPA's public participation Web site for additional information on this process (*http://www2.epa.gov/pesticide-registration/public-participation-process-registration-actions).* EPA received the following applications to register pesticide products containing active ingredients not included in any currently registered pesticide products:

1. *File Symbol:* 67690–TT. *Docket ID Number:* EPA–HQ–OPP–2016–0251. *Applicant:* SePRO Corporation, 11550 North Meridian St., Suite 600, Carmel, IN 46032–4565. *Product Name:* Zio. *Active Ingredient:* Fungicide—*Pseudomonas chlororaphis* strain AFS009 at 50.0%. *Proposed Use:* Turf and ornamental plants.

2. *File Symbol:* 71840–EA. *Docket ID Number:* EPA–HQ–OPP–2016–0689. *Applicant:* BASF Corporation, 26 Davis Dr., P.O. Box 13528, Research Triangle Park, NC 27709. *Product Name:* Velondis Plus. *Active Ingredients:* Fungicide—*Bacillus subtilis* strain BU1814 at 1.706% and *Bacillus amyloliquefaciens* strain MBI 600 at 3.132%. *Proposed Use:* Seed treatment.

3. *File Symbol:* 71840–EG. *Docket ID Number:* EPA–HQ–OPP–2016–0689. *Applicant:* BASF Corporation, 26 Davis Dr., P.O. Box 13528, Research Triangle Park, NC 27709. *Product Name: Bacillus subtilis* strain BU1814 Technical. *Active Ingredient:* Fungicide—*Bacillus subtilis* strain BU1814 at 100%. *Proposed Use:* Manufacturing use.

4. *File Symbol:* 71840–EL. *Docket ID Number:* EPA–HQ–OPP–2016–0689. *Applicant:* BASF Corporation, 26 Davis Dr., P.O. Box 13528, Research Triangle Park, NC 27709. *Product Name:* Velondis Flex. *Active Ingredient:* Fungicide—*Bacillus subtilis* strain BU1814 at 1.706%. *Proposed Use:* Seed treatment.

5. *File Symbol:* 71840–EU. *Docket ID Number:* EPA–HQ–OPP–2016–0689. *Applicant:* BASF Corporation, 26 Davis Dr., P.O. Box 13528, Research Triangle Park, NC 27709. *Product Name:* Velondis Extra. *Active Ingredients:* Fungicide—*Bacillus subtilis* strain BU1814 at 0.213% and *Bacillus amyloliquefaciens* strain MBI 600 at 3.915%. *Proposed Use:* Seed treatment.

6. *File Symbol:* 90641–E. *Docket ID Number:* EPA–HQ–OPP–2016–0652. *Applicant:* Technology Sciences Group, Inc., 1150 18th St. NW., Suite 1000, Washington, DC 20036 (on behalf of Bee Vectoring Technology, Inc., 4160 Sladeview Crescent #7, Mississauga, Ontario L5L 0A1, Canada). *Product Name:* Vectorite with CR–7. *Active Ingredient:* Fungicide—*Clonostachys rosea* strain CR–7 at 4.2%. *Proposed Use:* Agricultural use.

7. *File Symbol:* 90641–R. *Docket ID Number:* EPA–HQ–OPP–2016–0652. *Applicant:* Technology Sciences Group, Inc., 1150 18th St. NW., Suite 1000, Washington, DC 20036 (on behalf of Bee Vectoring Technology, Inc., 4160 Sladeview Crescent #7, Mississauga, Ontario L5L 0A1, Canada). *Product Name:* CR–7 Technical. *Active Ingredient:* Fungicide—*Clonostachys rosea* strain CR–7 at 50%. *Proposed Use:* Manufacturing use.

Authority: 7 U.S.C. 136 *et seq.*

Dated: December 20, 2016.

Robert McNally,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 2016–31831 Filed 12–30–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2015–0022; FRL–9956–33]

Pesticide Product Registrations; Receipt of Applications for New Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before February 2, 2017.

ADDRESSES: Submit your comments, identified by the Docket Identification (ID) Number and the EPA Registration Number of interest as shown in the body of this document, 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 Confidential Business Information (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.*

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, EPA seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or

environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. Registration Applications

EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the provisions of FIFRA section 3(c)(4) (7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by EPA on these applications. For actions being evaluated under EPA's public participation process for registration actions, there will be an additional opportunity for public comment on the proposed decisions. Please see EPA's public participation Web site for additional information on this process (*http://www2.epa.gov/pesticide-registration/public-participation-process-registration-actions*). EPA received the following applications to register new uses for pesticide products containing currently registered active ingredients:

1. *EPA Registration Numbers:* 100–739, 100–1262, 100–1312, 100–1313, 100–1317, and 100–1554. *Docket ID Number:* EPA–HQ–OPP–2016–0254. *Applicant:* Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419. *Active Ingredient:* Difenoconazole. *Product Type:* Fungicide. *Proposed Use:* Cranberry; Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F; Guava; Kohlrabi; Papaya; Crop group conversion from Brassica, leafy greens, subgroup 5B to Brassica, leafy greens, subgroup 4–16B; and Crop group conversion from Brassica, head and stem, subgroup 5A to Vegetable, brassica, head and stem, group 5–16.

2. *EPA Registration Number:* 100–1481. *Docket ID Number:* EPA–HQ–OPP–2016–0640. *Applicant:* Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419. *Active Ingredient:* Indoxacarb. *Product Type:* Insecticide. *Proposed Use:* Commercial ornamental plant nurseries, pastures grazed by horses and other companion animals not used for consumption, and sod farms.

3. *EPA Registration Numbers:* 59639–139, 59639–140, and 59639–141. *Docket ID Number:* EPA–HQ–OPP–2016–0257. *Applicant:* Valent USA Corporation, P.O. Box 8025, Walnut Creek, CA 94596. *Active Ingredient:* Fluopicolide. *Product Type:* Fungicide. *Proposed Use:* Basil; Beans, succulent; Fruit, citrus, crop group 10–10; Hop, dried cones; Crop group conversion from Vegetable, fruiting, crop group 8 to Vegetable, fruiting, crop group 8–10; and Crop group expansion from Grape to Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F.

Authority: 7 U.S.C. 136 *et seq.*

Dated: December 20, 2016.

Robert McNally,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 2016–31829 Filed 12–30–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2016–0264; FRL–9957–21]

Agency Information Collection Activities; Proposed Renewal of an Existing Collection (EPA ICR No. 1246.13); Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces that EPA is planning to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). The ICR, entitled: ''Reporting and Recordkeeping for Asbestos Abatement Worker Protection'' and identified by EPA ICR No. 1246.13 and OMB Control No. 2070–0072, represents the renewal of an existing ICR that is scheduled to expire on August 31, 2017. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before March 6, 2017.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2016–0264, 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 Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 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.*

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Lea Carmichael, National Program Chemicals Division (7404T), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–4689; email address: *carmichael.lea@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What information is EPA particularly interested in?

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.

2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

3. Enhance the quality, utility, and clarity of the information to be collected.

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What information collection activity or ICR does this action apply to?

Title: Reporting and Recordkeeping for Asbestos Abatement Worker Protection.

ICR number: EPA ICR No. 1246.13.

OMB control number: OMB Control No. 2070–0072.

ICR status: This ICR is currently scheduled to expire on August 31, 2017. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: EPA's asbestos worker protection rule is designed to provide occupational exposure protection to state and local government employees who are engaged in asbestos abatement activities in states that do not have state plans approved by the Occupational Safety and Health Administration (OSHA). The rule provides protection for public employees not covered by the OSHA standard from the adverse health effects associated with occupational exposure to asbestos. Specifically, the rule requires state and local governments to monitor employee exposure to asbestos, take action to reduce exposure to asbestos, monitor employee health and train employees about asbestos hazards.

The rule includes a number of information reporting and recordkeeping requirements. State and local government agencies are required to provide employees with information about exposures to asbestos and the associated health effects. The rule also requires state and local governments to notify EPA before commencing any asbestos abatement project. State and local governments must maintain medical surveillance and monitoring records and training records on their employees, must establish a set of written procedures for respirator programs and must maintain procedures and records of respirator fit tests. EPA will use the information to monitor compliance with the asbestos worker protection rule. This request addresses these reporting and recordkeeping requirements.

Responses to the collection of information are mandatory (see 40 CFR 763 Subpart G). EPA will disclose information that is covered by a claim of confidentiality only to the extent permitted by, and in accordance with, the procedures in the Toxic Substances Control Act (TSCA) and 40 CFR part 2.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 0.32 hours per response. Burden is defined in 5 CFR 1320.3(b).

The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized here:

Respondents/Affected Entities: Entities potentially affected by this ICR are state and local government employers in 24 states, the District of Columbia, and certain U.S. Territories that have employees engaged in asbestos-related construction, custodial and brake and clutch repair activities without OSHA-approved state plans.

Estimated total number of potential respondents: 23,437.

Frequency of response: On occasion.

Estimated total average number of responses for each respondent: 49.9.

Estimated total annual burden hours: 372,969 hours.

Estimated total annual costs: $ 15,763,007. This includes an estimated burden cost of $ 15,763,007 and an estimated cost of $ 0 for capital investment or maintenance and operational costs.

III. Are there changes in the estimates from the last approval?

There is an overall increase of 9,452 hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB. This change reflects an increase of 24,371 hours to account for updates made from previous ICRs to standardize methodology and a decrease of 14,919 hours due to Maine's new status of having an OSHA-approved state plan whereby its entities are no longer covered under this ICR. This change is an adjustment.

IV. What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: December 22, 2016.

James Jones,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2016–31821 Filed 12–30–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OGC–2016–0776; FRL 9957–83–OGC]

Proposed Consent Decree, Clean Air Act Citizen Suit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Proposed Consent Decree; Request for Public Comment.

SUMMARY: In accordance with section 113(g) of the Clean Air Act, as amended (''CAA'' or the ''Act''), notice is hereby given of a proposed consent decree to address a lawsuit filed by Citizens for Clean Air and Sierra Club (''Plaintiffs'') in the United States District Court for the Western District of Washington: *Citizens for Clean Air, et al.* v. *McCarthy, et al.* No. 2:16–cv–01594–RAJ (W.D. WA.). On October 11, 2016, Plaintiffs filed a lawsuit alleging that Gina McCarthy, in her official capacity as Administrator of the United States Environmental Protection Agency and Dennis McLerran, in his official capacity as Regional Administrator of the United States Environmental Protection Agency, Region 10 (collectively, ''EPA''), failed to perform a duty mandated by CAA to make a determination as to whether the Fairbanks North Star Borough nonattainment area in Alaska attained the 2006 24-hour $PM_{2.5}$ NAAQS by December 31, 2015, and to publish a notice of that determination within six months of that date. If EPA determines that the area did not attain the 2006 24-hour $PM_{2.5}$ NAAQS by December 31, 2015, then the nonattainment area will be reclassified from ''moderate'' to a ''serious'' for these NAAQS. The proposed consent decree would establish deadlines for EPA to take certain specified actions.

DATES: Written comments on the proposed consent decree must be received by February 2, 2017.

ADDRESSES: Submit your comments, identified by Docket ID number EPA–HQ–OGC–2016–0776, online at *www.regulations.gov.* For comments submitted at *www.regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *www.regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA generally will not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets*.

FOR FURTHER INFORMATION CONTACT: Geoffrey L. Wilcox, Air and Radiation Law Office (2344A), Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone: (202) 564–5601; fax number: (202) 564–5603; email address: *wilcox.geoffrey@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Additional Information About the Proposed Consent Decree

The proposed consent decree would resolve a lawsuit filed by the Plaintiffs seeking to compel EPA to make a determination required under CAA section 188(b)(2), as to whether the Fairbanks North Star Borough nonattainment area in Alaska attained the 2006 24-hour $PM_{2.5}$ NAAQS by December 31, 2015. Under the terms of the proposed consent decree, no later than April 28, 2017, EPA will be required to sign a notice of final rulemaking determining whether the Fairbanks North Star Borough area attained the 2006 24-hour $PM_{2.5}$ NAAQS by December 31, 2015. If EPA determines that the area did not attain the NAAQS by that date, then EPA must reclassify the area as a ''serious'' nonattainment area for the 2006 24-hour $PM_{2.5}$ NAAQS pursuant to CAA section 188(b)(2). By statute, reclassification from ''moderate'' to ''serious'' is required by operation of law for an area that fails to attain the NAAQS by the outermost permissible attainment date for moderate nonattainment areas. This reclassification would obligate the State of Alaska to submit an attainment plan for the area that meets statutory and regulatory requirements applicable to a serious nonattainment area for these NAAQS. Under the proposed consent decree, EPA will also be required to deliver the signed final notice to the Office of Federal Register for review and publication within 15 business days after signature. See the proposed consent decree for the specific details.

For a period of thirty (30) days following the date of publication of this notice, the Agency will accept written comments relating to the proposed consent decree from persons who are not named as parties or intervenors to the litigation in question. EPA or the Department of Justice may withdraw or withhold consent to the proposed consent decree if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act. Unless EPA or the Department of Justice determines that consent to this proposed consent decree should be withdrawn, the terms of the consent decree will be affirmed.

II. Additional Information About Commenting on the Proposed Consent Decree

A. How can I get a copy of the proposed consent decree?

The official public docket for this action (identified by EPA–HQ–OGC–2016–0776) contains a copy of the proposed consent decree. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OEI Docket is (202) 566–1752.

An electronic version of the public docket is available through *www.regulations.gov.* You may use *www.regulations.gov* to submit or view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select ''search''.

It is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing online at *www.regulations.gov* without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. Information claimed as CBI and other information whose disclosure is restricted by statute is not included in the official public docket or in the electronic public docket. EPA's policy is that copyrighted material, including copyrighted material contained in a public comment, will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the EPA Docket Center.

B. How and to whom do i submit comments?

You may submit comments as provided in the **ADDRESSES** section. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment and with any disk or CD–ROM you submit. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the *www.regulations.gov* Web site to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an ''anonymous access'' system, which means EPA will not know your identity, email address, or other contact information unless you

provide it in the body of your comment. In contrast to EPA's electronic public docket, EPA's electronic mail (email) system is not an ''anonymous access'' system. If you send an email comment directly to the Docket without going through *www.regulations.gov,* your email address is automatically captured and included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

Dated: December 22, 2016.

Gautam Srinivasan,

Acting Associate General Counsel.

[FR Doc. 2016–31822 Filed 12–30–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2011–0855; FRL–9955–72]

Paraquat Dichloride Human Health Mitigation Decision; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's human health mitigation decision for the pesticide paraquat dichloride, case 0262. Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, that the pesticide can perform its intended function without causing unreasonable adverse effects on human health or the environment. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment. EPA may pursue mitigation at any time during the registration review process if it finds that a pesticide poses unreasonable adverse effects to human health or the environment. Based on the number and severity of paraquat human health incidents, the EPA believes that the mitigation measures outlined in this human health mitigation decision are necessary to address identified human health risk concerns.

FOR FURTHER INFORMATION CONTACT: *For pesticide specific information, contact:* Marianne Mannix, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 347–0275; email address: *Mannix.marianne@epa.gov.*

For general information on the registration review program, contact: Richard Dumas, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8015; email address: *dumas.richard@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the pesticide specific contact person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2011–0855, 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.*

II. What action is the agency taking?

Pursuant to 40 CFR 155.58(c), this notice announces the availability of EPA's human health mitigation decision for paraquat dichloride, case 0262. Paraquat is a widely used broad spectrum herbicide for the control of weeds in many agricultural and non-agricultural settings. It is also used as a desiccant on crops, prior to harvest. It is classified as restricted use due to high toxicity. An estimated 1.5 teaspoons (tsp) can be lethal if ingested and there is no known antidote. Paraquat dichloride is associated with a disproportionately high number of incidents including accidental ingestions typically leading to fatalities as well as occupational spills, splashes, and leaks resulting in severe and often damaging dermal or ocular contact. Paraquat is known to be corrosive to skin and eyes. EPA recently reviewed all available incident information and determined that mitigation measures to address these human health risk concerns are necessary.

In addition to the human health mitigation decision document, the registration review docket for paraquat dichloride also includes other relevant documents related to the registration review of this case. The proposed human health mitigation decision was posted to the docket in March 2016, and the public was invited to submit any comments or new information.

During the 60-day comment period, comments were received that resulted in changes to the Agency's human health mitigation decision, including that backpack and hand-held application methods will remain, but will require the development of special containers as part of a 'closed system' that prevents spills, mixing, pouring or other actions that could lead to paraquat exposure.

Pursuant to 40 CFR 155.58(c), the registration review case docket for paraquat dichloride will remain open until registration review has been completed.

Background on the registration review program is provided at: *http://www2.epa.gov/pesticide-reevaluation.* Links to earlier documents related to the registration review of this pesticide are provided at: *http://www.epa.gov/ingredients-used-pesticide-products/paraquat.*

Authority: 7 U.S.C. 136 *et seq.*

Dated: December 7, 2016.

Yu-Ting Guilaran,

Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2016–31832 Filed 12–30–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2015–0765; FRL–9957–77–ORD]

Board of Scientific Counselors Executive Committee; Notification of Public Meeting and Public Comment

AGENCY: Environmental Protection Agency.

ACTION: Notification of public meeting and public comment.

SUMMARY: Pursuant to the Federal Advisory Committee Act, the U.S. Environmental Protection Agency hereby provides notice that the Board of Scientific Counselors (BOSC) Executive Committee (EC) will host a public meeting at the EPA's Main Campus Facility, 109 T.W. Alexander Drive, Research Triangle Park, North Carolina 27711. The meeting will be held on Wednesday, January 11, 2017 from 9:00 a.m. till 6:00 p.m., Thursday, January 12, 2017 from 8:30 a.m. till 5:00 p.m. and Friday, January 13, 2017 from 8:30 a.m. till 11:00 a.m. All times noted are Eastern Time and are approximate. The primary discussions will focus on the draft reports from the BOSC subcommittees: Air, Climate and Energy, Chemical Safety for Sustainability, Safe and Sustainable Water Resources, and Sustainable and Healthy Communities. The EC will also deliberate on the four ORD Cross-Cutting Research Roadmap Annual Reports: Environmental Justice, Climate Change, Children's Environmental Health, and Nitrogen and Co-pollutant. There will be a public comment period from 10:05 a.m. to 10:20 a.m. Wednesday, January 11, 2017. For information on registering to attend the meeting or to provide public comment, please see the **SUPPLEMENTARY INFORMATION** section.

DATES: The BOSC EC meeting will be held on Wednesday, January 11, 2017 from 9:00 a.m. till 6:00 p.m., Thursday, January 12, 2017 from 8:30 a.m. till 5:00 p.m. and Friday, January 13, 2017 from 8:30 a.m. till 11:00 a.m. All times noted are Eastern Time and are approximate.

FOR FURTHER INFORMATION CONTACT: Questions or correspondence concerning the meeting should be directed to Tom Tracy, Designated Federal Officer, Environmental Protection Agency, by mail at 1200 Pennsylvania Avenue NW., (MC 8104 R), Washington, DC 20460; by telephone at 202–564–6518; fax at 202–565–2911; or via email at *tracy.tom@epa.gov.*

SUPPLEMENTARY INFORMATION: The Charter of the BOSC states that the advisory committee shall provide independent advice to the Administrator on technical and management aspects of the ORD's research program. Additional information about the BOSC is available at: *http://www2.epa.gov/bosc.*

Registration: In order to attend the meeting, you must register at the following site: *https://www.eventbrite.com/e/us-epa-2017-bosc-executive-committee-public-meeting-registration-30037268278.* Once you have completed the online registration, you will be contacted and provided with the meeting information. In-person participant registration will close on January 3, 2017. Virtual participant registration will close on January 9, 2017.

Oral Statements: Members of the public who wish to provide oral comment during the meeting must preregister. Individuals or groups making remarks during the public comment period will be limited to five (5) minutes. To accommodate the number of people who want to address the BOSC EC, only one representative of a particular community, organization, or group will be allowed to speak.

Written Statements: Written comments for the public meeting must be received by Monday, January 9, 2017, and will be included in the materials distributed to the BOSC EC prior to the meeting. Written comments should be sent to Tom Tracy, Environmental Protection Agency, via email at *tracy.tom@epa.gov* or by mail to 1200 Pennsylvania Avenue NW., (MC 8104 R), Washington, DC 20460, or submitted through *regulations.gov*, Docket ID No. EPA–HQ–ORD–2015–0765. Members of the public should be aware that their personal contact information, if included in any written comments, may be posted online at *regulations.gov*.

Information about Services for Individuals with Disabilities: For information about access or services for individuals with disabilities, please contact Tom Tracy, at 202–564–6518 or via email at *tracy.tom@epa.gov.* To request special accommodations, please contact Tom Tracy no later than August 19, 2016, to give the Environmental Protection Agency sufficient time to process your request. All requests should be sent to the address, email, or phone number listed in the **FOR FURTHER INFORMATION** section above.

Dated: December 16, 2016.

Fred S. Hauchman

Director, Office of Science Policy.

[FR Doc. 2016–31825 Filed 12–30–16; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

[BAC 6735–01]

Sunshine Act Meeting

December 29, 2016.

TIME AND DATE: 10:00 a.m., Friday, February 3, 2017.

PLACE: The Richard V. Backley Hearing Room, Room 511N, 1331 Pennsylvania Avenue NW., Washington, DC 20004 (enter from F Street entrance).

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following in open session: *Secretary of Labor on behalf of Greathouse, et al.* v. *Monongalia County Coal Company, et al.,* Docket Nos. WEVA 2015–904–D, et al. (Issues include whether the Judge erred in ruling that certain bonus plans instituted by the operators interfered with miners' rights under the Mine Act.)

Any person attending this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and § 2706.160(d).

CONTACT PERSON FOR MORE INFO: Emogene Johnson (202) 434–9935/(202) 708–9300 for TDD Relay/1–800–877–8339 for toll free.

PHONE NUMBER FOR LISTENING TO ARGUMENT: 1 (866) 867–4769; Passcode: 129–339.

Sarah L. Stewart,

Deputy General Counsel.

[FR Doc. 2016–31879 Filed 12–29–16; 11:15 am]

BILLING CODE 6735–01–P

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

[BAC 6735–01]

Sunshine Act Meeting

December 29, 2016.

TIME AND DATE: 10:00 a.m., Thursday, February 2, 2017.

PLACE: The Richard V. Backley Hearing Room, Room 511N, 1331 Pennsylvania Avenue NW., Washington, DC 20004 (enter from F Street entrance).

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will hear oral argument in the matter *Secretary of Labor on behalf of Greathouse, et al.* v. *Monongalia County Coal Company, et al.,* Docket Nos. WEVA 2015–904–D, *et al.* (Issues include whether the Judge erred in ruling that certain bonus plans instituted by the operators interfered with miners' rights under the Mine Act.)

Any person attending this oral argument who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and § 2706.160(d).

CONTACT PERSON FOR MORE INFO: Emogene Johnson (202) 434–9935/(202) 708–9300 for TDD Relay/1–800–877–8339 for toll free.

PHONE NUMBER FOR LISTENING TO ARGUMENT: 1 (866) 867–4769; Passcode: 129–339.

Sarah L. Stewart,

Deputy General Counsel.

[FR Doc. 2016–31878 Filed 12–29–16; 11:15 am]

BILLING CODE 6735–01–P

FEDERAL TRADE COMMISSION

[File No. 161 0126]

Abbott Laboratories and St. Jude Medical, Inc.; Analysis to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent orders—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before January 26, 2017.

ADDRESSES: Interested parties may file a comment at *https://ftcpublic.commentworks.com/ftc/abbottjudeconsent* online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''In the Matter of St. Jude Medical, Inc./Abbott Laboratories, File No. 161 0126- Consent Agreement'' on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/abbottjudeconsent* by following the instructions on the web-based form. If you prefer to file your comment on paper, write ''In the Matter of St. Jude Medical, Inc./Abbott Laboratories, File No. 161 0126—Consent Agreement'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Jordan Andrew (202–326–3678), Bureau of Competition, 600 Pennsylvania Avenue NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent orders to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for December 27, 2016), on the World Wide Web, at *http://www.ftc.gov/os/actions.shtm.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before January 26, 2017. Write ''In the Matter of St. Jude Medical, Inc./Abbott Laboratories, File No. 161 0126—Consent Agreement'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which . . . is privileged or confidential,'' as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/abbottjudeconsent* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment on paper, write ''In the Matter of St. Jude Medical, Inc./Abbott Laboratories, File No. 161 0126- Consent Agreement'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before January 26, 2017. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

Analysis of Agreement Containing Consent Orders To Aid Public Comment

Introduction

The Federal Trade Commission (''Commission'') has accepted, subject to final approval, an Agreement Containing Consent Orders (''Consent Agreement'') from Abbott Laboratories (''Abbott'') and St. Jude Medical, Inc. (''St. Jude'') that is designed to remedy the anticompetitive effects that otherwise would have resulted from Abbott's proposed acquisition of St. Jude. Under the terms of the proposed Consent Agreement, the parties are required to divest St. Jude's vascular closure device business and Abbott's steerable sheath business to Terumo Corporation (''Terumo''). Abbott is also required to provide notice if it intends to acquire the assets of Advanced Cardiac Therapeutics, Inc. (''ACT'').

The Consent Agreement has been placed on the public record for thirty days to solicit comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the Consent Agreement, along with the comments received, and decide whether it should withdraw from the Consent Agreement, modify it, or make final the Decision and Order (''Order'').

Pursuant to an Agreement and Plan of Merger dated April 27, 2016, Abbott proposes to acquire St. Jude in exchange for cash and stock valued at approximately $25 billion (the ''Proposed Acquisition''). The Commission's Complaint alleges that the Proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by lessening competition in the U.S. markets for vascular closure devices, steerable sheaths, and lesion-assessing ablation catheters. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that would otherwise be eliminated by the Proposed Acquisition.

The Parties

Headquartered in Abbott Park, Illinois, Abbott is a global health care company that offers a large portfolio of vascular products, including coronary, endovascular, vascular closure, electrophysiology, and structural heart devices.

St. Jude, headquartered in St. Paul, Minnesota, is a leading manufacturer of vascular products and medical devices. St. Jude's vascular products include vascular closure devices, pressure measurement guidewires, percutaneous catheter introducers, heart failure monitoring devices, cardiac mapping and navigation systems, diagnostic catheters, ablation catheters, and introducer sheaths.

The Relevant Products and Structure of the Markets

Vascular closure devices are used to close arterial holes resulting from vascular catheterization procedures. Physicians perform these catheterization procedures to diagnose or treat a cardiovascular condition. Typically, physicians access the femoral artery and direct a specialized catheter to the heart or peripheral arteries to deploy a balloon, diagnose an arrhythmia, or insert a stent or other device. The procedures leave a hole in the artery that must be closed quickly after the catheter is removed. Vascular closure devices provide a fast and effective way for physicians to close these holes while minimizing complications and the time patients must spend recovering from the procedure. Abbott and St. Jude are the two largest suppliers of vascular closure devices in the United States, with a combined market share of over 70%. The only other firms that supply vascular closure devices in the U.S. market are Cardinal Health, Inc. and Cardiva Medical, Inc.

Steerable sheaths are used in electrophysiology procedures to treat complex heart arrhythmias, such as atrial fibrillation. Unlike a fixed sheath, the tip of a steerable sheath is deflectable, which provides better maneuverability and stability for an ablation catheter. Steerable sheaths allow physicians to more easily puncture the transseptal wall of the heart and guide the sheath and catheter into the left atrium or ventricle of the heart. St. Jude is, by far, the largest supplier of steerable sheaths in the U.S. market. Abbott recently entered this market through its acquisition of Kalila Medical, Inc. (''Kalila'') in early 2016. Other suppliers in this market, though not recent entrants, have low single-digit market shares.

Lesion-assessing ablation catheters are used during ablation procedures to treat heart arrhythmias. They also provide feedback to physicians regarding the force being applied by the catheter or the temperature of the ablation target. These products are becoming more important, and more frequently used, as physicians treat more cases of complex atrial fibrillation. Currently, only St. Jude and Biosense Webster Inc. (''Biosense'') provide lesion-assessing ablation catheters in the United States. Abbott and ACT entered into a strategic partnership to develop lesion-assessing ablation catheters.

The United States is the relevant geographic market in which to assess the competitive effects of the Proposed Acquisition. Vascular closure devices, steerable sheaths, and lesion-assessing ablation catheters are all medical devices that are regulated by the FDA. Products that are sold outside the United States, but not approved for sale in the United States, are not alternatives for U.S. consumers.

Effects of the Acquisition

The Proposed Acquisition would cause significant competitive harm in the U.S. markets for vascular closure devices, steerable sheaths, and lesion-assessing ablation catheters. For vascular closure devices, the merger would combine the largest and second-largest suppliers in the United States. The merger would eliminate the substantial price competition that currently exists between these competitors.

In the market for steerable sheaths, St. Jude is currently the largest supplier in the United States and has held a near-monopoly position in this market for over a decade. Abbott entered this market recently and its product is well positioned to compete head-to-head with St. Jude. The Proposed Acquisition would eliminate the competition that would have occurred between Abbott and St. Jude in this market.

Finally, if Abbott acquires ACT's lesion-assessing ablation catheter assets, it could eliminate potential competition in the U.S. market for lesion-assessing ablation catheters. ACT's lesion-assessing ablation catheter currently in development would compete directly with offerings from St. Jude and Biosense. It would thus be the third competitor in the highly-concentrated U.S. market for lesion-assessing ablation catheters. Abbott's acquisition of the ACT assets would reduce the additional competition that would have resulted from an additional U.S. supplier of lesion-assessing ablation catheters.

Entry

Entry into the U.S. markets for vascular closure devices, steerable sheaths, and lesion-assessing ablation catheters would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisition. The development process for each of these devices is difficult, time-consuming, and expensive. It can take tens of millions of dollars of research and development, significant

further funding for clinical trials, and an extensive amount of time to even reach the stage of applying to the FDA for approval. The regulatory approval process itself can also be time-consuming as the FDA reviews the volume of material and data a company submits in support of its application.

The Consent Agreement

The Consent Agreement remedies the competitive concerns raised by Abbott's proposed acquisition of St. Jude by requiring that the parties divest to Terumo all of the assets and resources needed for it to become an independent, viable, and effective competitor in the U.S. markets for vascular closure devices and steerable sheaths. It also requires Abbott to provide notice if it intends to acquire ACT's lesion-assessing ablation catheter assets.

Terumo possesses the industry experience and reputation necessary to replace competition that would be lost in the U.S. markets for vascular closure devices and steerable sheaths. Terumo is headquartered in Tokyo, Japan. It has been active in the U.S. medical device market for over thirty years and has a U.S. subsidiary based in Somerset, New Jersey. Terumo offers a portfolio of products that are highly complementary to the vascular closure and steerable sheath products being acquired but does not sell any competing products. Through its Interventional Systems business unit, Terumo manufactures and sells guidewires, catheters, and sheaths, as well as other vascular access devices. As a result, it currently sells its products to many of the same customers as Abbott and St. Jude. Terumo is thus well positioned to restore the benefits of competition that would be lost through the Proposed Acquisition.

Pursuant to the Order, Terumo will receive all rights and assets related to St. Jude's vascular closure device business and Abbott's steerable sheath business, including all of the intellectual property used in those businesses. In addition, Terumo will take over part of the facility in Caguas, Puerto Rico where St. Jude currently manufactures most of its vascular closure device products. In order to ensure continuity of supply for certain vascular closure devices and components that are not currently manufactured in the Puerto Rico facility, the Order requires that St. Jude supply Terumo with finished vascular closure devices and components for up to two years while Terumo transitions to independent manufacturing.

To ensure that the divestiture is successful, the Order requires the parties to enter into a transitional services agreement with Terumo to assist the company in establishing its manufacturing capabilities. Further, the Order requires that the parties transfer all confidential business information to Terumo, as well as provide access to employees who possess or are able to identify such information. Terumo also will have the right to interview and offer employment to employees associated with St. Jude's vascular closure device business and Abbott's steerable sheath business.

The parties must accomplish the divestiture no later than forty-five days after the consummation of the Proposed Acquisition. If the Commission determines that Terumo is not an acceptable acquirer, or that the manner of the divestiture is not acceptable, the Order requires the parties to unwind the sale and accomplish the divestiture within 180 days of the date the Order becomes final to another Commission-approved acquirer.

To ensure compliance with the Order, the Commission has agreed to appoint an Interim Monitor to ensure that Abbott and St. Jude comply with all of their obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of the rights and assets to Terumo. Further, the Order allows the Commission to appoint a Divestiture Trustee to accomplish the divestiture should the parties fail to comply with their divestiture obligations. Lastly, the Order terminates after ten years.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

April J. Tabor,

Acting Secretary.

[FR Doc. 2016–31800 Filed 12–30–16; 8:45 am]

BILLING CODE 6750–01–P

GENERAL SERVICES ADMINISTRATION

[Notice–MA–2016–08; Docket No. 2016–0002; Sequence No. 31]

Federal Management Regulations; Transportation Prepayment Audit Requirements

AGENCY: Office of Government-wide Policy, General Services Administration (GSA).

ACTION: Notice of a bulletin.

SUMMARY: GSA has issued a guidance for agencies and wholly-owned Government corporations, which provides a deadline to comply with recent regulatory changes that prohibit agencies from using prepayment auditors that have any affiliation with, or financial interest, in the transportation company (providing the transportation services) for which a prepayment audit is being conducted.

DATES: *Effective:* January 3, 2017.

FOR FURTHER INFORMATION CONTACT: Mr. Ron Siegel, Program Analyst, Office of Government-wide Policy (MAF), Office of Asset and Transportation Management, General Services Administration at 202–357–9540, or via email at *ron.siegel@gsa.gov.* Please cite FMR Bulletin D–03.

SUPPLEMENTARY INFORMATION: FMR Bulletin D–03 provides guidance to all agencies (including the Department of Defense) and wholly-owned Government corporations as defined in 31 United States Code (U.S.C.) 101, *et seq.* and 31 U.S.C. 9101(3). This bulletin provides agencies notice of a governmentwide policy revision for mandatory transportation prepayment audit plans, and provides a deadline for compliance with regulatory changes provided in FMR 102–118, Transportation Payment and Audit. FMR Bulletin D–03 and all other FMR bulletins are located at *http://www.gsa.gov/fmrbulletins.*

Kevin Kampschroer,

Associate Administrator (Acting), Office of Government-wide Policy, General Services Administration.

[FR Doc. 2016–31786 Filed 12–30–16; 8:45 am]

BILLING CODE 6820–14–P

OFFICE OF GOVERNMENT ETHICS

Request for Public Input on the Application of the Criminal Conflict of Interest Prohibition to Certain Beneficial Interests in Discretionary Trusts.

AGENCY: Office of Government Ethics (OGE).

ACTION: Notice of request for public comments.

SUMMARY: This notice and request seeks input from members of the public with expertise in trust law concerning the following question: Are there any circumstances under which an eligible income beneficiary of a discretionary trust might, in the absence of a vested remainder interest, be able to compel the trust to make a distribution or payment? OGE will take into consideration all relevant expert input submitted by the public within 60 days of the date of this notice. To be

considered, any submission exceeding five (5) pages in length must include a one-page summary of key points and conclusions. Commenters are requested to state briefly the nature of their expertise in trust law.

DATES: To be assured consideration, comments must be received at the address provided below, by no later than 5:00 p.m. on March 6, 2017.

ADDRESSES: You may submit comments, in writing, to OGE regarding this notice and request by any of the following methods:

E-Mail: usoge@oge.gov. Include the reference ''Request for Input on Discretionary Trusts'' in the subject line of the message.

Fax: (202) 482–9237.

Mail/Hand Delivery/Courier: U.S. Office of Government Ethics, Suite 500, 1201 New York Avenue NW., Washington, DC 20005–3917, Attention: ''Request for Input on Discretionary Trusts.''

Instructions: All submissions must include OGE's agency name and the words ''Discretionary Trusts.'' All comments, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Comments may be posted on OGE's Web site, *www.oge.gov.* Sensitive personal information, such as account numbers or Social Security numbers, should not be included. Comments generally will not be edited to remove any identifying or contact information.

FOR FURTHER INFORMATION CONTACT: Jennifer A. Matis, Assistant Counsel, Office of Government Ethics, Suite 500, 1201 New York Avenue NW., Washington, DC 20005–3917; Telephone: 202–482–9300; TTY: 800–877–8339; FAX: 202–482–9237.

SUPPLEMENTARY INFORMATION: During the administration of President George W. Bush, a former Director of the U.S. Office of Government Ethics (OGE), Hon. Robert I. Cusick, issued a guidance memorandum addressing a novel legal issue concerning the application of the primary criminal conflict of interest statute to the interests of eligible income beneficiaries of discretionary trusts who lack vested remainder interests. *Discretionary Trusts,* DO–08–024 (2008). That conflict of interest statute, 18 U.S.C. 208, prohibits an executive branch employee from participating personally and substantially in any particular matter that directly and predictably affects a ''financial interest'' of either the employee or a person whose interests are imputed to the employee (*e.g.,* the. employee's spouse or minor child). *See* 5 CFR part 2640, subpart A. The 2008 memorandum articulated OGE's conclusion that, for purposes of the conflict of interest statute, an eligible income beneficiary of a discretionary trust would not be considered to have a financial interest in the holdings of the trust, provided that the beneficiary was not the grantor and did not have a vested remainder interest. *Discretionary Trusts,* DO–08–024 (2008). The premise underlying OGE's conclusion was that such a beneficiary could never have an ''enforceable right to payment.'' *Id.* at 1. For this premise OGE relied upon the American Law Institute's Second Restatement of the Law of Trusts. *Id.* (citing Restatement of the Law (Second) Trusts, § 155).

In 2013, OGE issued a second guidance memorandum on the topic of reporting requirements applicable to a beneficiary who could meet the requirements articulated in its 2008 memorandum. The 2013 memorandum clarified that such a beneficiary would not have to report the holdings of the discretionary trust in an executive branch financial disclosure report filed under the Ethics in Government Act, 5 U.S.C. app. 101, *et seq.,* in the event that the beneficiary were to receive income from the trust during the reporting period, though the beneficiary would have to report the income itself. *Reporting Requirements for Discretionary Trusts,* LA–13–04 (April 9, 2013). The 2013 memorandum did not otherwise modify the 2008 memorandum or revisit its underlying premise.

The 2008 memorandum, which OGE has continued to apply, is based wholly on the premise that there are no circumstances under which such a beneficiary could ever compel a distribution or payment from a discretionary trust. This month, however, OGE learned that the American Law Institute's Third Restatement of the Law of Trusts may suggest a contrary analysis as to the financial interests of eligible income beneficiaries of discretionary trusts, at least in some jurisdictions. *See* Restatement of the Law (Third) Trusts, § 60, cmt. e (Am. Law Inst. 2003) (''A transferee or creditor of a trust beneficiary cannot compel the trustee to make discretionary distributions if the beneficiary personally could not do so. It is rare, however, that the beneficiary's circumstances, the terms of the discretionary power, and the purposes of the trust leave the beneficiary so powerless. The exercise or nonexercise of fiduciary discretion is always subject to judicial review to prevent abuse.'').

This discovery drew OGE's attention to an article in the Quinnipiac Probate Law Journal by Alan Newman, Professor of Law for the University of Akron School of Law. *See* Newman, Alan, *Trust Law in the Twenty-First Century: Challenges to Fiduciary Accountability,* 29 Quinnipiac Prob. L.J. 261 (2016). Professor Newman writes,

> ''[I]f, in fact, the beneficiary of a discretionary trust had only an expectancy with respect to the trust, arguably the beneficiary would be unable to hold the trustee accountable to enforce the trust. However, as noted elsewhere, 'the difficulty with this theory is that it is not true.' Although there is a longstanding debate whether a beneficiary of a trust has a property interest in the trust assets, merely a claim against the trustee, or both, it is well-established that: (i) the beneficiary's interest in the trust itself is property, regardless of whether the trust terms provide that distributions to the beneficiary are at the trustee's discretion; and (ii) the beneficiary may enforce them.

Id. at 282 (quoting Jesse Dukeminier & Robert H. Sitkoff, Wills, Trusts, and Estates 689 (9th ed. 2013)).

Professor Newman further explains that cases denying the claims of a beneficiary's creditors against the trust reflect only a ''policy-oriented'' approach to addressing the claims of creditors and do not necessarily stand as evidence that the beneficiary lacks ''an enforceable property interest with respect to the trust.'' *Id.* at 283. At the time of its 2008 memorandum, OGE's research focused on cases addressing the rights of creditors or the eligibility of beneficiaries for public assistance, but Professor Newman's article raises a question as to whether OGE should have focused instead on cases addressing the rights of beneficiaries as to trustees of discretionary trusts. *See, e.g., id* at 284 (''[R]ecently enacted statutes stating that beneficiaries of discretionary trusts do not have property interests with respect to those trusts are part of the enacting jurisdictions' trust codes addressing the rights of beneficiaries' creditors, not the relationship between the trustee and beneficiaries, and appear intended to apply only in the creditors' rights context.'').

OGE reviewed one of the cases cited in Professor Newman's article. In that case, the Seventh Circuit wrote,

> We see no reason why a beneficiary, simply by virtue of being the beneficiary of discretionary trust, should be denied the ordinary equitable rights that flow from the fiduciary duty that runs from a trustee to a beneficiary. Included in those rights is the right to bring an action for breach of trust.

Scanlan v. *Eisenberg,* 669 F.3d 838, 844 (7th Cir. Ill. 2012). The plaintiff in

that case, a beneficiary of several trusts, sued for malpractice and breach of fiduciary duty after the trusts invested millions of dollars in a real estate investment trust that later went bankrupt. The Seventh Circuit found that an eligible beneficiary possessed the required stake to establish standing as a result of her interest in the trust. *Id.* at 846. To the extent that the plaintiff had standing by virtue of being affected by the trust's potential for gain or loss, that ''stake'' would appear to meet OGE's definition of a disqualifying financial interest for purposes of the conflict of interest prohibition. *See* 5 CFR 2640.103(b) (''the term financial interest means the potential for gain or loss'').

Other cases also seem to lead to this conclusion. For example, a New York court similarly provided the following guidance, under the trust law of that state, as to the rights of the beneficiary of a discretionary trust:

> In the present case, the trustees' discretion is absolute and not limited by any standard. However, even in such a case, the trustees may be compelled to distribute funds to the beneficiary if they abuse their discretion in refusing to make distribution.

Estate of Gilbert, 156 Misc. 2d 379, 383 (N.Y. Sur. Ct. 1992). Likewise, a California court held that, under that state's trust law, a trustee who has discretion to make or withhold a payment, may not withhold a payment with the intent of avoiding child support. *Ventura County Dept. of Child Support Services* v. *Brown,* 117 Cal. App. 4th 144, 150 (Cal. App. 2d Dist. 2004) (quoting Prof. Russell Niles, consultant to Cal. Law Revision Com., Memo Re Spendthrift and Related Trusts (Nov. 6, 1984)). In the California case, the outcome may well have been determined in part by language in the trust instrument requiring that the trust be administered for the benefit of the beneficiary's children in the event of the beneficiary's death, *see id.* at 148; however, this contributing factor would serve only to complicate the issue for OGE by leaving open the possibility that subtle variations in trust language may be relevant in determining the existence of a financial interest for purposes of the conflict of interest law.

Because it is not clear to OGE whether these materials represent the rule, an exception, or differing approaches to trust law in various jurisdictions, OGE would benefit from the input of members of the public who have expertise in trust law. Specifically, OGE seeks expert input concerning the following question: *Are there any circumstances under which an eligible income beneficiary of a discretionary trust might, in the absence of a vested remainder interest, be able to compel the trust to make a distribution or payment?* Should this question be appropriately answered in the affirmative, OGE may need to revisit the premise underlying its 2008 guidance memorandum on discretionary trusts—*i.e.,* that such a beneficiary could never have enforceable right to a distribution or payment from the trust. OGE will take into consideration all relevant expert input submitted by the public within 60 days of the date of this notice in response to the question posed before evaluating the continuing validity of OGE's guidance memorandum, *Discretionary Trusts,* DO–08–024 (2008). To be considered, any submission exceeding five (5) pages in length must include a one-page summary of key points and conclusions. Commenters are requested to state briefly the nature of their expertise in trust law.

Approved: December 23, 2016.

Walter M. Shaub, Jr.

Director, U.S. Office of Government Ethics.

[FR Doc. 2016–31583 Filed 12–30–16; 8:45 am]

BILLING CODE 6345–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[60Day–17–17IY; Docket No. ATSDR–2016–0007]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Agency for Toxic Substances and Disease Registry (ATSDR), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on ''Biomonitoring of Great Lakes Populations Program III.'' The purpose of the proposed study is to evaluate body burden levels of priority contaminants in Great Lakes residents, particularly those who are at high exposure risk, in the Milwaukee Bay Estuary Area of Concern (AOC) area that was not previously addressed in ATSDR's previous biomonitoring programs around the Great Lakes.

DATES: Written comments must be received on or before March 6, 2017.

ADDRESSES: You may submit comments, identified by Docket No. ATSDR–2016–0007 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

Please note: All public comment should be submitted through the Federal eRulemaking portal (*Regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have

practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Biomonitoring of Great Lakes Populations Program III—New—Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

The Agency for Toxic Substances and Disease Registry (ATSDR) is requesting a three-year Paperwork Reduction Act (PRA) clearance for a new information collection request (ICR) titled ''Biomonitoring of Great Lakes Populations Program III.'' ATSDR awarded funds to the Wisconsin Department of Health Services (WIDHS) to conduct this information collection under cooperative agreement #NU61TS000269–01–00. The purpose of the current program is to evaluate body burden levels of legacy and emerging contaminants in susceptible Great Lakes populations in the Milwaukee Estuary Area of Concern (AOC) in Wisconsin, an area that has not been previously covered by other Great Lakes initiatives.

The Great Lakes Basin has suffered decades of pollution and ecosystem damage. Many chemicals persist in Great Lakes waters and sediments, as well as in wildlife. These chemicals can build up in the aquatic food chain, and eating contaminated fish is a known route of human exposure.

In 2009, the Great Lakes Restoration Initiative (GLRI) was enacted by Public Law 111–88 to make restoration and protection of the Great Lakes a national priority. The GLRI is led by the U.S. Environmental Protection Agency (US EPA). Under a 2015 interagency agreement with the US EPA, ATSDR initiated the Biomonitoring of Great Lakes Populations Program III program. This project will provide additional public health information to supplement the previous cooperative agreement programs CDC–RFA–TS10–1001 ''Biomonitoring of Great Lakes Populations'' (hereafter referred to as ''Program I,'' OMB Control Number 0923–0044) and CDC–RFA–TS13–1302 ''Biomonitoring of Great Lakes Populations-II'' (hereafter referred to as ''Program II,'' OMB Control Number 0923–0052) initiated in FY2010 and FY2013, respectively.

WIDHS received funding for the current program. WIDHS will recruit and enroll two subpopulations of adults in the Milwaukee Bay Estuary Area of Concern (AOC) who are known to eat fish from the Milwaukee River Basin and Lake Michigan. This study will not include pregnant women.

The target populations are: (1) Licensed anglers living in proximity to the Milwaukee Estuary AOC and (2) Burmese refugees who are known to eat a substantial amount of fish from this area. WIDHS study staff will work closely with local refugee and citizen support organizations on participant recruitment.

The aims of the information collection in this surveillance project are:

1. Assess levels of contaminants (metals, polychlorinated biphenyls, chlorinated pesticides, perfluorinated compounds, and polyaromatic hydrocarbons) in blood and urine of residents who consume fish from contaminated areas that had not been studied in previous Programs I and II;

2. Use the project findings to inform public health officials and offer guidance on public health actions to reduce exposure to Great Lakes contaminants.

This applied public health program aims to measure contaminants in biological samples (blood, urine and hair) from people who may be at high risk of chemical exposure in the Great Lakes area. These measurements will provide a baseline for current and future restoration activities. The results will be compared to available national estimates, such as those reported by the National Health and Nutrition Examination Survey (NHANES).

Respondents will be screened for eligibility and consent will be obtained. Participants who consent will respond to a questionnaire and participate in clinic visits for body measurements and biological specimen collection (blood, urine, and hair). Their blood will be tested for polychlorinated biphenyls, metals, perfluorinated compounds, persistent pesticides, and lipids. Urine will be tested for polycyclic aromatic hydrocarbons and creatinine. The hair samples (optional) will be saved for a later analysis.

Respondents will also be interviewed. They will be asked about demographic and lifestyle factors, hobbies, health conditions that may affect fish consumption and fishing habits, and types of jobs which can contribute to chemical exposure. Some dietary questions will be asked with a focus on consumption of Great Lakes fish.

Participation in the study is voluntary and there is no cost to respondents other than their time. The estimated annualized burden for the program averaged over the three-year study period is 231 hours among 166 respondents. There is no cost to respondents other than their time spent in the study.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Licensed Anglers	Eligibility Screening Survey (paper)	156	1	5/60	13
	Eligibility Screening Survey (online)	28	1	5/60	2
	Study Questionnaire (paper)	58	1	30/60	29
	Study Questionnaire online)	87	1	30/60	44
	Clinic Visit Checklist and Body Measurements.	133	1	35/60	78

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Burmese Refugees	Follow-up Survey	133	1	5/60	11
	Eligibility Screening Survey	42	1	5/60	4
	Contact Information Form	33	1	5/60	3
	Study Questionnaire	33	1	40/60	22
	Clinic Visit Checklist and Body Measurements.	33	1	35/60	19
	Network Size Questions	33	1	5/60	3
	Follow-up Survey	33	1	5/60	3
Total					231

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2016–31772 Filed 12–30–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[60Day-17–17IV; Docket No. ATSDR–2016–0008]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Agency for Toxic Substances and Disease Registry (ATSDR), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the information collection request titled ''APPLETREE Performance Measures.'' Under the APPLETREE cooperative agreement program (Funding Opportunity Announcement No. CDC–RFA–TS17–1701), awardees will be required to submit an Annual Plan of Work (APOW), several standardized outcome and performance measures, and an Annual Performance Report (APR).

DATES: Written comments must be received on or before March 6, 2017.

ADDRESSES: You may submit comments, identified by Docket No. ATSDR–2016–0008 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

Please note: All public comment should be submitted through the Federal eRulemaking portal (*Regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov*.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

APPLETREE Performance Measures—New—Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

The Agency for Toxic Substances and Disease Registry (ATSDR) serves the public through responsive public health actions to promote healthy and safe environments and to prevent harmful exposures in communities across the nation. ATSDR's Partnership to Promote Local Efforts to Reduce Environmental Exposure (APPLETREE) Program is critical to ATSDR's success in this mission. The purpose of the program is to: (1) Identify pathways of exposure to hazardous substances at hazardous waste sites and releases; (2) identify, implement, and coordinate public health interventions to reduce exposures to hazardous substances which occur at levels of health concern; and (3) provide training at the state level to promote and achieve the safe siting of child care facilities in the United States. The APPLETREE Program is also a mechanism which enhances ATSDR's communication with state, local, and federal health and environmental agencies. This program is authorized under Sections 104(i)(15) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986 [42 U.S.C. 9604(i)(15)].

Under the new three-year APPLETREE cooperative agreement (Funding Opportunity Announcement No. CDC–RFA–TS17–1701), eligible applicants include federally recognized American Indian/Alaska Native tribal governments; American Indian/Alaska native tribally designated organizations; political subdivisions of states (in consultation with states); and state and local governments or their bona fide agents. ATSDR technical project officers (TPOs) will assist approximately 25 APPLETREE awardees to address site-specific issues involving human exposure to hazardous substances. Key capacities include identification of human exposure pathways at ATSDR sites, education of affected communities and local health professionals about site contamination and potential health effects; making appropriate recommendations to prevent exposure; reviewing health outcome data to evaluate potential links between site contaminants and community health; and documenting the effects of environmental remediation on health.

ATSDR will collect information related to awardee activities, and the process and outcome performance measures outlined by the cooperative agreement program. Information will be used to monitor progress toward program goals and objectives, and for quality improvement.

Annual Plan of Work (APOW): Each budget year, awardees shall deliver an APOW. The APOW will include awardee workplans for site-specific activities, environmental health assessment outputs, and overarching milestones for child care safe siting activities. The estimated annual time burden to prepare and report the APOW is eight hours per awardee.

ATSDR Health Education Activity Tracking (HEAT) Performance Measure: For each environmental health assessment and health education activity conducted at ATSDR sites, APPLETREE awardees shall quantitatively assess and report efforts to educate community members about site recommendations and health risks using indicators to assess community understanding of site findings about health risks and community understanding of agency recommendations to reduce health risks. This information will be entered in to the ATSDR HEAT system for each activity at ATSDR sites. Based on past experience, ATSDR assumes a maximum of 925 activities will be entered into the HEAT database each year; therefore, each of the 25 awardees will enter an average of 37 activities into the HEAT database.

ATSDR Site Impact Assessment (SIA) Performance Measure: For each environmental health assessment and health education activity conducted at ATSDR sites, awardees shall estimate and report the number of people protected from exposure to toxic substances at each site where implementation of agency recommendations has taken place and at each child care center where safe siting guidelines have been implemented. To the extent possible, awardees shall estimate the disease burden prevented due to the implementation of site recommendations and safe siting guidelines. This information will be entered into the ATSDR SIA database by the awardee. ATSDR assumes a maximum of 150 ATSDR sites will undergo an environmental assessment, or an average of 6 sites per awardee, per year.

APPLETREE Annual Performance Report (APR): Awardees must provide an APR at the end of each budget year. The report must include a minimum of three site activity success stories; a synopsis of the number of people involved in environmental health assessments at sites, the number of public health recommendations accepted, the number of health education activities conducted at sites; and the outcomes achieved during the budget year. The APR must also demonstrate annual progress in implementing child care safe siting policies in their jurisdictions over the three-year program period. ATSDR assumes that ASARs will take 15 burden hours for each awardee to prepare.

ATSDR seeks to request a three-year clearance from OMB to collect the necessary information for this project.

The awardee reporting is a requirement of the APPLETREE cooperative agreement. The total annual time burden requested is 635 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents per year	Number of responses per respondent per year	Average burden per response (in hours)	Total burden (in hours)
APPLETREE Awardees	Annual Plan of Work (APOW)	25	1	8	200
	ATSDR Health Education Activity Tracking (HEAT) Form.	25	37	3/60	47
	ATSDR Site Impact Assessment (SIA) Form.	25	6	5/60	13
	APPLETREE Annual Performance Report (APR).	25	1	15	375
Total					635

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2016–31773 Filed 12–30–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–4436]

Premarket Notification (510(k)) Submissions for Bone Anchors; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Premarket Notification (510(k)) Submissions for Bone Anchors.'' The guidance provides recommendations for the information and testing that should be included in premarket submissions for bone anchor (suture anchor) devices used in the appendicular skeleton for attachment of soft tissue to bone. This draft guidance is not final nor is it in effect at this time.

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 of 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 March 6, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* 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–4436 for ''Premarket Notification (510(k)) Submissions for Bone Anchors.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the 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 *https://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 *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Premarket Notification (510(k)) Submissions for Bone Anchors'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Daniel Ramsey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1451, Silver Spring, MD 20993–0002, 301–796–6451.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled '''Premarket Notification (510(k)) Submissions for Bone Anchors.'' FDA has developed this guidance document for members of industry who submit and FDA staff who review premarket submissions regarding bone anchor (suture anchor) devices used in the appendicular skeleton for attachment of soft tissue to bone. When finalized, this guidance is intended to provide recommendations for information to include in premarket notifications (510(k)) for bone anchor (suture anchor) devices (*e.g.,* descriptive characteristics, labeling, biocompatibility, sterility, and bench testing). This guidance is a reissuance of the April 20, 1996 ''Guidance Document for Testing Bone Anchor Devices'' with updated content.

II. Significance of Guidance

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 the current thinking of FDA on Premarket Notification (510(k)) Submissions for Bone Anchors. 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.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Premarket Notification (510(k)) Submissions for Bone Anchors'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1400005 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft 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 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

Dated: December 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31779 Filed 12–30–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1428]

Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a guidance for industry entitled ''Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' The final guidance addresses new provisions in the Federal Food, Drug, and Cosmetic Act (the FD&C Act) added by the Drug Quality and Security Act (DQSA) and updates reporting instructions for drug compounders that choose to register as outsourcing facilities. Such compounders must report information on the drugs they compounded in Structured Product Labeling (SPL) format using FDA's electronic submissions system unless FDA grants a request for a waiver of such requirement because use of electronic means is not reasonable for the person requesting the waiver. This guidance supersedes the revised draft guidance entitled ''Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.''

DATES: 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: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* 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–2013–N–1428 for ''Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the 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 *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Lysette Deshields, Center for Drug Evaluation and Research Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993 301–796–3100.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' In the **Federal Register** of November 24, 2014 (79 FR 69857), FDA announced the availability of a revised draft guidance for industry entitled ''Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' On November 27, 2013, President Obama signed the DQSA into law (Pub. L. 113–54). The DQSA added a new section 503B to the FD&C Act (21 U.S.C. 353b). Under section 503B(b), a compounder can register as an outsourcing facility with FDA. If the conditions outlined in section 503B(a) of the FD&C Act are satisfied, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from certain sections of the FD&C Act, including section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use) and section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications or abbreviated new drug applications). Drugs compounded in outsourcing facilities are not exempt from the requirements of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice for drugs).

Under section 503B, an outsourcing facility must, at the time of initial registration and twice each year, in June and December, submit to FDA a report identifying the drugs compounded by the facility during the previous 6-month period. For each identified drug, the outsourcing facility must report the following information to FDA for each product that it compounds:

- The active ingredient and strength of active ingredient per unit;
- the source of the active ingredient (bulk or finished drug);
- the National Drug Code (NDC) number of the source drug or bulk active ingredient, if available;
- the dosage form and route of administration;
- the package description;
- the number of individual units produced; and
- the NDC number of the final product, if assigned.[1]

This final guidance explains that registered outsourcing facilities must provide reports to FDA on compounded drugs in SPL format using FDA's electronic submissions system unless FDA grants a request for a waiver of such requirement because use of electronic means is not reasonable for the person requesting the waiver. It supersedes the revised draft guidance entitled ''Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.''

The comment period for the revised draft guidance ended on January 23, 2015. FDA received three comments on the draft. In response to received comments or on its own initiative, FDA made the following changes and updates in the final guidance: (1) Clarified FDA's definition of the source of the active ingredient used to compound the final product and the information the outsourcing facility should submit to FDA, including the appropriate format of the NDC code; (2) clarified what information submitted as part of a product report will be made public; and (3) made grammatical and other minor editorial changes for clarity. In some cases, comments raised issues that were not directly pertinent to the topics addressed in the revised draft guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' 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 contains collections of information that 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 have been approved under OMB control number 0910–0827.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: December 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31789 Filed 12–30–16; 8:45 am]

BILLING CODE 4164–01–P

[1] Section 503B(b)(2)(A)(ii) of the FD&C Act.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–4308]

Labeling of Red Blood Cell Units With Historical Antigen Typing Results; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled ''Labeling of Red

Blood Cell Units with Historical Antigen Typing Results; Draft Guidance for Industry.'' The draft guidance document provides establishments that collect blood and blood components for transfusion with recommendations for labeling Red Blood Cell (RBC) units with non-ABO/Rh(D) antigen typing results obtained from previous donations (historical antigen typing results). The draft guidance provides recommendations to transfusion services for managing RBC units labeled with historical antigen typing results. The guidance also provides licensed blood collection establishments that choose to implement labeling of RBC units with historical antigen typing results instructions regarding how to report the manufacturing and labeling changes under the biologics regulations. The guidance does not apply to test results for ABO and Rh(D) antigens.

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 April 3, 2017. Submit electronic or written comments on the information collection issues under the Paperwork Reduction Act of 1995 by March 6, 2017.

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. [Insert docket number xxxxx] for ''Labeling of Red Blood Cell Units with Historical Antigen Typing Results; Draft Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit comments on information collection issues to the Office of Management and Budget in the following ways:

• Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or email to *oira_ubmission@omb.eop.gov.* All comments should be identified with the title, Labeling of Red Blood Cell Units with Historical Antigen Typing Results; Draft Guidance for Industry.

Submit written requests for single copies of the draft 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 draft 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Melissa Segal, 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 draft document entitled ''Labeling of Red Blood Cell Units with Historical Antigen Typing Results; Draft Guidance for Industry.'' The draft guidance document provides establishments that collect blood and blood components for transfusion with recommendations for labeling RBC units with historical antigen typing results. The guidance provides recommendations to transfusion services for managing RBC units labeled with historical antigen typing results. This guidance also provides licensed blood collection establishments that choose to implement labeling of RBC units with historical antigen typing results instructions regarding how to report the

manufacturing and labeling changes under 21 CFR 601.12. The guidance does not apply to test results for ABO and Rh(D) antigens. For ABO and Rh(D) antigens, establishments must follow FDA requirements in 21 CFR 640.5(b), 640.5(c), and 606.121(c)(9) and (13), as well as all other applicable requirements.

At the AABB–FDA Liaison Meeting held on April 12, 2012, AABB stated that it is the practice of some blood collection establishments to provide historical RBC antigen typing results to transfusion services using a tie-tag attached to the RBC unit. AABB asked for recommendations from FDA regarding labeling of RBC units with historical RBC antigen typing results. FDA's Blood Products Advisory Committee discussed this topic on December 4, 2012, and supported the concept of using historical RBC antigen typing results to label RBC units.

AABB has revised its standards to include accommodations for labeling RBC units with historical RBC typing results. According to the 30th edition of the AABB Standards for Blood Banks and Transfusion Services, RBC units may be labeled as RBC antigen negative without testing the current donation if two previous separate donations were tested by the collection facility and results of RBC typing were found to be concordant. The standards indicate that facilities have the option to put the non-ABO/Rh(D) historical antigen typing results on a tie-tag or directly on the container label.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on labeling of red blood cell units with historical antigen typing results. 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

The draft guidance document contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). Under the PRA, Federal Agencies must obtain approval from OMB for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Labeling of Red Blood Cell Units with Historical Antigen Typing Results; Draft Guidance for Industry; OMB Control No. 0910–NEW

The draft guidance document provides establishments that collect blood and blood components for transfusion with recommendations for labeling RBC units with non-ABO/Rh(D) antigen typing results obtained from previous donations (historical antigen typing results). The draft guidance provides recommendations to transfusion services for managing RBC units labeled with historical antigen typing results. The guidance also provides licensed blood collection establishments that choose to implement labeling of RBC units with historical antigen typing results instructions regarding how to report the manufacturing and labeling changes under 21 CFR 601.12.

Description of Respondents: Establishments that collect blood and blood components for transfusion, transfusion services, and licensed blood collection establishments.

Burden Estimate: We believe that the information collection provisions in the draft guidance do not create a new burden for respondents and are part of usual and customary business practices. According to the 30th edition of the AABB Standards for Blood Banks and Transfusion Services, RBC units may be labeled as RBC antigen negative without testing the current donation if two previous separate donations were tested by the collection facility and results of RBC typing were found to be concordant. The standards indicate that facilities have the option to put the non-ABO/Rh(D) historical antigen typing results on a tie-tag or directly on the container label.

We believe that facilities have already developed standard operating procedures for putting the non-ABO/Rh(D) historical antigen typing results on a tie-tag or directly on the container label.

The draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338; and the collections of information in 21 CFR 606.100, 606.121, 606.160, 606.171 have been approved under OMB control number 0910–116, 0910–0795 and 0910–0458.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: December 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31771 Filed 12–30–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development, Manufacture and Commercialization of Gene Therapy Products for Human Gene Therapy Use To Treat and/or Prevent Methylmalonic Acidemia (MMA)

AGENCY: National Institutes of Health (NIH).

ACTION: Notice.

SUMMARY: The National Human Genome Research Institute (NHGRI), an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive commercialization patent license to practice the inventions embodied in the Patent Applications listed in the Supplementary Information section of this notice License to Selecta Biosciences (''Selecta'') located in Watertown, Massachusetts.

DATES: Only written comments and/or applications for a license which are received by the NCI Technology Transfer Center on or before January 18, 2017 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Eggerton Campbell Ph.D., Licensing and Patenting Manager, Technology Transfer Office (TTO) National Human Genome Research Institute, National Institutes of Health, 5635 Fishers Lane, Suite 3058, MSC 9307, Bethesda, MD 20892–9307. Telephone: 301–402–1648. Fax: 301–402–9722. email: *eggerton.campbell@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. US Provisional Patent Application No.: 61/792,081
   HHS Ref. No.: E–243–2012/0–US–01
2. PCT Patent Application No.: PCT/2014/028045
   HHS Ref. No.: E–243–2012/0–PCT–02
3. EP Patent Application 14729502.6
   HHS Ref. No.: E–243–2012/0–EP–03
4. US Patent Application No.: 14/773,885
   HHS Ref. No.: E–243–2012/0–US–04
5. US Patent Application No.: 15/070,787
   HHS Ref. No.: E–243–2012/1–US–01

and all continuing applications and foreign counterparts. The patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of Licensed Patent Rights for the following:

Development, manufacture and commercialization of gene therapy products for human gene therapy use to treat and/or prevent Methylmalonic Acidemia (MMA) comprised of the following: all of or fragments of the synthetic methylmalonyl-CoA mutase (MUT) human polynucleotide (synMUT) and/or recombinant synMUT constructs, in combination with the following:

the Anc80 vector or vectors derived from the Anc80 vectors, wherein the derived Anc80 vectors have capsid sequences possessing 90% or greater sequence identity to the Anc80 capsid sequences.

For purposes of clarity, the above gene therapy products may be combined with Selecta's synthetic vaccine particles (SVP™) technology encapsulating an immunomodulator.

The subject technology discloses a synthetic codon-optimized human methylmalonyl-CoA mutase (MUT) cDNA gene (co-MUT) encoding human MUT protein, co-MUT constructs and uses thereof for treatment of MMA disorders. Such uses, may include the administration of immunomodulator(s) in order to maximize the advantage of the gene therapy, with fewer side effects. MMA is an autosomal recessive disorder caused by defects in the mitochondria-localized enzyme methylmalonyl-CoA mutase (MUT). MUT deficiency, the most common cause of MMA, is characterized by the accumulation of methylmalonic acid. MMA can lead to metabolic instability, seizures, strokes, and kidney failure, and can be lethal even when patients are being properly managed. If successfully developed, this invention would be a first of its kind therapy for MMA, by administering the disclosed nucleic acid, vector, or recombinant virus to a subject, optionally with an immunomodulator.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective Exclusive Patent License will be royalty bearing and may be granted unless within fifteen (15) days from the date of this published notice, the National Human Genome Research Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated Exclusive Patent License. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: *December 27, 2016.*

Claire T. Driscoll,

Director, NHGRI Technology Transfer Office.

[FR Doc. 2016–31834 Filed 12–30–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, February 16, 2017, 08:00 a.m. to February 17, 2017, 05:00 p.m., Bethesda North Marriott Conference Hotel, 5701 Marinelli Road, Bethesda, MD 20852 which was published in the **Federal Register** on December 13, 2016, 81 FR 89953.

The meeting notice is amended to change the date of the meeting to February 16, 2017 from 8:00 a.m. to 5:00 p.m. The meeting is closed to the public.

Dated: December 27, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–31759 Filed 12–30–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Grant Review Neonatal Anemia.

Date: January 25, 2017.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Melissa E. Nagelin, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7202, Bethesda, MD 20892, 301–435–0297, *nagelinmh2@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: December 27, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–31760 Filed 12–30–16; 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 Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel Human Aging and Somatic Mutations.

Date: February 3, 2017.

Time: 7:45 a.m. to 8:30 a.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Greg Bissonette, Ph.D., Scientific Review Officer, National Institute on Aging, National Institutes of Health, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–402–1622, *bissonettegb@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 27, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–31761 Filed 12–30–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS

ACTION: Notice

SUMMARY: The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); and on April 30, 2010 (75 FR 22809).

A notice listing all currently HHS-certified laboratories and IITFs is published in the **Federal Register** during the first week of each month. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at *http://www.samhsa.gov/workplace.*

FOR FURTHER INFORMATION CONTACT: Giselle Hersh, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N03A, Rockville, Maryland 20857; 240–276–2600 (voice).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. The ''Mandatory Guidelines for Federal Workplace Drug Testing Programs,'' as amended in the revisions listed above, requires strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on urine specimens for federal agencies.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A HHS-certified laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that it has met minimum standards.

In accordance with the Mandatory Guidelines dated November 25, 2008 (73 FR 71858), the following HHS-certified laboratories and IITFs meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

HHS-Certified Instrumented Initial Testing Facilities

Dynacare, 6628 50th Street NW., Edmonton, AB Canada T6B 2N7, 780–784–1190, (Formerly: Gamma-Dynacare Medical Laboratories)

HHS-Certified Laboratories

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 844–486–9226

Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615–255–2400, (Formerly: Aegis Sciences Corporation, Aegis Analytical Laboratories, Inc., Aegis Analytical Laboratories)

Alere Toxicology Services, 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823, (Formerly: Kroll Laboratory Specialists, Inc., Laboratory Specialists, Inc.)

Alere Toxicology Services, 450 Southlake Blvd., Richmond, VA 23236, 804–378–9130, (Formerly: Kroll Laboratory Specialists, Inc., Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.)

Baptist Medical Center-Toxicology Laboratory, 11401 I–30, Little Rock, AR 72209–7056, 501–202–2783, (Formerly: Forensic Toxicology Laboratory Baptist Medical Center)

Clinical Reference Laboratory, Inc., 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917

DrugScan, Inc., 200 Precision Road, Suite 200, Horsham, PA 19044, 800–235–4890

Dynacare *, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519–679–1630, (Formerly: Gamma-Dynacare Medical Laboratories)

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662–236–2609

Fortes Laboratories, Inc., 25749 SW Canyon Creek Road, Suite 600, Wilsonville, OR 97070, 503–486–1023

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400/800–437–4986, (Formerly: Roche Biomedical Laboratories, Inc.)

Laboratory Corporation of America Holdings, 1904 Alexander Drive,

Research Triangle Park, NC 27709, 919–572–6900/800–833–3984, (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866–827–8042/800–233–6339, (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center)

LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–873–8845, (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)

MedTox Laboratories, Inc., 402 W. County Road D, St. Paul, MN 55112, 651–636–7466/800–832–3244

MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2088, Testing for Veterans Affairs (VA) Employees Only

National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661–322–4250/800–350–3515

One Source Toxicology Laboratory, Inc., 1213 Genoa-Red Bluff, Pasadena, TX 77504, 888–747–3774, (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory)

Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942, (Formerly: Centinela Hospital Airport Toxicology Laboratory)

Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509–755–8991/800–541–7891x7

Phamatech, Inc., 15175 Innovation Drive, San Diego, CA 92128, 888–635–5840

Quest Diagnostics Incorporated, 1777 Montreal Circle, Tucker, GA 30084, 800–729–6432, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)

Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610–631–4600/877–642–2216, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)

Quest Diagnostics Incorporated, 8401 Fallbrook Ave., West Hills, CA 91304, 818–737–6370, (Formerly: SmithKline Beecham Clinical Laboratories)

Redwood Toxicology Laboratory, 3700 Westwind Blvd., Santa Rosa, CA 95403, 800–255–2159

STERLING Reference Laboratories, 2617 East L Street, Tacoma, Washington 98421, 800–442–0438

US Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235, 301–677–7085, Testing for Department of Defense (DoD) Employees Only

The following laboratory has voluntarily withdrawn from the National Laboratory Certification Program, as of January 6, 2017:

Southwest Laboratories, 4625 E. Cotton Center Boulevard, Suite 177, Phoenix, AZ 85040, 602–438–8507/800–279–0027

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on November 25, 2008 (73 FR 71858). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

Charles LoDico,

Chemist.

[FR Doc. 2016–31775 Filed 12–30–16; 8:45 am]

BILLING CODE 4162–20–P

*The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5909–N–98]

30-Day Notice of Proposed Information Collection: Public Housing Capital Fund Program

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD has submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date:* February 2, 2017.

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: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QMAC, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. 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.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on September 14, 2016 at FR 81 63199.

A. Overview of Information Collection

Title of Information Collection: Public Housing Capital Fund Program.

OMB Approval Number: 2577–0157.

Type of Request: Extension of currently approved collection.

Form Number: HUD Form 50075.1—Annual Statement/Performance and Evaluation Report and HUD–50075.2—Capital Fund Program Five-Year Action Plan, HUD–5084, HUD–5087, HUD–51000, HUD–51001, HUD–51002, HUD–51003, HUD–51004, HUD–51915, HUD–51915–A, HUD–51971–I–II, HUD–52396, HUD–52427, HUD–52482, HUD–52483–A, HUD–52484, HUD–52485, HUD–52651–A, HUD–52829, HUD–52830, HUD–52833, HUD–52845, HUD–52846, HUD–52847, HUD–52849, HUD–53001, HUD–53015, HUD–5370, HUD–5370EZ, HUD–5370C, HUD–5372,

HUD–5378, HUD–5460, HUD–52828, 50071, 5370–C1, 5370–C2.

Description of the need for the information and proposed use: Each year Congress appropriates funds to approximately 3,100 Public Housing Authorities (PHAs) for modernization, development, financing, and management improvements. The funds are allocated based on a complex formula. The forms in this collection are used to appropriately disburse and utilize the funds provided to PHAs. Additionally, these forms provide the information necessary to approve a financing transaction in addition to any Capital Fund Financing transactions. Respondents include the approximately 3,100 PHA receiving Capital Funds and any other PHAs wishing to pursue financing.

Respondents (*i.e.* affected public): Public Housing Authorities.

Form/Document	Number of respondents	Frequency	Total responses	Hours per response	Total hours	Cost per hour ($)	Total cost ($)
1. HUD–5084	3,100	1	3,100	1.5	4,650.00	30	139,500
2. HUD–5087	50	1	50	3	150	50	7,500
3. HUD–50071	10	1	10	0.5	5	50	250
4. HUD–50075.1	3,100	1	3,100	2.2	6,820	30	204,600
5. HUD–50075.2	3,100	1	3,100	1	3,100	30	93,000
6. HUD–51000	590	1	590	1	590	30	17,700
7. HUD–51001	2,550	12	30,600	3.5	107,100.00	30	3,213,000
8. HUD–51002	1,600	5	8,000	1	8,000.00	30	240,000
9. HUD–51003	500	2	1,000	1.5	1,500.00	30	45,000
10. HUD–51004	500	2	1,000	2.5	2,500.00	30	75,000
11. HUD–51915 HUD–51915–A	2,630	1	2,630	3	7,890.00	30	236,700
12. HUD–51971–I, II	80	1	80	1.5	120	30	3,600
13. HUD–52396	96	1	96	2	192	30	5,760
14. HUD–52427	88	1	88	0.5	44	30	1,320
15. HUD–52482	40	1	40	2	80	30	2,400
16. HUD–52483–A	40	1	40	2	80	30	2,400
17. HUD–52484	532	4	2,128	10	21,280.00	30	638,400
18. HUD–52485	40	1	40	1	40	30	1,200
19. HUD–52651–A	40	1	40	2.5	100	30	3,000
20. HUD–52829	25	1	25	40	1000	50	50,000
21. HUD–52830	25	1	25	16	400	50	20,000
22. HUD–52833	3,100	1	3,100	13	40,300.00	30	1,209,000
23. HUD–52836	10	1	10	0.5	5	50	250
24. HUD–52845	25	1	25	8	200	50	10,000
25. HUD–52846	25	1	25	16	400	50	20,000
26. HUD–52847	25	1	25	8	200	50	10,000
27. HUD–52849	25	1	25	1	25	50	1,250
28. HUD–53001	3,100	1	3,100	2.5	7,750.00	30	232,500
29. HUD–53015	40	1	40	3	120	30	3,600
30. HUD–5370, 5370EZ	2,694	1	2,694	1	2,694.00	30	80,820
31. HUD–5370C	2,694	1	2,694	1	2,694.00	30	80,820
32. HUD–5372	590	1	590	1	590	30	17,700
33. HUD–5378	158	24	3,792	0.25	948	30	28,440
34. HUD–5460	40	1	40	1	40	30	1,200
35. Public Housing Information Center Certification of Accuracy	3,100	1	3,100	2	6,200.00	30	186,000
36. HUD–52828 Physical Needs Assessment form	3,100	1	3,100	15.4	47,740.00	50	2,387,000
37. Broadband Feasibility determination	3,100	1	3,100	10	31,000	50	1,550,000
Totals					306,547.00		10,818,910

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.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: December 21, 2016.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2016–31791 Filed 12–30–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR01041000, 17XR0680G3, RX.16786921.2000100]

Notice To Extend the Public Comment Period for the Notice of Intent To Prepare the Columbia River System Operations Environmental Impact Statement

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of extension.

SUMMARY: The U.S. Army Corps of Engineers, Bonneville Power Administration, and Bureau of Reclamation (Action Agencies) are extending the public comment period for the Notice of Intent (NOI) to Prepare the Columbia River System Operations Environmental Impact Statement (EIS) to Tuesday February 7, 2017. The NOI and Notice of Public Meetings was published in the **Federal Register** on Friday, September 30, 2016. The public comment period for the NOI was originally scheduled to end on Tuesday, January 17, 2017.

DATES: Comments on the NOI will be accepted until close of business on Tuesday February 7, 2017.

ADDRESSES: Written comments, requests to be placed on the project mailing list, and requests for information may be mailed by letter to U.S. Army Corps of Engineers Northwestern Division Attn: CRSO EIS, P.O. Box 2870, Portland, OR 97208–2870; or online at *comment@crso.info.* All comment letters will be available via the project Web site at *www.crso.info.* All personally identifiable information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Call the toll-free telephone 1-(800) 290–5033, or email *info@crso.info.* Additional information can be found at the project Web site: *www.crso.info.*

SUPPLEMENTARY INFORMATION: In response to requests for an extension, the Action Agencies are extending the close of the public comment period for the NOI to Prepare the Columbia River System Operations Environmental Impact Statement to Tuesday February 7, 2017.

Public Disclosure

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: December 6, 2016.

Lorri J. Lee,

Regional Director—Pacific Northwest Region, Bureau of Reclamation.

[FR Doc. 2016–31621 Filed 12–30–16; 8:45 am]

BILLING CODE 4332–90–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–410 (Fourth Review)]

Light-Walled Rectangular Pipe and Tube From Taiwan Institution of a Five-Year Review

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice that it has instituted a review pursuant to the Tariff Act of 1930 (''the Act''), as amended, to determine whether revocation of the antidumping duty order on light-walled rectangular pipe and tube from Taiwan would be likely to lead to continuation or recurrence of material injury. Pursuant to the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission.

DATES: Effective January 3, 2017. To be assured of consideration, the deadline for responses is February 2, 2017. Comments on the adequacy of responses may be filed with the Commission by March 17, 2017.

FOR FURTHER INFORMATION CONTACT: Mary Messer (202–205–3193), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On March 27, 1989, the Department of Commerce issued an antidumping duty order on imports of light-walled rectangular pipe and tube from Taiwan (54 FR 12467). Following first five-year reviews by Commerce and the Commission, effective August 22, 2000, Commerce issued a continuation of the antidumping duty order on imports of light-walled rectangular pipe and tube from Taiwan (65 FR 50955). Following second five-year reviews by Commerce and the Commission, effective August 9, 2006, Commerce issued a continuation of the antidumping duty order on imports of light-walled welded rectangular carbon steel tubing from Taiwan (71 FR 45521). Following the third five-year reviews by Commerce and the Commission, effective February 2, 2012, Commerce issued a continuation of the antidumping duty order on imports of light-walled welded rectangular carbon steel tubing from Taiwan (77 FR 5240). The Commission is now conducting a fourth review pursuant to section 751(c) of the Act, as amended (19 U.S.C. 1675(c)), to determine whether revocation of the order would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time. Provisions concerning the conduct of this proceeding may be found in the Commission's Rules of Practice and Procedure at 19 CFR parts 201, subparts A and B and 19 CFR part 207, subparts A and F. The Commission will assess the adequacy of interested party responses to this notice of institution to determine whether to conduct a full review or an expedited review. The Commission's determination in any expedited review will be based on the facts available, which may include information provided in response to this notice.

Definitions.—The following definitions apply to this review:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the scope of the five-year review, as defined by the Department of Commerce.

(2) The *Subject Country* in this review is Taiwan.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the *Subject Merchandise.* In its original investigation determination, its full first and second five-year review determinations, and its expedited third

five-year review determination, the Commission defined a single *Domestic Like Product* as light-walled rectangular pipe and tube coextensive with Commerce's scope definition.

(4) The *Domestic Industry* is the U.S. producers as a whole of the *Domestic Like Product,* or those producers whose collective output of the *Domestic Like Product* constitutes a major proportion of the total domestic production of the product. In its original investigation determination, its full first and second five-year review determinations, and its expedited third five-year review determination, the Commission defined the *Domestic Industry* as the U.S. producers of light-walled rectangular pipe and tube.

(5) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the *Subject Merchandise* into the United States from a foreign manufacturer or through its selling agent.

Participation in the proceeding and public service list.—Persons, including industrial users of the *Subject Merchandise* and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the proceeding as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the proceeding.

Former Commission employees who are seeking to appear in Commission five-year reviews are advised that they may appear in a review even if they participated personally and substantially in the corresponding underlying original investigation or an earlier review of the same underlying investigation. The Commission's designated agency ethics official has advised that a five-year review is not the same particular matter as the underlying original investigation, and a five-year review is not the same particular matter as an earlier review of the same underlying investigation for purposes of 18 U.S.C. 207, the post employment statute for Federal employees, and Commission rule 201.15(b) (19 CFR 201.15(b)), 79 FR 3246 (Jan. 17, 2014), 73 FR 24609 (May 5, 2008). Consequently, former employees are not required to seek Commission approval to appear in a review under Commission rule 19 CFR 201.15, even if the corresponding underlying original investigation or an earlier review of the same underlying investigation was pending when they were Commission employees. For further ethics advice on this matter, contact Carol McCue Verratti, Deputy Agency Ethics Official, at 202–205–3088.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and APO service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in this proceeding available to authorized applicants under the APO issued in the proceeding, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the proceeding. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification.—Pursuant to section 207.3 of the Commission's rules, any person submitting information to the Commission in connection with this proceeding must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that information submitted in response to this request for information and throughout this proceeding or other proceeding may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Written submissions.—Pursuant to section 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is February 2, 2017. Pursuant to section 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct an expedited or full review. The deadline for filing such comments is March 17, 2017. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's Handbook on E-Filing, available on the Commission's Web site at *https://edis.usitc.gov,* elaborates upon the Commission's rules with respect to electronic filing. Also, in accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the proceeding must be served on all other parties to the proceeding (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the proceeding you do not need to serve your response).

No response to this request for information is required if a currently valid Office of Management and Budget (OMB) number is not displayed; the OMB number is 3117 0016/USITC No. 16–5–377, expiration date June 30, 2017. Public reporting burden for the request is estimated to average 15 hours per response. Please send comments regarding the accuracy of this burden estimate to the Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436.

Inability to provide requested information.—Pursuant to section 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to section 776(b) of the Act (19 U.S.C. 1677e(b)) in making its determination in the review.

INFORMATION TO BE PROVIDED IN RESPONSE TO THIS NOTICE OF INSTITUTION: As used below, the term ''firm'' includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address) and name, telephone number, fax number, and Email address of the certifying official.

(2) A statement indicating whether your firm/entity is an interested party under 19 U.S.C. 1677(9) and if so, how,

including whether your firm/entity is a U.S. producer of the *Domestic Like Product,* a U.S. union or worker group, a U.S. importer of the *Subject Merchandise*, a foreign producer or exporter of the *Subject Merchandise,* a U.S. or foreign trade or business association (a majority of whose members are interested parties under the statute), or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this proceeding by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the antidumping duty order on the *Domestic Industry* in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of *Subject Merchandise* on the *Domestic Industry.*

(5) A list of all known and currently operating U.S. producers of the *Domestic Like Product.* Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the *Subject Merchandise* and producers of the *Subject Merchandise* in the *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries after 2010.

(7) A list of 3–5 leading purchasers in the U.S. market for the *Domestic Like Product* and the *Subject Merchandise* (including street address, World Wide Web address, and the name, telephone number, fax number, and Email address of a responsible official at each firm).

(8) A list of known sources of information on national or regional prices for the *Domestic Like Product* or the *Subject Merchandise* in the U.S. or other markets.

(9) If you are a U.S. producer of the *Domestic Like Product,* provide the following information on your firm's operations on that product during calendar year 2016, except as noted (report quantity data in short tons and value data in U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the *Domestic Like Product* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm to produce the *Domestic Like Product* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix);

(c) the quantity and value of U.S. commercial shipments of the *Domestic Like Product* produced in your U.S. plant(s);

(d) the quantity and value of U.S. internal consumption/company transfers of the *Domestic Like Product* produced in your U.S. plant(s); and

(e) the value of (i) net sales, (ii) cost of goods sold (COGS), (iii) gross profit, (iv) selling, general and administrative (SG&A) expenses, and (v) operating income of the *Domestic Like Product* produced in your U.S. plant(s) (include both U.S. and export commercial sales, internal consumption, and company transfers) for your most recently completed fiscal year (identify the date on which your fiscal year ends).

(10) If you are a U.S. importer or a trade/business association of U.S. importers of the *Subject Merchandise* from the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2016 (report quantity data in short tons and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') imports;

(b) the quantity and value (f.o.b. U.S. port, including antidumping duties) of U.S. commercial shipments of *Subject Merchandise* imported from the *Subject Country;* and

(c) the quantity and value (f.o.b. U.S. port, including antidumping duties) of U.S. internal consumption/company transfers of *Subject Merchandise* imported from the *Subject Country.*

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2016 (report quantity data in short tons and value data in U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise* in the *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in the *Subject Country* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) the quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in the *Subject Country* after 2010, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in the *Subject*

Country, and such merchandise from other countries.

(13) (OPTIONAL) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry;* if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This proceeding is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.61 of the Commission's rules.

By order of the Commission.

Issued: December 22, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–31465 Filed 12–30–16; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–379 and 731–TA–788, 792, and 793 (Third Review)]

Stainless Steel Plate From Belgium, South Africa, and Taiwan; Determinations

On the basis of the record [1] developed in the subject five-year reviews, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that revocation of the antidumping duty orders on stainless steel plate from Belgium, South Africa, and Taiwan and revocation of the countervailing duty order on stainless steel plate from South Africa would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission, pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)), instituted these reviews on July 1, 2016 (81 FR 43245) and determined on October 4, 2016 that it would conduct expedited reviews (81 FR 73421, October 25, 2016).

The Commission made these determinations pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determinations in these reviews on December 22, 2016. The views of the Commission are contained in USITC Publication 4658 (December 2016), entitled *Stainless Steel Plate from Belgium, South Africa, and Taiwan: Investigation Nos. 701–TA–379 and 731–TA–788, 792, and 793 (Third Review).*

By order of the Commission.

Issued: December 28, 2016.

Katherine M. Hiner,

Acting Supervisory Attorney.

[FR Doc. 2016–31837 Filed 12–30–16; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–703 (Fourth Review)]

Furfuryl Alcohol From China; Institution of a Five-Year Review

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice that it has instituted a review pursuant to the Tariff Act of 1930 (''the Act''), as amended, to determine whether revocation of the antidumping duty order on furfuryl alcohol from China would be likely to lead to continuation or recurrence of material injury. Pursuant to the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission.

DATES: Effective January 3, 2017. To be assured of consideration, the deadline for responses is February 2, 2017. Comments on the adequacy of responses may be filed with the Commission by March 17, 2017.

FOR FURTHER INFORMATION CONTACT: Mary Messer (202–205–3193), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.— On June 21, 1995, the Department of Commerce (''Commerce'') issued an antidumping duty order on imports of furfuryl alcohol from China (60 FR 32302). Following first five-year reviews by Commerce and the Commission, effective May 4, 2001, Commerce issued a continuation of the antidumping duty order on imports of furfuryl alcohol from China (66 FR 22519). Following second five-year reviews by Commerce and the Commission, effective October 6, 2006, Commerce issued a continuation of the antidumping duty order on imports of furfuryl alcohol from China (71 FR 59072). Following the third five-year reviews by Commerce and the Commission, effective February 16, 2012, Commerce issued a continuation of the antidumping duty order on imports of furfuryl alcohol from China (77 FR 9203). The Commission is now conducting a fourth review pursuant to section 751(c) of the Act, as amended (19 U.S.C. 1675(c)), to determine whether revocation of the order would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time. Provisions concerning the conduct of this proceeding may be found in the Commission's Rules of Practice and Procedure at 19 CFR parts 201, subparts A and B and 19 CFR part 207, subparts A and F. The Commission will assess the adequacy of interested party responses to this notice of institution to determine whether to conduct a full review or an expedited review. The Commission's determination in any expedited review will be based on the facts available, which may include information provided in response to this notice.

Definitions.—The following definitions apply to this review:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the scope of the five-year review, as defined by the Department of Commerce.

(2) The *Subject Country* in this review is China.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the *Subject Merchandise.* In its original determination, its full first five-year review determination, and its expedited second and third five-year review determinations, the Commission defined the *Domestic Like Product* as furfuryl alcohol, coextensive with Commerce's scope.

(4) The *Domestic Industry* is the U.S. producers as a whole of the *Domestic Like Product,* or those producers whose collective output of the *Domestic Like Product* constitutes a major proportion of the total domestic production of the product. In its original determination, the Commission defined the *Domestic Industry* as QO Chemicals, generally known as Great Lakes, an integrated

producer of furfuryl alcohol. In its full first five-year review determination, the Commission defined the *Domestic Industry* as all producers of furfuryl alcohol, namely, Penn Chemicals, Ferro Industries, and Great Lakes. In its expedited second and third review determinations, the Commission defined a single *Domestic Industry* consisting of the sole domestic producer of furfuryl alcohol, Penn Chemicals (including its successor firm, Penn A Kem LLC).

(5) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the *Subject Merchandise* into the United States from a foreign manufacturer or through its selling agent.

Participation in the proceeding and public service list.—Persons, including industrial users of the *Subject Merchandise* and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the proceeding as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the proceeding.

Former Commission employees who are seeking to appear in Commission five-year reviews are advised that they may appear in a review even if they participated personally and substantially in the corresponding underlying original investigation or an earlier review of the same underlying investigation. The Commission's designated agency ethics official has advised that a five-year review is not the same particular matter as the underlying original investigation, and a five-year review is not the same particular matter as an earlier review of the same underlying investigation for purposes of 18 U.S.C. 207, the post employment statute for Federal employees, and Commission rule 201.15(b) (19 CFR 201.15(b)), 79 FR 3246 (Jan. 17, 2014), 73 FR 24609 (May 5, 2008). Consequently, former employees are not required to seek Commission approval to appear in a review under Commission rule 19 CFR 201.15, even if the corresponding underlying original investigation or an earlier review of the same underlying investigation was pending when they were Commission employees. For further ethics advice on this matter, contact Carol McCue Verratti, Deputy Agency Ethics Official, at 202–205–3088.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and APO service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in this proceeding available to authorized applicants under the APO issued in the proceeding, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the proceeding. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification.—Pursuant to section 207.3 of the Commission's rules, any person submitting information to the Commission in connection with this proceeding must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that information submitted in response to this request for information and throughout this proceeding or other proceeding may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Written submissions.—Pursuant to section 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is February 2, 2017. Pursuant to section 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct an expedited or full review. The deadline for filing such comments is March 17, 2017. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's Handbook on E-Filing, available on the Commission's Web site at *https://edis.usitc.gov,* elaborates upon the Commission's rules with respect to electronic filing. Also, in accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the proceeding must be served on all other parties to the proceeding (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the proceeding you do not need to serve your response).

No response to this request for information is required if a currently valid Office of Management and Budget (OMB) number is not displayed; the OMB number is 3117 0016/USITC No. 16–5–376, expiration date June 30, 2017. Public reporting burden for the request is estimated to average 15 hours per response. Please send comments regarding the accuracy of this burden estimate to the Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436.

Inability to provide requested information.—Pursuant to section 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to section 776(b) of the Act (19 U.S.C. 1677e(b)) in making its determination in the review.

INFORMATION TO BE PROVIDED IN RESPONSE TO THIS NOTICE OF INSTITUTION: As used below, the term ''firm'' includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address) and name, telephone number, fax number, and Email address of the certifying official.

(2) A statement indicating whether your firm/entity is an interested party under 19 U.S.C. 1677(9) and if so, how, including whether your firm/entity is a U.S. producer of the *Domestic Like Product,* a U.S. union or worker group, a U.S. importer of the *Subject Merchandise*, a foreign producer or

exporter of the *Subject Merchandise,* a U.S. or foreign trade or business association (a majority of whose members are interested parties under the statute), or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this proceeding by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the antidumping duty order on the *Domestic Industry* in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of *Subject Merchandise* on the *Domestic Industry.*

(5) A list of all known and currently operating U.S. producers of the *Domestic Like Product.* Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the *Subject Merchandise* and producers of the *Subject Merchandise* in the *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries after 2010.

(7) A list of 3–5 leading purchasers in the U.S. market for the *Domestic Like Product* and the *Subject Merchandise* (including street address, World Wide Web address, and the name, telephone number, fax number, and Email address of a responsible official at each firm).

(8) A list of known sources of information on national or regional prices for the *Domestic Like Product* or the *Subject Merchandise* in the U.S. or other markets.

(9) If you are a U.S. producer of the *Domestic Like Product,* provide the following information on your firm's operations on that product during calendar year 2016, except as noted (report quantity data in pounds and value data in U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the *Domestic Like Product* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm to produce the *Domestic Like Product* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix);

(c) the quantity and value of U.S. commercial shipments of the *Domestic Like Product* produced in your U.S. plant(s);

(d) the quantity and value of U.S. internal consumption/company transfers of the *Domestic Like Product* produced in your U.S. plant(s); and

(e) the value of (i) net sales, (ii) cost of goods sold (COGS), (iii) gross profit, (iv) selling, general and administrative (SG&A) expenses, and (v) operating income of the *Domestic Like Product* produced in your U.S. plant(s) (include both U.S. and export commercial sales, internal consumption, and company transfers) for your most recently completed fiscal year (identify the date on which your fiscal year ends).

(10) If you are a U.S. importer or a trade/business association of U.S. importers of the *Subject Merchandise* from the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2016 (report quantity data in pounds and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') imports;

(b) the quantity and value (f.o.b. U.S. port, including antidumping duties) of U.S. commercial shipments of *Subject Merchandise* imported from the *Subject Country;* and

(c) the quantity and value (f.o.b. U.S. port, including antidumping duties) of U.S. internal consumption/company transfers of *Subject Merchandise* imported from the *Subject Country.*

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2016 (report quantity data in pounds and value data in U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise* in the *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in the *Subject Country* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) the quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in the *Subject Country* after 2010, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in the *Subject Country,* and such merchandise from other countries.

(13) (OPTIONAL) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry;* if you disagree

with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This proceeding is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.61 of the Commission's rules.

By order of the Commission.

Issued: December 22, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–31464 Filed 12–30–16; 8:45 am]

BILLING CODE 7020–02–P

JUDICIAL CONFERENCE OF THE UNITED STATES

Hearings of the Judicial Conference Advisory Committee on the Federal Rules of Bankruptcy Procedure

AGENCY: Advisory Committee on the Federal Rules of Bankruptcy Procedure, Judicial Conference of the United States.

ACTION: Notice of cancellation of public hearing.

SUMMARY: The following public hearing on proposed amendments to the Federal Rules of Bankruptdcy Procedure has been canceled: Bankruptcy Rules Hearing on January 24, 2017, in Pasadena, California. Announcement for this meeting was previously published in 81 FR 52713.

FOR FURTHER INFORMATION CONTACT: Rebecca A. Womeldorf, Rules Committee Secretary, Rules Committee Support Office, Administrative Office of the United States Courts, Washington, DC 20544, telephone (202) 502–1820.

Dated: December 28, 2016.

Rebecca A. Womeldorf,

Rules Committee Secretary.

[FR Doc. 2016–31783 Filed 12–30–16; 8:45 am]

BILLING CODE 2210–55–P

LIBRARY OF CONGRESS

Copyright Royalty Board

[Docket No. 17–CRB–0001–BER (2019–2023)]

Determination of Royalty Rates and Terms for Making Ephemeral Copies of Sound Recordings for Transmission to Business Establishments (Business Establishments III)

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Notice announcing commencement of proceeding with request for Petitions to Participate.

SUMMARY: The Copyright Royalty Judges (Judges) announce commencement of a proceeding [1] to determine reasonable royalty rates and terms for the recording of ephemeral copies of sound recordings pursuant to 17 U.S.C. 112(e)(1) to facilitate digital audio transmissions of those sound recordings to business establishments pursuant to the limitation on exclusive rights specified by 17 U.S.C. 114(d)(1)(C)(iv). The royalty rates and terms the Judges determine in this proceeding will apply during the period beginning January 1, 2019, and ending December 31, 2023. The Judges also announce the date by which a party wishing to participate in the rate determination proceeding must file its Petition to Participate and pay the accompanying $150 filing fee.

DATES: Petitions to Participate and the filing fee are due no later than February 2, 2017.

ADDRESSES: This notice and request is also posted on the agency's Web site (*www.loc.gov/crb*). Parties who plan to participate should see How to Submit Petitions to Participate in the Supplementary Information section below for addresses and further instructions.

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

SUPPLEMENTARY INFORMATION: The Copyright Act provides that the Copyright Royalty Judges (Judges) commence a proceeding every fifth year [2] to determine royalty rates and terms for the recording of ephemeral copies of sound recordings pursuant to the statutory license in 17 U.S.C. 112(e)(1) to facilitate digital audio transmissions of those sound recordings to business establishments pursuant to the limitation on exclusive rights specified by 17 U.S.C. 114(d)(1)(C)(iv). *See* sec. 804(b)(2). This notice commences the rate determination proceeding for the license period 2019–2023, inclusive. Section 803(b)(1)(A)(i)(II) directs the Judges to publish in the **Federal Register** a notice commencing this proceeding by no later than January 5, 2017.

Petitions to Participate

Parties with a significant interest in the outcome of the ''business establishments'' royalty rate proceeding must file Petitions to Participate in accordance with § 351.1(b) of the Judges' regulations. *See* 37 CFR 351.1(b). Parties must send the $150 filing fee with each Petition to Participate. Parties must pay the filing fee with a check or money order made payable to the ''Copyright Royalty Board.'' The Copyright Royalty Board will not accept payment by cash. If a check received in payment of the filing fee is returned for lack of sufficient funds, the Judges will dismiss the corresponding Petition to Participate.

Only attorneys admitted to the bar in one or more states or the District of Columbia and who are in good standing with the bar will be allowed to represent parties before the Judges. Only an individual may represent herself or himself and appear without legal counsel. 37 CFR 350.2.

How To Submit Petitions to Participate

Any party wishing to participate in the proceeding to determine the ''business establishments'' royalty rates for 2019 through 2023 must submit to the Copyright Royalty Board the filing fee (U.S. $150), an original (paper) Petition to Participate, five paper copies, and an electronic copy on a CD or other portable memory device in Portable Document Format (PDF) that contains searchable, accessible text (not a scanned image of text). Participants should conform all electronic documents to the Judges' Guidelines for Electronic Documents posted on the Copyright Royalty Board Web site at *http://www.loc.gov/crb/docs/Guidelines_for_Electronic_Documents.pdf.*

Participants shall deliver Petitions to Participate to only one of the following addresses. *U.S. mail:* Copyright Royalty Board, P.O. Box 70977, Washington, DC 20024–0977; or

Overnight service (only USPS Express Mail is acceptable): Copyright Royalty Board, P.O. Box 70977, Washington, DC 20024–0977; or

Commercial courier: Address package to: Copyright Royalty Board, Library of Congress, James Madison Memorial Building, LM–403, 101 Independence Avenue SE., Washington, DC 20559–6000. *Deliver between 8:30 a.m. and 4:00 p.m. to:* Congressional Courier Acceptance Site, 2nd Street NE and D Street NE., Washington, DC; or

Hand delivery: Deliver between 8:30 a.m. and 5:00 p.m. to: The Library of Congress, James Madison Memorial Building, LM–401, 101 Independence Avenue SE., Washington, DC 20559–6000.

[1] CRB docket number 17–CRB–0001–BER (2019–2023).

[2] The Judges commenced a proceeding to determine the 2014–2018 rates and terms in 2012. *See* 77 FR 133 (Jan. 3, 2012).

Dated: December 23, 2016.

Suzanne M. Barnett,

Chief Copyright Royalty Judge.

[FR Doc. 2016–31685 Filed 12–30–16; 8:45 am]

BILLING CODE 1410–72–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 52–018 and 52–019; NRC–2008–0170]

Duke Energy Carolinas, LLC; William States Lee III Nuclear Station Units 1 and 2

AGENCY: Nuclear Regulatory Commission.

ACTION: Combined licenses and record of decision; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued combined licenses (Nos. NPF–101 and NPF–102) to Duke Energy Carolinas, LLC (DEC) William States Lee III Nuclear Station Units 1 and 2. In addition, the NRC has prepared a Summary Record of Decision (ROD) that supports the NRC's decision to issue the above-named combined licenses.

DATES: Combined licenses NPF–101 and NPF–102 became effective on December 19, 2016.

ADDRESSES: Please refer to Docket ID NRC–2008–0170 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0170. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *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 a document is referenced. For the convenience of the reader, the ADAMS accession numbers are provided in a table in the ''Availability of Documents'' section of 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.

FOR FURTHER INFORMATION CONTACT: Brian Hughes, telephone: 301- 415–6582, email: *Brian.Hughes@nrc.gov* regarding safety matters; or Patricia Vokoun, telephone: 301–415–3470, email: *Patricia.Vokoun@nrc.gov* regarding environmental matters. Both are staff of the Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Introduction

Under section 2.106 of title 10 of the *Code of Federal Regulations* (10 CFR), the NRC is providing notice of the issuance of combined licenses NPF–101 and NPF–102 to DEC, and under 10 CFR 50.102(c), the NRC is providing notice of the Commission's Memorandum and Order documenting its final decision on the uncontested hearing, which serves as the ROD in this proceeding. With respect to the application for combined licenses filed by DEC, the NRC finds that the applicable standards and requirements of the Atomic Energy Act of 1954, as amended, (AEA) and the Commission's regulations have been met. The NRC finds that any required notifications to other agencies or bodies have been duly made and that there is reasonable assurance that the facilities will be constructed and will operate in conformity with the license, the provisions of the AEA, and the Commission's regulations. Furthermore, the NRC finds that DEC is technically and financially qualified to engage in the activities authorized, and that issuance of the licenses will not be inimical to the common defense and security or to the health and safety of the public. Finally, the NRC has determined that the findings required by subpart A of 10 CFR part 51 have been made.

Accordingly, the combined licenses were issued on December 19, 2016, and became effective immediately.

II. Further Information

The NRC has prepared a Final Safety Evaluation Report (FSER) and Final Environmental Impact Statement (FEIS) that document the information reviewed and the NRC's conclusion. The Commission has also issued its Memorandum and Order documenting its final decision on the uncontested hearing held on October 5, 2016, which serves as the ROD in this proceeding. The NRC also prepared a document summarizing the ROD to accompany its actions on the combined license application; this ''Summary ROD'' incorporates by reference materials contained in the FEIS. The FSER, FEIS, Summary ROD, and accompanying documentation included in the combined license package, as well as the Commission's hearing decision and ROD, are available online in the ADAMS Public Document collection at *http://www.nrc.gov/reading-rm/adams.html.* From this site, persons can access the NRC's ADAMS, which provides text and image files of NRC's public documents.

The ADAMS accession numbers for the documents related to this notice are listed below.

III. Availability of Documents

The documents identified in the following table are available to interested persons through the ADAMS Public Documents collection. A copy of the combined license application is also available for public inspection at the NRC's PDR and at *http://www.nrc.gov/reactors/new-reactors/col.html.*

Document	Adams Accession No.
Final Safety Evaluation Report for Combined Licenses for Lee Units 1 and 2	ML16160A414
Reader's Guide	ML13352A015
Final Environmental Impact Statement for Combined Licenses for Lee Units 1 and 2	ML13340A005 (Volume 1) ML13340A006 (Volume 2) ML13340A007 (Volume 3)
Commission's Memorandum and Order on the uncontested hearing (Record of Decision)	ML16350A070
Summary Record of Decision	ML16277A243
Letter transmitting Combined Licenses Nos. NPF–101 and NPF–102 and accompanying documentation	ML16354A256

Document	Adams Accession No.
Combined Licenses Nos. NPF–101 and NPF–102	ML16333A329 (Unit 1) ML16333A331 (Unit 2)

Dated at Rockville, Maryland, this 22nd day of December 2016.

For the Nuclear Regulatory Commission.

Francis M. Akstulewicz,

Director, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. 2016–31814 Filed 12–30–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0258]

Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving Proposed No Significant Hazards Considerations and Containing Sensitive Unclassified Non-Safeguards Information and Safeguards Information and Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information and 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 one amendment request. The amendment request is for Kewaunee Power Station. For this amendment request, the NRC proposes to determine that it involves no significant hazards consideration. Because the amendment request contains sensitive unclassified non-safeguards information (SUNSI) and safeguards information (SGI), an order imposes procedures to obtain access to SUNSI and SGI for contention preparation.

DATES: Comments must be filed by February 2, 2017. A request for a hearing must be filed by March 6, 2017. Any potential party as defined in § 2.4 of title 10 of the *Code of Federal Regulations* (10 CFR), who believes access to SUNSI and/or SGI is necessary to respond to this notice must request document access by January 13, 2017.

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–2016–0258. 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: Shirley Rohrer, Licensing Assistant, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–5411, email: *Shirley.Rohrer@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2016–0258, 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–2016–0258.
- *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–2016–0258, 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.

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 notice of an amendment containing SUNSI and SGI.

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 request involves 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 the 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 persons (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. 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/.* Alternatively, a copy of the regulations is available at the NRC's Public Document Room, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

As required by 10 CFR 2.309(d) the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) The name, address, and telephone number of the petitioner; (2) the nature of the petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the 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 petitioner's interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions which the petitioner seeks to have litigated in 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 petitioner must 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 petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) 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. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the 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) through (iii). The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document.

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 establish 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 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 the 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 March 6, 2017. 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 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. Alternatively, a State,

local governmental body, Federally-recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a hearing is granted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at 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 his or her 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 and petition for leave to intervene (petition), 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 that request to participate 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. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC Web site at *http://www.nrc.gov/site-help/e-submittals.html.* 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 (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (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.* Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions should be in Portable Document Format (PDF). Additional guidance on PDF submissions is 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 document is 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 document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's 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 6 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, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory documents 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 personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. 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.

Dominion Energy Kewaunee, Inc., Docket No. 50–305, Kewaunee Power Station (KPS), Carlton, Wisconsin

Date of amendment request: October 15, 2015, as supplemented by letters dated October 27, 2015, and November 16, 2016. Publicly-available versions are in ADAMS under Accession Nos. ML15294A072, ML15302A402, and ML16323A193, respectively.

Description of amendment request: This amendment request contains sensitive unclassified non-safeguards information (SUNSI) and safeguards

information (SGI). This amendment requests NRC approval of the Kewaunee Power Station Security Plan, Training and Qualification Plan, and Safeguards Contingency Plan (the Plan) and removal of the Cyber Security requirements from the Operating License. The Plan will supersede the current Security Plan, Training and Qualification Plan, and Safeguards Contingency Plan at KPS.

The Plan will be used at KPS after all spent fuel has been transferred to the KPS Independent Spent Fuel Storage Installation (ISFSI).

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), in its supplemental letter dated November 16, 2016, 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?

No.

The irradiated fuel at KPS is currently stored in the spent fuel pool (SFP) and at the ISFSI. In this condition, the number of credible accidents/transients is significantly smaller than for a plant authorized to operate the reactor or emplace or retain fuel in the reactor vessel. Accidents/transients that are no longer applicable in a permanently defueled condition have been deleted from the KPS Updated Safety Analysis Report (USAR) Chapter 14. The remaining USAR Chapter 14 accident is the Fuel Handling Accident (FHA). The Plan reflects the future site configuration where all the remaining spent fuel in the SFP has been moved to the ISFSI and there are no requirements to return spent fuel to the SFP. The FHA will no longer be credible after all fuel has been removed from the spent fuel pool.

The proposed amendment has no effect on plant systems, structures, and components (SSCs) and no effect on the capability of any plant SSC to perform its design function. The proposed amendment would not increase the likelihood of the malfunction of any plant SSC.

Therefore, the proposed amendment does not involve a significant increase in the probability or consequences of a previously evaluated accident.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

No.

The proposed amendment does not involve significant physical alteration of the plant. Minor modifications are associated with this proposed amendment (*e.g.,* wiring changes in security equipment, the addition of telecommunications equipment, and software changes to the security computer system.) The proposed license amendment would not physically change any SSCs involved in the mitigation of any postulated accident. Thus, no new initiators or precursors of a new or different kind of accident are created. Furthermore, the proposed amendment does not create the possibility of a new failure mode associated with any equipment or personnel failures. The credible events for the ISFSI remain unchanged.

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?

No.

Because the 10 CFR part 50 license for KPS no longer authorizes operation of the reactor or emplacement or retention of fuel into the reactor vessel, as specified in 10 CFR 50.82(a)(2), the occurrence of postulated accidents associated with reactor operation is no longer credible. With all spent fuel transferred from the SFP to the ISFSI, a fuel handling accident is no longer credible. The proposed amendment does not involve a change in the plant's design, configuration, or operation. The modifications associated with this proposed amendment (*e.g.,* wiring changes in security equipment, the addition of telecommunications equipment, and software changes to the security computer system) would not affect either the way in which the plant SSCs perform their safety functions or their design margins.

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: Lillian M. Cuoco, Senior Counsel, Dominion Resource Services, Inc., 120 Tredegar Street, RS–2, Richmond, VA 23219.

NRC Branch Chief: Bruce A. Watson, CHP.

Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information and Safeguards Information for Contention Preparation

Dominion Energy Kewaunee, Inc., Docket No. 50–305, Kewaunee Power Station, Carlton, Wisconsin

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing sensitive unclassified information (including Sensitive Unclassified Non-Safeguards Information (SUNSI) and Safeguards Information (SGI)). Requirements for access to SGI are primarily set forth in 10 CFR parts 2 and 73. Nothing in this Order is intended to conflict with the SGI regulations.

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 or SGI is necessary to respond to this notice may request access to SUNSI or SGI. 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 or SGI submitted later than 10 days after publication 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 requestor shall submit a letter requesting permission to access SUNSI, SGI, or both 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, U.S. Nuclear Regulatory Commission, 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);

(3) If the request is for SUNSI, the identity of the individual or entity requesting access to SUNSI and the requestor'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; and

(4) If the request is for SGI, the identity of each individual who would have access to SGI if the request is granted, including the identity of any expert, consultant, or assistant who will aid the requestor in evaluating the SGI.

[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 and/or SGI under these procedures should be submitted as described in this paragraph.

In addition, the request must contain the following information:

(a) A statement that explains each individual's ''need to know'' the SGI, as required by 10 CFR 73.2 and 10 CFR 73.22(b)(1). Consistent with the definition of ''need to know'' as stated in 10 CFR 73.2, the statement must explain:

(i) Specifically why the requestor believes that the information is necessary to enable the requestor to proffer and/or adjudicate a specific contention in this proceeding; [2] and

(ii) The technical competence (demonstrable knowledge, skill, training or education) of the requestor to effectively utilize the requested SGI to provide the basis and specificity for a proffered contention. The technical competence of a potential party or its counsel may be shown by reliance on a qualified expert, consultant, or assistant who satisfies these criteria.

(b) A completed Form SF–85, ''Questionnaire for Non-Sensitive Positions,'' for each individual who would have access to SGI. The completed Form SF–85 will be used by the Office of Administration to conduct the background check required for access to SGI, as required by 10 CFR part 2, subpart C, and 10 CFR 73.22(b)(2), to determine the requestor's trustworthiness and reliability. For security reasons, Form SF–85 can only be submitted electronically through the electronic questionnaire for investigations processing (e-QIP) Web site, a secure Web site that is owned and operated by the Office of Personnel Management. To obtain online access to the form, the requestor should contact the NRC's Office of Administration at 301–415–3710.[3]

(c) A completed Form FD–258 (fingerprint card), signed in original ink, and submitted in accordance with 10 CFR 73.57(d). Copies of Form FD–258 may be obtained by writing the Office of Administrative Services, Mail Services Center, Mail Stop P1–37, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by email to *MAILSVC.Resource@nrc.gov.* The fingerprint card will be used to satisfy the requirements of 10 CFR part 2, subpart C, 10 CFR 73.22(b)(1), and Section 149 of the Atomic Energy Act of 1954, as amended, which mandates that all persons with access to SGI must be fingerprinted for an FBI identification and criminal history records check.

(d) A check or money order payable in the amount of $324.00 [4] to the U.S. Nuclear Regulatory Commission for each individual for whom the request for access has been submitted.

(e) If the requestor or any individual(s) who will have access to SGI believes they belong to one or more of the categories of individuals that are exempt from the criminal history records check and background check requirements in 10 CFR 73.59, the requestor should also provide a statement identifying which exemption the requestor is invoking and explaining the requestor's basis for believing that the exemption applies. While processing the request, the Office of Administration, Personnel Security Branch, will make a final determination whether the claimed exemption applies. Alternatively, the requestor may contact the Office of Administration for an evaluation of their exemption status prior to submitting their request. Persons who are exempt from the background check are not required to complete the SF–85 or Form FD–258; however, all other requirements for access to SGI, including the need to know, are still applicable.

Note: Copies of documents and materials required by paragraphs C.(4)(b), (c), and (d) of this Order must be sent to the following address: U.S. Nuclear Regulatory Commission, ATTN: Personnel Security Branch, Mail Stop TWFN–03–B46M, 11555 Rockville Pike, Rockville, MD 20852.

These documents and materials should *not* be included with the request letter to the Office of the Secretary, but the request letter should state that the forms and fees have been submitted as required.

D. To avoid delays in processing requests for access to SGI, the requestor should review all submitted materials for completeness and accuracy (including legibility) before submitting them to the NRC. The NRC will return incomplete packages to the sender without processing.

E. Based on an evaluation of the information submitted under paragraphs C.(3) or C.(4) above, as applicable, 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 or need to know the SGI requested.

F. For requests for access to SUNSI, if the NRC staff determines that the requestor satisfies both E.(1) and E.(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 setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.[5]

G. For requests for access to SGI, if the NRC staff determines that the requestor has satisfied both E.(1) and E.(2) above, the Office of Administration will then determine, based upon completion of the background check, whether the proposed recipient is trustworthy and reliable, as required for access to SGI by 10 CFR 73.22(b). If the Office of Administration determines that the individual or individuals are trustworthy and reliable, the NRC will promptly notify the requestor in writing. The notification will provide the names of approved individuals as well as the conditions under which the SGI will be provided. Those conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order [6] by each individual who will be granted access to SGI.

H. Release and Storage of SGI. Prior to providing SGI to the requestor, the NRC staff will conduct (as necessary) an inspection to confirm that the recipient's information protection system is sufficient to satisfy the requirements of 10 CFR 73.22. Alternatively, recipients may opt to view SGI at an approved SGI storage location rather than establish their own

[2] Broad SGI requests under these procedures are unlikely to meet the standard for need to know; furthermore, NRC staff redaction of information from requested documents before their release may be appropriate to comport with this requirement. These procedures do not authorize unrestricted disclosure or less scrutiny of a requestor's need to know than ordinarily would be applied in connection with an already-admitted contention or non-adjudicatory access to SGI.

[3] The requestor will be asked to provide his or her full name, social security number, date and place of birth, telephone number, and email address. After providing this information, the requestor usually should be able to obtain access to the online form within one business day.

[4] This fee is subject to change pursuant to the Office of Personnel Management's adjustable billing rates.

[5] 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.

[6] Any motion for Protective Order or draft Non-Disclosure Agreement or Affidavit for SGI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 180 days of the deadline for the receipt of the written access request.

SGI protection program to meet SGI protection requirements.

I. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI or SGI must be filed by the requestor no later than 25 days after receipt of (or access to) that information. 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 or SGI contentions by that later deadline.

J. Review of Denials of Access.

(1) If the request for access to SUNSI or SGI is denied by the NRC staff either after a determination on standing and requisite need, or after a determination on trustworthiness and reliability, the NRC staff shall immediately notify the requestor in writing, briefly stating the reason or reasons for the denial.

(2) Before the Office of Administration makes a final adverse determination regarding the trustworthiness and reliability of the proposed recipient(s) for access to SGI, the Office of Administration, in accordance with 10 CFR 2.336(f)(1)(iii), must provide the proposed recipient(s) any records that were considered in the trustworthiness and reliability determination, including those required to be provided under 10 CFR 73.57(e)(1), so that the proposed recipient(s) have an opportunity to correct or explain the record.

(3) The requestor may challenge the NRC staff's adverse determination with respect to access to SUNSI or with respect to standing or need to know for SGI 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) if another officer has been designated to rule on information access issues, with that officer.

(4) The requestor may challenge the Office of Administration's final adverse determination with respect to trustworthiness and reliability for access to SGI by filing a request for review in accordance with 10 CFR 2.336(f)(1)(iv).

(5) Further appeals of decisions under this paragraph must be made pursuant to 10 CFR 2.311.

K. Review of Grants of Access. A party other than the requestor 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 within 5 days of the notification by the NRC staff of its grant of access and must be filed 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) if another officer has been designated to rule on information access issues, with that officer.

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.[7]

L. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI or SGI, 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 propounded contentions meeting the specificity and basis requirements in 10 CFR part 2. The attachment 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 22nd of December, 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 and 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) and/or Safeguards Information (SGI) 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; demonstrating that access should be granted (*e.g.,* showing technical competence for access to SGI); and, for SGI, including application fee for fingerprint/background check.
60	Deadline for submitting petition for intervention containing: (i) Demonstration of standing; (ii) all contentions whose formulation does not require access to SUNSI and/or SGI (+25 Answers to petition for intervention; +7 requestor/petitioner reply).
20	U.S. Nuclear Regulatory Commission (NRC) staff informs the requestor of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows (1) need for SUNSI or (2) need to know for SGI. (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). If NRC staff makes the finding of need to know for SGI and likelihood of standing, NRC staff begins background check (including fingerprinting for a criminal history records check), information processing (preparation of redactions or review of redacted documents), and readiness inspections.
25	If NRC staff finds no ''need,'' no ''need to know,'' or no likelihood of standing, the deadline for requestor/petitioner 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.

[7] Requestors 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/SGI 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 AND SAFEGUARDS INFORMATION IN THIS PROCEEDING—Continued

Day	Event/activity
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.
190	(Receipt +180) If NRC staff finds standing, need to know for SGI, and trustworthiness and reliability, deadline for NRC staff to file motion for Protective Order and draft Non-disclosure Affidavit (or to make a determination that the proposed recipient of SGI is not trustworthy or reliable). Note: Before the Office of Administration makes a final adverse determination regarding access to SGI, the proposed recipient must be provided an opportunity to correct or explain information.
205	Deadline for petitioner to seek reversal of a final adverse NRC staff trustworthiness or reliability determination under 10 CFR 2.336(f)(1)(iv).
A	If access granted: Issuance of a decision by a presiding officer or other designated officer 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 and/or SGI consistent with decision issuing the protective order.
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI and/or SGI. 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 opportunity to request a hearing and petition for leave to intervene), the petitioner may file its SUNSI or SGI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI and/or SGI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.
>A + 60	Decision on contention admission.

[FR Doc. 2016–31450 Filed 12–30–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–166; NRC–2010–0250]

University of Maryland; Maryland University Training Reactor

AGENCY: Nuclear Regulatory Commission.

ACTION: License renewal; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) issued a renewal of Facility Operating License No. R–70, held by the University of Maryland (UMD or the licensee) for the continued operation of its Maryland University Training Reactor (MUTR or the facility) Training, Research, Isotope Production, General Atomics (TRIGA) reactor for an additional 20 years.

DATES: The operating license renewal No. R–70 is effective on December 22, 2016.

ADDRESSES: Please refer to Docket ID NRC–2010–0250 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2010–0250. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it available in ADAMS) is provided the first time that a document is referenced. For the convenience of the reader, the ADAMS accession numbers are provided in a table in the ''Availability of Documents'' section of 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.

FOR FURTHER INFORMATION CONTACT: Eben Allen, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–4246; email: *Eben.Allen@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Discussion

The NRC has issued renewed Facility Operating License No. R–70, held by the licensee, which authorizes continued operation of the MUTR, located in College Park, Maryland. The MUTR is a heterogeneous pool-type, natural convection, light-water cooled, and shielded TRIGA reactor. The MUTR is licensed to operate at a steady-state power level of 250 kilowatts thermal. The renewed Facility Operating License No. R–70 will expire 20 years from its date of issuance.

The renewed facility operating license 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 regulations in chapter I of title 10 of the *Code of Federal Regulations* (10 CFR), and sets forth those findings in the renewed facility operating license. The agency afforded an opportunity for hearing in the Notice of Opportunity for Hearing published in the **Federal Register** on July 26, 2010 (75 FR 43566). The NRC received no request for a hearing or petition for leave to intervene following the notice.

The NRC staff prepared a safety evaluation report for the renewal of Facility Operating License No. R–70 and concluded, based on that evaluation, that the licensee can continue to operate the facility without endangering the health and safety of the public. The NRC staff also prepared an Environmental Assessment and Finding of No

Significant Impact for the renewal of the facility operating license, noticed in the **Federal Register** on December 22, 2016 (81 FR 93969), and concluded that renewal of the facility operating license will not have a significant impact on the quality of the human environment.

II. Availability of Documents

The documents identified in the following table are available to interested persons through ADAMS accession numbers, as indicated.

Document	ADAMS accession No.
University of Maryland, Request for Renewal of Class 104 Operating License R–70., May 12, 2000	ML052910399
University of Maryland—Request for Additional Information Re: Renewal of License R–70, October 10, 2002	ML022690533
Transmittal of the University of Maryland's Response to the Request for Additional Information Pertaining to Sections Six through Ten of the Safety Analysis Report (SAR), June 7, 2004.	ML101970211
University of Maryland's Response to the Request for Additional Information Re: Environmental Report for Training Reactor, August 4, 2004.	ML042240227
Submittal of Additional Information as it Pertains to Section Eleven of the Safety Analysis Report for the Maryland University Training Reactor, September 17, 2004.	ML042940317
Response to the Request for Additional Information as it Pertains to Section Twelve of the Safety Analysis Report for the Maryland University Training Reactor, October 7, 2004.	ML042940408
University of Maryland—Response to RAI Regarding the Technical Specifications for the Maryland University Training Reactor, April 18, 2005.	ML051160054
University of Maryland's Response to Request for Additional Information, as it Pertains to Section Two of Safety Analysis Report for Maryland University Training Reactor, April 25, 2006.	ML061250233
University of Maryland's Response to Request for Additional Information, as it Pertains to Section Two of Safety Analysis Report for Maryland University Training Reactor, April 25, 2006.	ML061280383
University of Maryland Responses to RAIs on the SAR, August 28, 2006	ML101970209
University of Maryland, Response to Request for Additional Information, September 7, 2006	ML16083A222
University of Maryland Responses to RAIs on the SAR, November 9, 2006	ML101970210
University of Maryland's Response to Request for Additional Information as it Pertains to Technical Specifications for Maryland University Training Reactor, December 18, 2006.	ML101480913
University of Maryland, Request for Additional Information Regarding the License Renewal for the Maryland University Training and Research Reactor, December 10, 2009.	ML093420068
University of Maryland, Request for Additional Information Regarding License Renewal Technical Matters (TAC ME1592), April 6, 2010.	ML100840239
University of MD Training Reactor (MUTR)—Submitting Responses to NRC 12/10/09 Request for Additional Information Regarding Financial Qualifications for Renewal of License, May 27, 2010.	ML101670413
University of Maryland Responses Request for Additional Information Regarding the License Renewal for Maryland University Training Reactor, July 28, 2010.	ML102110049
University of Maryland Training Reactor, Request for Additional Information Regarding License Renewal Revised Technical Specifications dated December 18, 2006 (TAC No. ME1592), August 20, 2010.	ML102230338
University of Maryland, Request for Additional Information Regarding the License Renewal for the Maryland University Training Reactor, September 22, 2010.	ML102710556
University of Maryland, Maryland University Training Reactor (MUTRA), Request for Additional Information (RAI) Regarding Remaining Technical Specifications, January 31, 2011.	ML110320459
University of Maryland, Maryland University Training Reactor, Response to Request No. #2 to the NRC's April 6, 2010, Request for Additional Information, February 2, 2011.	ML110350175
University of Maryland, Maryland University Training Reactor ("MUTR"), Technical Specifications, Response to February 18, 2011, Request for Additional Information ("RAI") Regarding Remaining Technical Specifications, May 2, 2011.	ML11124A124
University of Maryland, NRC Response to Letter Dated May 2, 2011, June 22, 2011	ML11171A566
University of Maryland, Maryland, Response to Request for Additional Information in Regard to Remaining Technical Specifications, July 5, 2011.	ML11189A065
University of Maryland, Response to Request for Additional Information Regarding Dose to General Public in the Event of Maximum Hypothetical Accident (MHA), July 29, 2011.	ML16231A339
University of Maryland—Request for Additional Information Regarding the License Renewal for the Maryland University Training Reactor (Related to May 2, 2011) (TAC No. ME1592), August 26, 2011.	ML112130086
University of Maryland—Request for Additional Information Regarding Dose Calculations, September 8, 2011	ML112380621
University of Maryland, Request for Additional Information Regarding License Renewal for Maryland University Training Reactor (TAC No. ME1592), September 28, 2011.	ML11277A026
University of Maryland—Request for Additional Information Regarding the License Renewal for the Maryland University Training Reactor, October 12, 2011.	ML11286A337
University of Maryland—Response to NRC Request for Additional Information Regarding the License Renewal for the Maryland University Training Reactor, February 9, 2012.	ML12060A344
University of Maryland—Request for Additional Information Re: Reactor Operator Requalification Program, February 15, 2012	ML102660113
University of Maryland—Request for Additional Information Re: Reactor Operator Requalification Program (TAC No. ME2431), March 14, 2012.	ML12081A017
University of Maryland, Request for Additional Information Regarding the License Renewal for the Maryland University Training Reactor ("MUTR"), May 22, 2012.	ML12172A139
University of Maryland—Request for Additional Information, Re: Reactor Operator Requalification Program (TAC ME2431), July 16, 2012.	ML121870709
University of Maryland, Response to Request for Additional Information Regarding the License Renewal for the Training Reactor ("MUTR"), August 29, 2012.	ML12255A400
University of Maryland—Review and Approval of the Requalification Training Program for Licensed Operators (TAC No. ME1592), November 15, 2012.	ML12306A112
University of Maryland—License Renewal for the Maryland University Training Reactor (MUTR), TAC ME1592), March 21, 2013.	ML13095A006

Document	ADAMS accession No.
University of Maryland, College Park Request for Additional Information Re: Financial Update for License Renewal for the University of Maryland (TAC ME1592), June 2, 2014.	ML14141A630
University of Maryland Training Reactor—Report on AR–41 Mitigation, June 18, 2014	ML14176A078
University of Maryland—Request for Additional Information Re: Review of the Argon-41 Radiological Dose Assessment for License Renewal (TAC ME1592), September 25, 2014.	ML14266A658
University of Maryland, Response to Request for Additional Information Regarding Financial Update for License Renewal, November 25, 2014.	ML14342A563
University of Maryland—Request for Additional Information Re: Review of the ARGON–41 Radiological Dose Assessment for License Renewal of the Maryland University Training Reactor (TAC No. ME1592) November 25, 2014.	ML14332A300
University Of Maryland—Revised Physical Security Plan For License Renewal Of The Maryland University Training Reactor (TAC ME1592) License No. 70; Docket No. 50–166, December 19, 2014.	ML14364A086
Letter Request for Additional Information RE: Physical Security Plan Review for License Renewal (TAC No. ME1592), March 12, 2015.	ML15058A276
University of Maryland—Request for Additional Information for License Renewal of the Maryland University Training Reactor (TAC No. ME1592), August 21, 2015.	ML15083A383
University of Maryland—Request for Additional Information for License Renewal of the Maryland University Training Reactor Pertaining to Thermal Hydraulics, September 10, 2015.	ML15219A471
University of Maryland—Request for Additional Information for License Renewal Pertaining to Thermal Hydraulics, December 2, 2015.	ML15349A894
University of Maryland—Response to Request for Additional Information for License Renewal, January 5, 2016	ML16008A072
University of Maryland—Request for Additional Information Re: For the Renewal of Facility Operating License No. R–70 the Maryland University Training Reactor Docket No. 50–166, February 29, 2016.	ML16061A003
University of Maryland—License Amendment Re: SNM Limit, Docket No. 50–166, License No. R–70, University of Maryland, November 1, 2016.	ML16312A066
University of Maryland—Request for Additional Information Re: For the Renewal of Facility Operating License No. R–70 the Maryland University Training Reactor Docket No. 50–166, November 2, 2016.	ML16309A184
University of Maryland—Request for Additional Information Re: For the Renewal of Facility Operating License No. R–70 the Maryland University Training Reactor Docket No. 50–166 ME1592, November 10, 2016.	ML16320A007
University of Maryland—Request for Additional Information Re: For the Renewal of Facility Operating License No. R–70 the Maryland University Training Reactor Docket No. 50–166, November 17, 2016.	ML16323A447
University of Maryland—Request for Additional Information Regarding The Review of License Renewal For the Maryland University Training Reactor (TAC No. ME1592), November 17, 2016.	ML16323A446
University of Maryland, Re: Conversation of Record Support of MUTR License Renewal, December 2, 2016	ML16337A389

Dated at Rockville, Maryland, this 22nd day of December 2016.

For the Nuclear Regulatory Commission.

Michael Balazik,

Branch Chief (Acting), Research and Test Reactors Licensing Branch, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation.

[FR Doc. 2016–31815 Filed 12–30–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0016]

Information Collection: NRC Forms 366, 366A, and 366B, "Licensee Event Report"; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment; extension of comment period and correction.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is correcting a notice that was published in the **Federal Register** (FR) on November 30, 2016, regarding Notice of submission to the Office of Management and Budget; request for comment. This action is necessary to amend the annual responses and burden hours to include the burden and responses associated cyber security events.

DATES: The correction is effective January 3, 2017.

ADDRESSES: Submit comments directly to the OMB reviewer at: Vlad Dorjets, Desk Officer, Office of Information and Regulatory Affairs (3150–0104), NEOB–10202, Office of Management and Budget, Washington, DC 20503; telephone: 202–395–7315, email: *oira_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: David Cullison, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION: In the FR on November 30, 2016, in FR Doc. 2016–0016, on page 86344, in the first column, the second sentence in the response to question 5 is changed from ''The total number of reports is estimated to be 350 per year'' to ''The total number of reports is estimated to be 442 per year''. In the first column, the response to question 7 is changed from ''The total number of reports is estimated to be 350 per year'' to ''The total number of responses is estimated to be 542 per year (442 reporting responses plus 100 recordkeepers)''. In the first column, the response to question 9 is changed from ''The total estimated burden from completing Licensee Event Reports is 28,000 hours (based on 80 hours for each of 350 reports)'' to ''The total estimated burden from completing Licensee Event Reports is 35,360 hours (28,288 hours reporting plus 7,072 hours recordkeeping)''.

Dated at Rockville, Maryland, this 23rd day of December, 2016.

For the Nuclear Regulatory Commission.

David Cullison,

NRC Clearance Officer, FOIA, Privacy and Information Collections Branch, Customer Services Division, Office of the Chief Information Officer.

[FR Doc. 2016–31768 Filed 12–30–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 52–018 and 52–019; NRC–2008–0170]

Duke Energy Carolinas, LLC; William States Lee III Nuclear Station Units 1 and 2

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of intent to enter into a modified indemnity agreement.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing a notice of intent to enter into a modified indemnity agreement with Duke Energy Carolinas, LLC, (DEC) to operate William States Lee III Nuclear Station (WLS) Units 1 and 2. The NRC is required to publish notice of its intent to enter into an indemnity agreement which contains provisions different from the general form found in the NRC's regulations. A modification to the general form is necessary to accommodate the unique timing provisions of a combined license (COL).

DATES: On December 15, 2016, the Commission authorized the Director of the Office of New Reactors to issue COLs to DEC to construct and operate WLS Units 1 and 2. The modified indemnity agreement would be effective upon issuance of the COLs.

ADDRESSES: Please refer to Docket ID NRC–2008–0170 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0170. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.*
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Brian Hughes, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–6582, email: *Brian.Hughes@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On December 15, 2016, the Commission authorized issuance of COLs to DEC for WLS Units 1 and 2. These COLs would include a license pursuant to part 70 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Domestic Licensing of Special Nuclear Material.'' Pursuant to 10 CFR 140.20(a)(1)(iii), the NRC will execute and issue agreements of indemnity effective on the date of a license under 10 CFR part 70 authorizing the licensee to possess and store special nuclear material at the site of the nuclear reactor for use as fuel in operation of the nuclear reactor after issuance of an operating license for the reactor. The general form of indemnity agreement to be entered into by the NRC with DEC is contained in 10 CFR 140.92, ''Appendix B—Form of Indemnity Agreement with licensees furnishing insurance policies as proof of financial protection.''

II. Request/Action

Pursuant to 10 CFR 140.9, the NRC is publishing notice of its intent to enter into an indemnity agreement that contains provisions different from the general form found in 10 CFR 140.92. Modifications to the general indemnity agreement are addressed in the following discussion.

III. Discussion

The provisions of the general form of indemnity agreement in 10 CFR 140.92 address insurance and indemnity for a licensee that is authorized to operate as soon as an operating license (OL) is issued pursuant to 10 CFR part 50, ''Domestic licensing of production and utilization facilities.'' The DEC, however, has requested a COL pursuant to 10 CFR part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants'' to construct and operate WLS Units 1 and 2. Unlike an OL, which authorizes operation of the facility as soon as the license is issued, a COL authorizes the construction of the facility but does not authorize operation of the facility until the Commission makes a finding pursuant to 10 CFR 52.103(g) that the acceptance criteria in the COL are met (also called a ''§ 52.103(g) finding''). The COL holders are not required to maintain financial protection in the amount specified in 10 CFR 140.11(a)(4) before the § 52.103(g) finding is made, but must maintain financial protection in the amount specified by 10 CFR 140.13 upon receipt of a COL because the COL includes a license issued pursuant to 10 CFR part 70. Therefore, the provisions in the general form of indemnity agreement must be modified to address the timing differences applicable to COLs.

Modifications to the general form of indemnity agreement will reflect the timing distinctions applicable to COLs. In addition, other modifications and their intent are described below:

(1) References to Mutual Atomic Energy Liability Underwriters have been removed because this entity no longer exists.

(2) Monetary amounts have been updated to reflect changes that have been made to Section 170. ''Indemnification and Limitation of Liability'' of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2210).

IV. Conclusions

Accordingly, for the reasons discussed in this notice and in accordance with 10 CFR 140.9, the NRC hereby provides notice of its intent to enter into an agreement of indemnity with DEC for WLS Units 1 and 2 with the described modifications to the general form of indemnity.

Dated at Rockville, Maryland, this 22nd day of December 2016.

For the Nuclear Regulatory Commission.

Anna Bradford,

Deputy Director, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. 2016–31812 Filed 12–30–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0273]

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 December 6 to December 19, 2016. The last biweekly notice was published on December 20, 2016.

DATES: Comments must be filed by February 2, 2017. A request for a hearing must be filed by March 6, 2017.

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–2016–0273. 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: Janet Burkhardt, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–1384, email: *Janet.Burkhardt@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2016–0273, 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–2016–0273.

• *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–2016–0273, 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.

II. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Proposed No Significant Hazards Consideration Determination

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in § 50.92 of title 10 of the *Code of Federal Regulations* (10 CFR), this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated, or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period 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 persons (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. 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/.* Alternatively, a copy of the regulations is available at the NRC's Public Document Room, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if

appropriate, a notice of a hearing will be issued.

As required by 10 CFR 2.309(d) the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) The name, address, and telephone number of the petitioner; (2) the nature of the petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the 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 petitioner's interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions which the petitioner seeks to have litigated in 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 petitioner must 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 petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) 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. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the 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) through (iii). The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document.

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 establish 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 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 the 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 March 6, 2017. 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 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. Alternatively, a State, local governmental body, Federally-recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a hearing is granted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at 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 his or her 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 and petition for leave to intervene (petition), 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 that request to participate 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. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC Web site at *http://www.nrc.gov/site-help/e-submittals.html.* 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 (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (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.* Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit

adjudicatory documents. Submissions should be in Portable Document Format (PDF). Additional guidance on PDF submissions is 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 document is 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 document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's 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, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory documents 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 personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. 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 accessing information related to this document, see the ''Obtaining Information and Submitting Comments'' section of this document.

Dominion Nuclear Connecticut, Inc. (DNC), Docket No. 50–336, Millstone Power Station, Unit No. 2 (MPS2), New London County, Connecticut.

Date of amendment request: December 14, 2016. A publicly-available version is in ADAMS under Accession No. ML16354A424.

Description of amendment request: The amendment would revise Technical Specification (TS) Surveillance Requirement (SR) 4.1.3.1.2 regarding control element assembly (CEA) freedom of movement surveillance, such that CEA 39 may be excluded from the last remaining quarterly performance of the SR in MPS2 Cycle 24.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed amendment would exclude CEA 39 from SR 4.1.3.1.2 for the remainder of MPS2 Cycle 24 operation. The function of CEA 39 is to provide negative reactivity addition into the core upon receipt of a signal from the Reactor Protection System (RPS). CEA 39 was demonstrated to be moveable and trippable during the last performance of SR 4.1.3.1.2. Since the functionality of CEA 39 has not been affected, the assumptions and conclusions of the Final Safety Analysis Report (FSAR) Chapter 14, Safety Analysis, are not affected by this license amendment request.

The misoperation of a CEA, which includes a CEA drop event, has been evaluated in the MPS2 FSAR and found acceptable. The proposed change would minimize the potential for inadvertent insertion of CEA 39 into the core by eliminating the requirement to place the CEA on the UGC to perform freedom of movement testing. The proposed change does not significantly increase the probability of a failure of a CEA to insert into the core on a reactor trip or the probability of an inadvertent CEA drop into the core at power.

No modifications are proposed to the RPS or associated Control Element Drive Mechanism (CEDM) system logic.

Based on the above, 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 amendment would exclude CEA 39 from SR 4.1.3.1.2 for the remainder of MPS2 Cycle 24 operation. CEA 39 was demonstrated to be moveable and trippable during the last performance of SR 4.1.3.1.2; therefore, the functionality of CEA 39 has not been affected. The proposed change will not introduce any new design changes or systems that can prevent the CEA from performing its specified safety function to insert on a reactor trip. The current MPS2 FSAR safety analysis considers the drop of a CEA into the core as an initiating event. This change does not alter assumptions made in the FSAR Chapter 14 safety analysis.

Based on the above, 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 the margin of safety?

Response: No.

The proposed amendment would exclude CEA 39 from SR 4.1.3.1.2 for the remainder of MPS2 Cycle 24 operation. SR 4.1.3.1.2 is intended to verify freedom of movement of CEAs (*i.e.,* trippable). CEA 39 was demonstrated to be moveable and trippable during the last performance of SR 4.1.3.1.2.

The physical and electrical design of the CEAs, and past operating experience, provides high confidence that CEAs remain trippable whether or not exercised during each SR interval. Eliminating further exercise of CEA 39 for the remainder of MPS2 Cycle 24 operation does not directly relate to the potential for CEA binding to occur. The current MPS2 FSAR safety analysis is unaffected by this license amendment request and there is no reduction in the margin of safety.

There is no known failure mechanism (*e.g.,* crud deposition) that would preclude the CEA from inserting into core on a valid trip signal or loss of power.

Based on the above, the proposed amendment does not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Lillian M. Cuoco, Senior Counsel, Dominion Resources Services, Inc., 120 Tredegar Street, RS–2, Richmond, VA 23219.

NRC Acting Branch Chief: Stephen S. Koenick.

Duke Energy Carolinas, LLC, Docket Nos. 50–369 and 50–370, McGuire Nuclear Station, Units 1 and 2, Mecklenburg County, North Carolina.

Date of amendment request: June 30, 2016. A publicly-available version is in ADAMS under Accession No. ML16193A656.

Description of amendment request: The amendments would modify Technical Specification 3.6.14, ''Divider Barrier Integrity,'' to revise Conditions A and D to allow one steam generator (SG) enclosure hatch or one pressurizer enclosure hatch to be open for up to 48 hours to facilitate potential inspections and maintenance and to enhance personnel and radiation safety.

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.

Implementation of this amendment will not involve a significant increase in the probability or consequences of an accident previously evaluated. Removal of the SG enclosure hatch or the pressurizer enclosure hatch will not cause an increase in the probability of an accident that has been previously evaluated because the hatches are not accident initiators.

The consequences of an accident, which have been previously evaluated, will not be significantly increased by removal of the pressurizer enclosure or SG enclosure hatch. As discussed in the technical justification supporting this amendment request, the new containment compression peak pressure will remain well below the acceptance criteria. Additionally, the long term containment peak pressure will not be adversely affected due to the delay time in melting of the ice.

The removal of the pressurizer enclosure hatch itself has been previously evaluated in Modes 1 through 4 in accordance with the analytical method described in NUREG–0612 and the NRC's December 22, 1980, letter regarding the control of heavy loads at nuclear power plants [(ADAMS Accession Nos. ML070250180 and ML071080219, respectively)]. Because the SG enclosure hatch weighs less than 300 pounds, it would not be considered a heavy load as defined by NUREG–0612. As such, it is not subject to heavy lift considerations. Regardless, there is no safety-related equipment directly under these hatch covers, so in the unlikely event that one fell, no damage is expected to be caused. The changes proposed in this [license amendment request (LAR)] have no adverse effect on the procedures used for the handling of heavy loads at McGuire.

In summary, the proposed changes will not involve any 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.

Operation in accordance with the proposed amendment does not create a new plant configuration and does not adversely affect how the plant is operated, so implementation of this amendment would not create the possibility of a new or different kind of accident from any accident previously evaluated. No new accident causal mechanisms are created as a result of the NRC approval of this license amendment request. As discussed above, extending the time that the pressurizer enclosure hatch or SG enclosure hatch is allowed to be open or inoperable does not create any new or different accidents from those previously evaluated. Removal of the pressurizer enclosure hatch to perform inspections or maintenance has been previously evaluated and determined to be acceptable. The analysis contained in the technical justification for this license amendment request provides results concluding that the containment compression peak pressure and the long term containment peak pressure are acceptable with either a pressurizer enclosure hatch or [an] SG enclosure hatch open. This proposed amendment does not impact any plant systems that are accident initiators; therefore, no new accident types are being created.

3. Does the proposed amendment involve a significant reduction in the margin of safety?

Response: No.

Implementation of this amendment would not involve a significant reduction in a margin of safety. 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 situation. These barriers include the fuel cladding, the reactor coolant system, and the containment system. The pressurizer enclosure hatch and the SG enclosure hatch, as well as their performances, have a direct impact on the containment boundary since peak containment pressure due to an accident could be affected. However, the analysis supporting this amendment request concludes that the containment compression peak pressure and the long term containment peak pressure continue to be acceptable with the increased time a single hatch is open.

Therefore, the performance of the fission product barriers will not be significantly impacted by implementation of this amendment, and no safety margins will be significantly impacted.

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 Nolan, Deputy General Counsel, Duke Energy Corporation, 526 South Church Street—DEC45A, Charlotte, NC 28202.

NRC Branch Chief: Michael T. Markley.

Duke Energy Progress, LLC, Docket Nos. 50–325 and 50–324, Brunswick Steam Electric Plant, Units 1 and 2 (BSEP), Brunswick County, North Carolina.

Date of amendment request: September 6, 2016, as supplemented by letter dated November 9, 2016. Publicly-available versions are in ADAMS under Accession Nos. ML16257A410 and ML16330A504, respectively.

Description of amendment request: The amendment would revise the Technical Specifications to support an expansion of the core power-flow operating range (*i.e.,* Maximum Extended Load Line Limit Analysis Plus (MELLLA+)).

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 operation in the MELLLA+ operating domain does not significantly increase the probability or consequences of an accident previously evaluated. The probability (*i.e.,* frequency of occurrence) of

Design Basis Accidents (DBAs) occurring is not affected by the MELLLA+ operating domain because BSEP continues to comply with the regulatory and design basis criteria established for plant equipment. Furthermore, a probabilistic risk assessment demonstrates that the calculated core damage frequencies do not significantly change due to the MELLLA+.

There is no change in consequences of postulated accidents when operating in the MELLLA+ operating domain compared to the operating domain previously evaluated. The results of accident evaluations remain within the NRC approved acceptance limits.

The spectrum of postulated transients has been investigated and is shown to meet the plant's currently licensed regulatory criteria. Continued compliance with the Safety Limit Minimum Critical Power Ratio (SLMCPR) will be confirmed on a cycle-specific basis consistent with the criteria accepted by the NRC.

Challenges to the reactor coolant pressure boundary were evaluated for the MELLLA+ operating domain conditions (*i.e.,* pressure, temperature, flow, and radiation) and were found to meet their respective acceptance criteria for allowable stresses and overpressure margin.

Challenges to the containment were evaluated and the containment and its associated cooling systems continue to meet the current licensing basis. The calculated post-Loss of Coolant Accident (LOCA) suppression pool temperature remains acceptable.

The proposed changes to the sodium pentaborate (SPB) enrichment and volume requirements maintain the capability of the Standby Liquid Control (SLC) system to perform this reactivity control function and ensure continued compliance with the requirements of 10 CFR 50.62. The SLC system is not considered to be an initiator of any event. The use of the proposed SPB solution with a higher boron-10 (B–10) isotope enrichment does not alter the design, function, or operation of the SLC system or increase the likelihood of malfunction that could 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.

The proposed operation in the MELLLA+ operating domain does not create the possibility of a new or different kind of accident from any previously evaluated.

Equipment that could be affected by the MELLLA+ operating domain has been evaluated. No new operating mode, safety-related equipment lineup, accident scenario, or equipment failure mode was identified. The full spectrum of accident considerations has been evaluated and no new or different kind of accident was identified. The MELLLA+ operating domain uses developed technology, and applies it within the capabilities of existing plant safety-related equipment in accordance with the regulatory criteria, including NRC-approved codes, standards and methods. The use of the proposed SPB solution with a higher B–10 isotope enrichment does not alter the design, function, or operation of the SLC system or create the possibility of a new or different kind of accident. The proposed changes have been assessed and determined not to introduce a different accident than that previously evaluated. No new accident or event precursor has been identified.

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 proposed operation in the MELLLA+ domain does not involve a significant reduction in the margin of safety.

The MELLLA+ operating domain can only affect design and operational margins. Challenges to the fuel, reactor coolant pressure boundary, and containment were evaluated for the MELLLA+ operating domain conditions. Fuel integrity is maintained by meeting existing design and regulatory limits. The calculated loads on affected structures, systems, and components, including the reactor coolant pressure boundary, will remain within their design allowables for design basis event categories. No NRC acceptance criterion is exceeded. The BSEP configuration and responses to transients and postulated accidents do not result in exceeding the presently approved NRC acceptance limits, thereby preserving safety margins.

The proposed changes to the SPB enrichment and volume requirements ensure SLC system shutdown margins and post-accident pH control margins are maintained while maintaining compliance with the requirements of 10 CFR 50.62.

Therefore, the proposed amendments do not result in a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Kathryn B. Nolan, Deputy General Counsel, 550 South Tryon St., M/C DEC45A, Charlotte, NC 28202.

NRC Acting Branch Chief: Jeanne D. Johnston.

Exelon Generation Company, LLC, and PSEG Nuclear LLC, Docket Nos. 50–277 and 50–278, Peach Bottom Atomic Power Station, Units 2 and 3 (PBAPS), York and Lancaster Counties, Pennsylvania.

Date of amendment request: November 4, 2016, as supplemented by letter dated December 7, 2016. Publicly-available versions are in ADAMS under Accession Nos. ML16309A298 and ML16342C455, respectively.

Description of amendment request: The amendments would revise the Allowable Value (AV) for the Turbine Condenser—Low Vacuum scram function specified in Technical Specification Table 3.3.1.1–1, ''Reactor Protection System Instrumentation.'' The licensee stated that the purpose of the proposed change is to minimize the potential for inadvertent scrams due to low condenser vacuum.

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 edits shown 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 implements a revised AV [allowable value] for the Turbine Condenser—Low Vacuum scram instrument function at PBAPS.

The proposed change to the PBAPS Turbine Condenser- Low Vacuum scram AV does not require modifying any system interface or affect the probability of any event initiators at the facility. Overall RPS [Reactor Protection System] performance will remain within the bounds of the previously performed accident analyses, since [the Turbine-Condenser—Low Vacuum scram is not specifically credited in any accident analysis.]

There will be no degradation in the performance of, or an increase in the number of challenges imposed on safety-related equipment that are assumed to function during an accident situation. The proposed change will not alter any assumptions or change any mitigation actions in the radiological consequence evaluations in the UFSAR [Updated Final Safety Analysis Report]. The proposed change is consistent with safety analysis assumptions and resultant consequences.

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 to the PBAPS Turbine Condenser—Low Vacuum scram AV does not affect the design, functional performance, or operation of the facility. Similarly, the proposed change does not affect the design or operation of any SSCs [structures, systems, or components] involved in the mitigation of any accidents, nor does it affect the design or operation of any component in the facility such that new equipment failure modes are created.

No new accident scenarios, transient precursors, failure mechanisms, or limiting single failures are introduced as a result of this change. There will be no adverse effect or challenges imposed on any safety-related system as a result of this change.

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 does not affect the acceptance criteria for any analyzed event, nor is there a change to any Safety Analysis Limit. There will be no effect on the manner in which safety limits, limiting safety system settings, or limiting conditions for operation are determined nor will there be any effect on those plant systems necessary to assure the accomplishment of protection functions.

The purpose of the condenser low vacuum turbine trip is to protect the main condenser against overpressure on loss of condenser vacuum. A condenser low vacuum condition provides a signal to trip the main turbine by providing automatic closure to the turbine stop valves. To anticipate the transient and scram which results from the closure of the turbine stop valves, a condenser low vacuum condition initiates a reactor scram. The condenser low vacuum scram trip setting is selected to initiate a reactor scram prior to initiation of closure of the [t]urbine [s]top [v]alves.

The proposed LAR [license amendment request] does not change the sequential relationship of the condenser low vacuum scram and turbine trip. The Automatic Scram signal (Actual Trip Setpoint greater than or equal to 21.95 inches [mercury (Hg)] vacuum) will still occur prior to the Turbine Trip signal (Actual Trip Setpoint 20.0 inches Hg vacuum). This aligns with UFSAR Section 7.2 in that the condenser low vacuum scram is an anticipatory trip prior to the scram that would result from the closure of the main turbine stop valves.

The condenser low vacuum scram is not specifically credited in any accident analysis. The integrity of the condenser is not compromised by the proposed change because the reactor will be shut down using both diverse and redundant tripping to ensure fission products are not released.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis. Based on this review, and the NRC edits shown in square brackets, 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: Tamra Domeyer, Associate General Counsel, Exelon Generation Company, LLC, 4300 Winfield Rd., Warrenville, IL 60555.

NRC Acting Branch Chief: Stephen S. Koenick.

Southern Nuclear Operating Company, Inc. (SNC), Docket Nos. 50–348 and 50–364, Joseph M. Farley Nuclear Plant, Units 1 and 2, Houston County, Alabama.

Date of amendment request: November 22, 2016. A publicly-available version is in ADAMS under Accession No. ML16336A024.

Description of amendment request: SNC requested to revise the licensing basis that support a selected scope application of an Alternative Source Term (AST) methodology and incorporate Technical Specification Task Force (TSTF) Traveler, TSTF–448–A, Revision 3, ''Control Room Habitability,'' and TSTF–312–A, ''Administrative Control of Containment Penetrations.''

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. The NRC staff has reviewed the licensee's analysis against the standards of 10 CFR 50.92(c). The licensee's analysis 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.

There are no physical changes to the plant being introduced by the proposed changes to the accident source term. Implementation of Alternative Source Term (AST) and the new atmospheric dispersion factors have no impact on the probability for initiation of any Design Basis Accidents (DBAs). Once the occurrence of an accident has been postulated, the new accident source term and atmospheric dispersion factors are an input to analyses that evaluate the radiological consequences. The proposed changes do not involve a revision to the design or manner in which the facility is operated that could increase the probability of an accident previously evaluated in Chapter 15 of the Final Safety Analysis Report (FSAR).

Based on the AST analyses, there are no proposed changes to performance requirements and no proposed revision to the parameters or conditions that could contribute to the consequences of an accident previously discussed in Chapter 15 of the FSAR. Plant-specific radiological analyses have been performed using the AST methodology and new atmospheric dispersion factors (X/Qs) have been established. Based on the results of these analyses, it has been demonstrated that the Control Room and off-site dose consequences of the limiting events considered in the analyses meet the regulatory guidance provided for use with the AST, and the doses are within the limits established by 10 CFR 50.67.

Regarding TSTF–312–A, the proposed change would allow containment penetrations to be unisolated under administrative controls during core alterations or movement of irradiated fuel assemblies within containment. The status of containment penetration flow paths (*i.e.,* open or closed) is not an initiator for any design basis accident or event, and therefore the proposed change does not increase the probability of any accident previously evaluated. The proposed change does not affect the design of the primary containment, or alter plant operating practices such that the probability of an accident previously evaluated would be significantly increased. The proposed change does not significantly change how the plant would mitigate an accident previously evaluated, and is bounded by the fuel handling accident (FHA) analysis.

Therefore, it is concluded that the proposed amendment does not involve a significant increase in the probability or the consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

No new modes of operation are introduced by the proposed changes. The proposed changes will not create any failure mode not bounded by previously evaluated accidents. Implementation of AST and the associated proposed Technical Specification changes and new X/Qs have no impact to the initiation of any DBAs. These changes do not affect the design function or modes of operation of structures, systems and components in the facility prior to a postulated accident. Since structures, systems and components are operated no differently after the AST implementation, no new failure modes are created by this proposed change. The AST change itself does not have the capability to initiate accidents.

Regarding TSTF–312–A, allowing penetration flow paths to be open is not an initiator for any accident. The proposed change to allow open penetration flow paths will not affect plant safety functions or plant operating practices such that a new or different accident could be created. There are no design changes associated with the proposed changes, and the change does not involve a physical alteration of the plant (*i.e.,* no new or different type of equipment will be installed). The change does not alter assumptions made in the safety analysis, and is consistent with the safety analysis assumptions and current plant operating practice.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

Consequently, 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 AST analyses have been performed using approved methodologies to ensure that analyzed events are bounding and safety

margin has not been reduced. The dose consequences of these limiting events are within the acceptance criteria presented in 10 CFR 50.67. Thus, by meeting the applicable regulatory limits for AST, there is no significant reduction in a margin of safety.

Regarding TSTF–312–A, TS 3.9.3 provides measures to ensure that the dose consequences of a postulated FHA inside containment are minimized. The proposed change to LCO 3.9.3 will allow penetration flow path(s) to be open during refueling operations under administrative control. These administrative controls will provide assurance that prompt closure of open penetrations flow paths can and will be achieved in the event of an FHA inside containment, and will minimize dose consequences. The proposed change does not affect the safety analysis acceptance criteria for ay [an] analyzed event, nor is there a change to any safety analysis limit. The proposed change does not alter the manner in which safety limits, limiting safety system settings or limiting conditions for operation are deterred, not [nor] is here [there] any adverse effect on those plant systems necessary to assure the accomplishment of protective functions. The proposed change will not result in plant operation in a configuration outside the design basis.

Therefore, because the proposed changes continue to result in dose consequences within the applicable regulatory limits, the proposed amendment does not involve a significant reduction in margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Jennifer M. Buettner, Associate General Counsel, Southern Nuclear Operating Company, 40 Inverness Center Parkway, Birmingham, AL 35201.

NRC Branch Chief: Michael T. Markley.

Southern Nuclear Operating Company, Inc., Docket Nos. 50–348 and 50–364, Joseph M. Farley Nuclear Plant, Units 1 and 2, Houston County, Alabama.

Date of amendment request: November 15, 2016. A publicly-available version is in ADAMS under Accession No. ML16320A540.

Description of amendment request: The proposed changes would revise Technical Specification 5.5.17, ''Containment Leakage Rate Testing Program.'' The revision would increase the existing Type A integrated leakage rate test program test interval from 10 years to 15 years; adopt an extension of the containment isolation valve leakage testing (Type C) frequency from 60 months to 75 months; adopt the use of American National Standards Institute/American Nuclear Society (ANSI/ANS) 56.8–2002, ''Containment System Leakage Testing Requirements''; and adopt a grace interval of 9 months for Type A, Type B, and Type C leakage tests, in accordance with Nuclear Energy Institute (NEI) 94–01, Revision 3–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 consequences of an accident previously evaluated?

Response: No.

The proposed activity involves the revision of Joseph M. Farley Nuclear Plant (FNP), Units 1 and 2, Technical Specification (TS) 5.5.17, ''Primary Containment Leakage Rate Testing Program,'' to allow the extension of the Type A integrated leakage rate test (ILRT) containment test interval to 15 years, and the extension of the Type C local leakage rate test (LLRT) interval to 75 months. The current Type A test interval of 120 months (10 years) would be extended on a permanent basis to no longer than 15 years from the last Type A test. The current Type C test interval of 60 months for selected components would be extended on a performance basis to no longer than 75 months. Extensions of up to nine months (total maximum interval of 84 months for Type C tests) are permissible only for non-routine emergent conditions.

The proposed extensions do not involve either a physical change to the plant or a change in the manner in which the plant is operated or controlled. The containment is designed to provide an essentially leak tight barrier against the uncontrolled release of radioactivity to the environment for postulated accidents. As such, the containment and the testing requirements invoked to periodically demonstrate the integrity of the containment exist to ensure the plant's ability to mitigate the consequences of an accident, and do not involve the prevention or identification of any precursors of an accident.

The change in Type A test frequency to once-per-fifteen years, measured as an increase to the total integrated plant risk for those accident sequences influenced by Type A testing, based on the internal events probabilistic risk analysis (PRA) is 1.08E–02 person-rem/year for Unit 1 and 9.89 E–03 person-rem/year for Unit 2. Electric Power Research Institute (EPRI) Report No. 1009325, Revision 2–A states that a very small population is defined as an increase of ≤ 1.0 person-rem per year or ≤ 1% of the total population dose, whichever is less restrictive for the risk impact assessment of the extended ILRT intervals. This is consistent with the Nuclear Regulatory Commission (NRC) Final Safety Evaluation for Nuclear Energy Institute (NEI) 94–01 and EPRI Report No. 1009325. Moreover, the risk impact when compared to other severe accident risks is negligible.

Therefore, this proposed extension does not involve a significant increase in the probability of an accident previously evaluated.

In addition, as documented in NUREG–1493, ''Performance-Based Containment Leak-Test Program,'' dated January 1995, Types B and C tests have identified a very large percentage of containment leakage paths, and the percentage of containment leakage paths that are detected only by Type A testing is very small. The FNP Type A test history supports this conclusion.

The integrity of the containment is subject to two types of failure mechanisms that can be categorized as: (1) Activity based, and (2) time based. Activity-based failure mechanisms are defined as degradation due to system and/or component modifications or maintenance. The LLRT requirements and administrative controls such as configuration management and procedural requirements for system restoration ensure that containment integrity is not degraded by plant modifications or maintenance activities. The design and construction requirements of the containment combined with the containment inspections performed in accordance with American Society of Mechanical Engineers (ASME) Section XI, and TS requirements serve to provide a high degree of assurance that the containment would not degrade in a manner that is detectable only by a Type A test. Based on the above, the proposed test interval extensions do not significantly increase the consequences of an accident previously evaluated.

The proposed amendment also deletes exceptions previously granted under TS Amendments 159 (FNP Unit 1) and 150 (FNP Unit 2) to allow one-time extensions of the ILRT test frequency for FNP. These exceptions were for activities that would have already taken place by the time this amendment is approved; therefore, their deletion is solely an administrative action that has no effect on any component and no impact on how the unit is operated.

Therefore, the proposed change does not result in 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 amendment to the TS 5.5.17, ''Containment Leakage Rate Testing Program,'' involves the extension of the FNP Type A containment test interval to 15 years and the extension of the Type C test interval to 75 months. The containment and the testing requirements to periodically demonstrate the integrity of the containment exist to ensure the plant's ability to mitigate the consequences of an accident do not involve any accident precursors or initiators. The proposed change does not involve a physical change to the plant (*i.e.,* no new or different type of equipment will be installed) or a change to the manner in which the plant is operated or controlled.

The proposed amendment also deletes exceptions previously granted under TS

Amendments 159 (FNP Unit 1) and 150 (FNP Unit 2) to allow one-time extensions of the ILRT test frequency for FNP. These exceptions were for activities that would have already taken place by the time this amendment is approved; therefore, their deletion is solely an administrative action that does not result in any change in how the unit is operated.

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 amendment to TS 5.5.17 involves the extension of the FNP Type A containment test interval to 15 years and the extension of the Type C test interval to 75 months for selected components. This amendment does not alter the manner in which safety limits, limiting safety system set points, or limiting conditions for operation are determined. The specific requirements and conditions of the TS Containment Leak 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 TS is maintained.

The proposed change involves only the extension of the interval between Type A containment leak rate tests and Type C tests for FNP. The proposed surveillance interval extension is bounded by the 15-year ILRT interval and the 75-month Type C test interval currently authorized within NEI 94–01, Revision 3–A. Industry experience supports the conclusions that Type B and C testing detects a large percentage of containment leakage paths and that the percentage of containment leakage paths that are detected only by Type A testing is small. The containment inspections performed in accordance with ASME Section XI and Technical Specifications serve to provide a high degree of assurance that the containment would not degrade in a manner that is detectable only by Type A testing. The combination of these factors ensures that the margin of safety in the plant safety analysis is maintained. The design, operation, testing methods and acceptance criteria for Types A, B, and C containment leakage tests specified in applicable codes and standards would continue to be met, with the acceptance of this proposed change, since these are not affected by changes to the Type A and Type C test intervals.

The proposed amendment also deletes an exception previously granted under TS Amendments 159 (FNP Unit 1) and 150 (FNP Unit 2) to allow one-time extensions of the ILRT test frequency for FNP. This exception was for an activity that would have already taken place by the time this amendment is approved; therefore, the deletion is solely an administrative action and does not change how the unit is operated and maintained. Therefore, there is no reduction in any margin of 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: Jennifer M. Buettner, Associate General Counsel, Southern Nuclear Operating Company, Inc., 40 Inverness Center Parkway, Birmingham, AL 35242.

NRC Branch Chief: Michael T. Markley.

Union Electric Company, Docket No. 50–483, Callaway Plant, Unit 1, Callaway County, Missouri.

Date of amendment request: October 11, 2016. A publicly-available version is in ADAMS under Accession No. ML16286A553.

Description of amendment request: The amendment would revise the Technical Specification (TS) requirements to reference and allow use of the NRC-approved core reload methodologies described in Westinghouse topical reports (TRs) WCAP–16045–P–A, ''Qualification of the Two-Dimensional Transport Code PARAGON,'' WCAP–16045–P–A, Addendum 1–A, ''Qualification of the NEXUS Nuclear Data Methodology,'' and WCAP–10965–P–A, Addendum 2–A, ''Qualification of the New Pin Power Recovery Methodology,'' for the Callaway Plant.

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 would revise TS 5.6.5.b to add additional TR references for NRC-approved methodologies used in core reload designs and the determination of core operating limits, thereby specifically approving the use of these methodologies for the Callaway Plant. The additional analytical methodologies are improvements over the current methodologies in use at Callaway Plant. The NRC staff reviewed and approved these methodologies and concluded that these analytical methods are acceptable as a replacement for the current analytical method.

This proposed license amendment does not involve any physical changes to the Callaway Plant. Additionally, the core operating limits determined using the proposed analytical methods will continue to assure that the reactor operates safely. On that basis, the proposed changes do not involve an increase in the probability of an accident.

The proposed changes will not alter or prevent the ability of structures, systems, and components (SSCs) from performing their intended functions to mitigate the consequences of an initiating event within the assumed acceptance limits and therefore, does not increase the likelihood of any failure mechanisms or precursors to transients or accidents postulated and analyzed in the Callaway Plant FSAR [Final Safety Analysis Report]. Operation of the reactor with core operating limits determined by use of the proposed analytical methods does not increase the reactor power level, does not increase the core fission product inventory, and does not change any radiological release assumptions. The proposed changes will not alter any accident analysis assumptions discussed in the FSAR, nor do they involve any changes to the requirement for Callaway Plant to operate within the power distribution limits and shutdown margins required by the TS and within the assumptions of the safety analyses described in the FSAR. Therefore the proposed methodology and TS changes do not involve a significant increase in the consequences of an accident.

Therefore, it is concluded that this change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change provides revised analytical methods for determining core operating limits, and does not change any system functions or requirements. Acceptance criteria required to be met for analyzed core performance under normal, transient and accident conditions are not being changed, as the core operating limits will continue to be established in accordance with NRC-approved methods. The change does not involve physical alteration of the plant, as no new or different type of equipment will be installed. The change does not alter assumptions made in the safety analyses, but ensures that the core will operate within safe limits. Consequently, this change does not create new failure modes or mechanisms, and no new accident precursors are generated.

Therefore, it is concluded that this change does not create the possibility 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 margin of safety is established through equipment design, operating parameters, and the setpoints at which automatic actions are initiated. The proposed changes do not physically alter safety-related systems, nor do they affect the way in which safety related systems perform their functions. The setpoints at which protective actions are initiated are not altered by the proposed changes. The availability of equipment

required to be available to actuate upon demand for mitigating an analyzed event is unchanged by the proposed amendment. The proposed analytical methodologies are an improvement that allows more accurate modeling of core performance. The NRC has reviewed and approved the additional methodologies for use in lieu of the current methodology; thus, the margin of safety is not reduced due to this change.

Therefore, it is concluded that 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: John O'Neill, Esq., Pillsbury Winthrop Shaw Pittman LLP, 2300 N Street NW., Washington, DC 20037.

NRC Branch Chief: Robert J. Pascarelli.

III. Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed no significant hazards consideration determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the 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.

Duke Energy Carolinas, LLC, Docket Nos. 50–369 and 50–370, McGuire Nuclear Station, Units 1 and 2, Mecklenburg County, North Carolina.

Date of amendment request: September 26, 2013, as supplemented by letters dated January 8, 2014; October 13, 2014; November 12, 2014; December 12, 2014; January 26, 2015; February 27, 2015; March 13, 2015; July 15, 2015; August 20, 2015; September 9, 2015; October 1, 2015; January 14, 2016; April 26, 2016; September 29, 2016; and November 21, 2016.

Brief description of amendments: The amendments revised the condition for the fire protection program (FPP) in Facility Operating Licenses such that the FPP is now based on the requirements of 10 CFR 50.48(c), ''National Fire Protection Association Standard NFPA 805.''

Date of issuance: December 6, 2016.

Effective date: As of the date of issuance and shall be implemented as stated in the revised License Condition 2.C(4).

Amendment Nos.: 291 and 270. A publicly-available version is in ADAMS under Accession No. ML16077A135; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. NPF–9 and NPF–17: Amendments revised the Renewed Facility Operating Licenses.

*Date of initial notice in **Federal Register**:* February 19, 2014 (79 FR 9492). The supplemental letters dated January 8, 2014; October 13, 2014; November 12, 2014; December 12, 2014; January 26, 2015; February 27, 2015; March 13, 2015; July 15, 2015; August 20, 2015; September 9, 2015; October 1, 2015; January 14, 2016; April 26, 2016; September 29, 2016; and November 21, 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 proposal 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 December 6, 2016.

No significant hazards consideration comments received: No.

Duke Energy Florida, Inc. (DEF), et al., Docket No. 50–302, Crystal River Unit 3 Nuclear Generating Plant (CR–3), Citrus County, Florida.

Date of application for amendment: July 28, 2015.

Brief description of amendment: The amendment incorporates into the license the transfer of ownership, held by Seminole Electric Cooperative, Inc. (SEC), in CR–3 to DEF. The transfer of ownership will take place pursuant to the Settlement, Release and Acquisition Agreement, dated April 30, 2015, wherein DEF will purchase the 1.6994 percent ownership share in CR–3 held by SEC, leaving DEF as the sole remaining licensee for CR–3.

Date of issuance: November 30, 2016.

Effective date: As of the date of issuance and shall be implemented within 60 days.

Amendment No.: 251. A publicly-available version is in ADAMS under Accession No. ML16293A200; documents related to this amendment are listed in the Safety Evaluation enclosed with the letter dated August 10, 2016 (ADAMS Accession No. ML16173A022).

Facility Operating License No. DPR–72: This amendment revised the Facility Operating License.

*Date of initial notice in **Federal Register**:* September 29, 2015 (80 FR 58513), and January 4, 2016 (81 FR 98).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 10, 2016.

No significant hazards consideration comments received: No.

Duke Energy Florida, Inc. (DEF), et al., Docket No. 50–302, Crystal River Unit 3 Nuclear Generating Plant (CR–3), Citrus County, Florida.

Date of application for amendment: August 27, 2015, as supplemented by letters dated March 2, 2016, and July 14, 2016.

Brief description of amendment: The amendment approved the CR–3 Permanently Defueled Emergency Plan, and Permanently Defueled Emergency Action Level Bases Manual, for the Independent Spent Fuel Storage Installation.

Date of issuance: December 5, 2016.

Effective date: As of the date of issuance and shall be implemented within 60 days.

Amendment No.: 252. A publicly-available version is in ADAMS under Accession No. ML16244A099; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Facility Operating License No. DPR–72: This amendment revised the License.

*Date of initial notice in **Federal Register**:* November 10, 2015 (80 FR 69711).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 5, 2016.

No significant hazards consideration comments received: No.

Entergy Nuclear Operations, Inc., Docket No. 50–255, Palisades Nuclear Plant, Van Buren County, Michigan.

Date of amendment request: March 3, 2016, as supplemented by letter dated June 7, 2016.

Brief description of amendment: The amendment approves the implementation of an alternate repair criteria (ARC) called C-star, for the portion of the steam generator (SG) tubes within the cold-leg tubesheet. In addition, the amendment clarifies the intent and improves the wording of the technical specifications regarding the previously incorporated ARC for the hot-leg side of the SG's tubesheet. This was previously approved by letter dated May 31, 2007, and Amendment No. 225.

Date of issuance: December 19, 2016.

Effective date: As of the date of issuance and shall be implemented within 60 days.

Amendment No.: 261. A publicly-available version is in ADAMS under Accession No. ML16300A030; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. DPR–20: Amendment revised the Renewed Facility Operating License and Technical Specifications.

*Date of initial notice in **Federal Register**:* August 2, 2016 (81 FR 50747).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 19, 2016.

No significant hazards consideration comments received: No.

Southern Nuclear Operating Company, Inc.; Georgia Power Company; Oglethorpe Power Corporation; Municipal Electric Authority of Georgia; City of Dalton, Georgia, Docket Nos. 50–321 and 50–366, Edwin I. Hatch Nuclear Plant, Unit Nos. 1 and 2, Appling County, Georgia.

Date of amendment request: December 15, 2015, as supplemented by letter dated April 11, 2016.

Brief description of amendments: The amendments revised the Technical Specifications (TSs) to incorporate risk-informed requirements regarding selected Required Action end states. Additionally, it modified TS Required Actions with a Note prohibiting the use of Limiting Condition for Operation Applicability 3.0.4.a when entering the preferred end state (Mode 3).

Date of issuance: December 19, 2016.

Effective date: As of the date of issuance and shall be implemented within 90 days of issuance.

Amendment Nos.: 281 (Unit No. 1); 225 (Unit No. 2). A publicly-available version is in ADAMS under Accession No. ML16257A724; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. DPR–57 and NPF–5: Amendments revised the Renewed Facility Operating Licenses and TSs.

*Date of initial notice in **Federal Register**:* February 16, 2016 (81 FR 7841). The supplemental letter dated April 11, 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 December 19, 2016.

No significant hazards consideration comments received: No.

Tennessee Valley Authority, Docket No. 50–390, Watts Bar Nuclear Plant (WBN), Unit 1, Rhea County, Tennessee.

Date of amendment request: February 23, 2016, as supplemented by letter dated July 22, 2016.

Brief description of amendment: The amendment approved revisions to the WBN Dual Unit Fire Protection Report and revised the associated License Condition regarding the WBN fire protection program.

Date of issuance: December 12, 2016.

Effective date: As of the date of issuance and shall be implemented within 30 days of issuance.

Amendment No.: 108. A publicly-available version is in ADAMS under Accession No. ML16307A013; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Facility Operating License No. NPF–90: Amendment revised the Facility Operating License.

*Date of initial notice in **Federal Register**:* May 10, 2016 (81 FR 28901). The supplemental letter dated July 22, 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 amendment is contained in a Safety Evaluation dated December 12, 2016.

No significant hazards consideration comments received: No.

Dated at Rockville, Maryland, this 21st day of December 2016.

For the Nuclear Regulatory Commission.

George A. Wilson,

Deputy Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2016–31813 Filed 12–30–16; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket No. R2017–2; Order No. 3707]

Type 2 Rate Adjustment

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recently filed Postal Service notice announcing a Type 2 rate adjustment to improve default rates established under the Universal Postal Union Acts. The adjustment and other changes are scheduled to take effect February 1, 2017. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* January 5, 2017.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Contents of Filing
III. Commission Action
IV. Ordering Paragraphs

I. Introduction

On December 22, 2016, the Postal Service filed a notice, pursuant to 39 CFR 3010.40 *et seq.,* announcing a Type

2 rate adjustment to improve default rates established under the Universal Postal Union Acts.[1] The Notice concerns the inbound portion of a bilateral agreement with Australia Post (Agreement) that the Postal Service contends is functionally equivalent to the baseline agreement with China Post (China Post 2010 Agreement) that the Commission included within the Inbound Market Dominant Multi-Service Agreements with Foreign Postal Operators 1 product in the market dominant product list of the Mail Classification Schedule.[2]

II. Contents of Filing

The Postal Service's filing consists of the Notice, two attachments, and redacted and unredacted versions of an Excel file with supporting financial workpapers. Notice at 2. Attachment 1 is an application for non-public treatment of material filed under seal with the Commission. *Id.* Attachment 2 is a redacted copy of the Agreement. *Id.*

The Postal Service states the intended effective date of the Agreement is February 1, 2017; asserts it is providing at least the 45 days advance notice required under 39 CFR 3010.41; and identifies the parties to the Agreement as the United States Postal Service and Australia Post, the designated postal operator for Australia.[3] The Postal Service states that the Agreement includes: A process for collecting tracking events associated with small packets with delivery scanning sent from Australia to the United States; the establishment of improved accounting and settlement processes for small packets with delivery scanning; sortation recommendations; and additional data exchange requirements and measurement objectives. Notice at 4–5.

Reporting requirements. Rule 3010.43 requires the Postal Service to submit a detailed data collection plan. In lieu of a special data collection plan for the Agreement, the Postal Service proposes to report information on the Agreement through the Annual Compliance Report. *Id.* at 7. The Postal Service also invokes, with respect to service performance measurement reporting under 39 CFR 3055.3(a)(3), the standing exception the Commission allowed in Order No. 996 for all agreements filed in the Inbound Market Dominant Multi-Service Agreements with Foreign Postal Operators 1 product grouping.[4]

Consistency with applicable statutory criteria. The Postal Service observes that Commission review of a negotiated service agreement addresses three statutory criteria under 39 U.S.C. 3622(c)(10), as identified in 39 CFR 3010.40, *i.e.,* whether the agreement: (1) Improves the Postal Service's net financial position or enhances the performance of operational functions; (2) will not cause unreasonable harm to the marketplace; and (3) will be available on public and reasonable terms to similarly situated mailers. *Id.* The Postal Service asserts that it addresses the first two criteria in its Notice and that the third is inapplicable, as there are no entities similarly situated to Australia Post in terms of its ability to tender small packet with delivery scanning flows from Australia or serve as the designated operator for letter post originating in Australia. *Id.* at 7–8.

Functional equivalence. The Postal Service addresses reasons why it considers the Agreement functionally equivalent to the China Post 2010 Agreement filed in Docket No. R2010–6.[5] The Postal Service identifies differences between the Agreement and the baseline agreement but asserts that these differences do not detract from the conclusion that the Agreement is functionally equivalent to the baseline agreement. Notice at 9–11.

III. Commission Action

The Commission, in conformance with rule 3010.44, establishes Docket No. R2017–2 to consider issues raised in the Notice. The Commission invites comments from interested persons on whether the Agreement is consistent with 39 U.S.C. 3622 and the requirements of 39 CFR part 3010. Comments are due no later than January 5, 2017.[6] The public portions of this filing can be accessed via the Commission's Web site (*http://www.prc.gov*). Information on how to obtain access to non-public material appears in 39 CFR part 3007.

The Commission appoints Katalin K. Clendenin to represent the interests of the general public (Public Representative) in this docket.

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. R2017–2 for consideration of matters raised by the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, Katalin K. Clendenin is appointed to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

3. Comments by interested persons in this proceeding are due no later than January 5, 2017.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2016–31770 Filed 12–30–16; 8:45 am]

BILLING CODE 7710–FW–P

[1] Notice of United States Postal Service of Type 2 Rate Adjustment, Notice of Filing Functionally Equivalent Agreement and Application for Non-Public Treatment of Materials Filed Under Seal, December 22, 2016, at 1 (Notice).

[2] Notice at 1–2; *see* Docket Nos. MC2010–35, R2010–5, and R2010–6, Order Adding Inbound Market Dominant Multi-Service Agreements with Foreign Postal Operators 1 to the Market Dominant Product List and Approving Included Agreements, September 30, 2010 (Order No. 549).

[3] *Id.* at 3. The Postal Service filed its Notice on December 22, 2016, 41 calendar days prior to the intended implementation date of February 1, 2017. The Postal Service is reminded that it is required to transmit notice to the Commission no later than 45 calendar days prior to the intended implementation date of a negotiated service agreement. *See* 39 CFR 3010.41.

[4] *Id.* (citing Docket No. R2012–2, Order Concerning an Additional Inbound Market Dominant Multi-Service Agreement with Foreign Postal Operators 1 Negotiated Service Agreement, November 23, 2011, at 7 (Order No. 996)).

[5] *Id.* at 8–9; *see* Docket Nos. MC2010–35, R2010–5, and R2010–6, Order No. 549.

[6] Pursuant to 39 CFR 3010.44(a)(5), comments are due 10 days from the Postal Service's filing of the Notice. However, due to the holiday season, the Commission is extending the comment deadline.

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2016–25; CP2016–89; CP2016–218; MC2017–67 and CP2017–95; MC2017–68 and CP2017–96; MC2017–69 and CP2017–97; MC2017–70 and CP2017–98; MC2017–71 and R2017–3]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing recent Postal Service filings for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* January 4, 2017 (Comment due date applies to MC2017–67 and CP2017–95; MC2017–68 and CP2017–96); January 5, 2017 (Comment due date applies to CP2016–89; CP2016–218; MC2017–69 and CP2017–97; MC2017–70 and CP2017–98); and January 6, 2017 (Comment due date applies to CP2016–25; MC2017–71 and R2017–3).

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact

the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's Web site (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.40.

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* CP2016–25; *Filing Title:* Notice of United States Postal Service of Amendment to Priority Mail Contract 155, with Portions Filed Under Seal; *Filing Acceptance Date:* December 22, 2016; *Filing Authority:* 39 CFR 3015.5; *Public Representative:* Max E. Schnidman; *Comments Due:* January 6, 2017.

2. *Docket No(s).:* CP2016–89; *Filing Title:* Notice of the United States Postal Service of Filing Modification One to Global Reseller Expedited Package Contracts 2 Negotiated Service Agreement; *Filing Acceptance Date:* December 23, 2016; *Filing Authority:* 39 CFR 3015.5; *Public Representative:* Christopher C. Mohr; *Comments Due:* January 5, 2017.

3. *Docket No(s).:* CP2016–218; *Filing Title:* Notice of United States Postal Service of Amendment to First-Class Package Service Contract 57, with Portions Filed Under Seal; *Filing Acceptance Date:* December 22, 2016; *Filing Authority:* 39 CFR 3015.5; *Public Representative:* Christopher C. Mohr; *Comments Due:* January 5, 2017.

4. *Docket No(s).:* MC2017–67 and CP2017–95; *Filing Title:* Request of the United States Postal Service to Add Priority Mail Express & Priority Mail Contract 41 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* December 22, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.; Public Representative:* Kenneth R. Moeller; *Comments Due:* January 4, 2017.

5. *Docket No(s).:* MC2017–68 and CP2017–96; *Filing Title:* Request of the United States Postal Service to Add Priority Mail Contract 282 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* December 22, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.; Public Representative:* Christopher C. Mohr; *Comments Due:* January 4, 2017.

6. *Docket No(s).:* MC2017–69 and CP2017–97; *Filing Title:* Request of the United States Postal Service to Add Priority Mail Contract 283 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* December 22, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.; Public Representative:* Christopher C. Mohr; *Comments Due:* January 5, 2017.

7. *Docket No(s).:* MC2017–70 and CP2017–98; *Filing Title:* Request of the United States Postal Service to Add First-Class Package Service Contract 72 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* December 22, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.; Public Representative:* Max E. Schnidman; *Comments Due:* January 5, 2017.

8. *Docket No(s).:* MC2017–71 and R2017–3; *Filing Title:* Request of United States Postal Service to Add Inbound Market Dominant Prime Tracked Service Agreement to the Market Dominant Product List, Notice of Type 2 Rate Adjustment, and Application for Non-Public Treatment; *Filing Acceptance Date:* December 23, 2016; *Filing Authority:* 39 U.S.C. 3622(c)(10) and 3642; 39 CFR 3010.40 and 3020.30 *et seq.; Public Representative:* Katalin K. Clendenin; *Comments Due:* January 6, 2017.

This notice will be published in the **Federal Register**.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2016–31769 Filed 12–30–16; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

International Product Change—Inbound PRIME Tracked Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add Inbound Market Dominant PRIME Tracked Service Agreement to the Market Dominant Product List.

DATES: *Effective date:* January 3, 2017.

FOR FURTHER INFORMATION CONTACT: Christopher C. Meyerson, (202) 268–7820.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642, on December 23, 2016, it filed with the Postal Regulatory Commission a Request of United States Postal Service to add Inbound Market Dominant PRIME Tracked Service Agreement to the Market Dominant Product List. Documents are available at *www.prc.gov,* Docket Nos. MC2017–71 and R2017–3.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–31767 Filed 12–30–16; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79697; File No. SR–CBOE–2016–088]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing of a Proposed Rule Change Related to the Nullification and Adjustment of Options Transactions

December 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 December 14, 2016, Chicago Board Options Exchange, Incorporated (the ''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange seeks to amend Rule 6.25. The text of the proposed rule change is available on the Exchange's Web site (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Last year, the Exchange and other options exchanges adopted a new, harmonized rule related to the adjustment and nullification of erroneous options transactions, including a specific provision related to coordination in connection with large-scale events involving erroneous options transactions.[3] The Exchange believes that the changes the options exchanges implemented with the new, harmonized rule have led to increased transparency and finality with respect to the adjustment and nullification of erroneous options transactions. However, as part of the initial initiative, the Exchange and other options exchanges deferred a few specific matters for further discussion.

Specifically, the options exchanges have been working together to identify ways to improve the process related to the adjustment and nullification of erroneous options transactions as it relates to complex orders[4] and stock-option orders. The goal of the process that the options exchanges have undertaken is to further harmonize rules related to the adjustment and nullification of erroneous options transactions. As described below, the Exchange believes that the changes the options exchanges and the Exchange have agreed to propose will provide transparency and finality with respect to the adjustment and nullification of erroneous complex order and stock-option order transactions. Particularly, the proposed changes seek to achieve consistent results for participants across U.S. options exchanges while maintaining a fair and orderly market, protecting investors and protecting the public interest.

The Proposed Rule is the culmination of this coordinated effort and reflects discussions by the options exchanges whereby the exchanges that offer complex orders and/or stock-option orders will universally adopt new provisions that the options exchanges collectively believe will improve the handling of erroneous options transactions that result from the execution of complex orders and stock-option orders.[5]

The Exchange believes that the Proposed Rule supports an approach consistent with long-standing principles in the options industry under which the general policy is to adjust rather than nullify transactions. The Exchange acknowledges that adjustment of transactions is contrary to the operation of analogous rules applicable to the equities markets, where erroneous transactions are typically nullified rather than adjusted and where there is no distinction between the types of market participants involved in a transaction. For the reasons set forth below, the Exchange believes that the distinctions in market structure between equities and options markets continue to support these distinctions between the rules for handling obvious errors in the equities and options markets.

Various general structural differences between the options and equities markets point toward the need for a different balancing of risks for options market participants and are reflected in this proposal. Option pricing is formulaic and is tied to the price of the underlying stock, the volatility of the underlying security and other factors. Because options market participants can generally create new open interest in response to trading demand, as new open interest is created, correlated trades in the underlying or related series are generally also executed to hedge a market participant's risk. This pairing of open interest with hedging interest differentiates the options market specifically (and the derivatives markets broadly) from the cash equities markets. In turn, the Exchange believes that the hedging transactions engaged in by market participants necessitates protection of transactions through adjustments rather than nullifications when possible and otherwise appropriate.

The options markets are also quote driven markets dependent on liquidity providers to an even greater extent than equities markets. In contrast to the approximately 7,000 different securities traded in the U.S. equities markets each day, there are more than 500,000 unique, regularly quoted option series. Given this breadth in options series the options markets are more dependent on liquidity providers than equities markets; such liquidity is provided most commonly by registered market makers but also by other professional traders. With the number of instruments in which registered market makers must quote and the risk attendant with quoting so many products simultaneously, the Exchange believes that those liquidity providers should be afforded a greater level of protection. In particular, the Exchange believes that liquidity providers should be allowed protection of their trades given the fact that they typically engage in hedging activity to protect them from significant financial risk to encourage continued

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 74898 (May 7, 2015), 80 FR 27354 (May 13, 2015) (SR–CBOE–2015–039) (the ''Initial Filing'').

[4] *See* Rule 6.53C(a) (defining complex orders and stock-option orders).

[5] An exchange that does not offer complex orders and/or stock-option orders will not adopt these new provisions until such time as the exchange offers complex orders and/or stock-option orders.

liquidity provision and maintenance of the quote-driven options markets.

In addition to the factors described above, there are other fundamental differences between options and equities markets which lend themselves to different treatment of different classes of participants that are reflected in this proposal. For example, there is no trade reporting facility in the options markets. Thus, all transactions must occur on an options exchange. This leads to significantly greater retail customer participation directly on exchanges than in the equities markets, where a significant amount of retail customer participation never reaches the Exchange but is instead executed in off-exchange venues such as alternative trading systems, broker-dealer market making desks and internalizers. In turn, because of such direct retail customer participation, the exchanges have taken steps to afford those retail customers—generally Priority Customers—more favorable treatment in some circumstances.

Complex Orders and Stock-Option Orders

As more fully described below, the Proposed Rule applies much of the Current Rule to complex orders and stock-option orders.[6] The Proposed Rule deviates from the Current Rule only to account for the unique qualities of complex orders and stock-option orders. The Proposed Rule reflects the fact that complex orders can execute against other complex orders or can execute against individual simple orders in the leg markets. When a complex order executes against the leg markets there may be different counterparties on each leg of the complex order, and not every leg will necessarily be executed at an erroneous price. With regards to stock-option orders, the Proposed Rule reflects the fact that stock-option orders contain a stock component that is executed on a stock trading venue, and the Exchange may not be able to ensure that the stock trading venue will adjust or nullify the stock execution in the event of an obvious or catastrophic error. In order to apply the Current Rule and account for the unique characteristics of complex orders and stock-option orders, proposed Interpretation and Policy .07 is split into three parts—paragraphs (a), (b), and (c).

First, proposed Interpretation and Policy .07(a) governs the review of complex orders that are executed against individual legs (as opposed to a complex order that executes against another complex order).[7] Proposed Rule 6.25.07(a) provides:

> If a complex order executes against individual legs and at least one of the legs qualifies as an Obvious or Catastrophic Error under this Rule 6.25, then the leg(s) that is an Obvious or Catastrophic Error will be adjusted in accordance with paragraphs (c)(4)(A) or (d)(3), respectively, regardless of whether one of the parties is a Customer. However, any Customer order subject to this paragraph (a) will be nullified if the adjustment would result in an execution price higher (for buy transactions) or lower (for sell transactions) than the Customer's limit price on the complex order or individual leg(s). If any leg of a complex order is nullified, the entire transaction is nullified.

As previously noted, at least one of the legs of the complex order must qualify as an obvious or catastrophic error under the Current Rule in order for the complex order to receive obvious or catastrophic error relief. Thus, when the Exchange is notified (within the timeframes set forth in paragraph (c)(2) or (d)(2)) of a complex order that is a possible obvious error or catastrophic error, the Exchange will first review the individual legs of the complex order to determine if one or more legs qualify as an obvious or catastrophic error.[8] If no leg qualifies as an obvious or catastrophic error, the transaction stands—no adjustment and no nullification.

Reviewing the legs to determine whether one or more legs qualify as an obvious or catastrophic error requires the Exchange to follow the Current Rule. In accordance with paragraphs (c)(1) and (d)(1) of the Current Rule, the Exchange compares the execution price of each individual leg to the Theoretical Price of each leg (as determined by paragraph (b) of the Current Rule). If the execution price of an individual leg is higher or lower than the Theoretical Price for the series by an amount equal to at least the amount shown in the obvious error table in paragraph (c)(1) of the Current rule or the catastrophic error table in paragraph (d)(1) of the Current Rule, the individual leg qualifies as an obvious or catastrophic error, and the Exchange will take steps to adjust or nullify the transaction.[9]

To illustrate, consider a Customer submits a complex order to the Exchange consisting of leg 1 and leg 2—Leg 1 is to buy 100 ABC calls and leg 2 is to sell 100 ABC puts. Also, consider that Market-Maker 1 is quoting the ABC calls $1.00–1.20 and Market-Maker 2 is quoting the ABC puts $2.00–2.20. If the complex order executes against the quotes of Market-Makers 1 and 2, the Customer buys the ABC calls for $1.20 and sells the ABC puts for $2.00. As with the obvious/catastrophic error reviews for simple orders, the execution price of leg 1 is compared to the Theoretical Price[10] of Leg 1 in order to determine if Leg 1 is an obvious error under paragraph (c)(1) of the Current Rule or a catastrophic error under paragraph (d)(1) of the Current Rule. The same goes for Leg 2. The execution price of Leg 2 is compared to the Theoretical Price of Leg 2. If it is determined that one or both of the legs are an obvious or catastrophic error, then the leg (or legs) that is an obvious or catastrophic error will be adjusted in accordance with paragraphs (c)(4)(A) or (d)(3) of the Current Rule, regardless of whether one of the parties is a Customer.[11] Although a single-legged execution that is deemed to be an obvious error under the Current Rule is nullified whenever a Customer is involved in the transaction, the Exchange believes adjusting execution prices is generally better for the marketplace than nullifying executions because liquidity providers often execute hedging transactions to offset options positions. When an options transaction is nullified the hedging position can adversely affect the liquidity provider. With regards to complex orders that execute against individual legs, the additional rationale for adjusting erroneous execution prices when possible is the fact that the counterparty on a leg that is not executed at an obvious or catastrophic error price cannot look at the execution price to determine whether the

[6] In order for a complex order or stock-option order to qualify as an obvious or catastrophic error at least one of the legs must itself qualify as an obvious or catastrophic error under the Current Rule. See Proposed Rule .07(a)–(c).

[7] The leg market consists of quotes and/or orders in single options series. A complex order may be received by the Exchange electronically, and the legs of the complex order may have different counterparties. For example, Market-Maker 1 may be quoting in ABC calls and Market-Maker 2 may be quoting in ABC puts. A complex order to buy the ABC calls and puts may execute against the quotes of Market-Maker 1 and Market-Maker 2.

[8] Because a complex order can execute against the leg market, the Exchange may also be notified of a possible obvious or catastrophic error by a counterparty that received an execution in an individual options series. If upon review of a potential obvious error the Exchange determines an individual options series was executed against the leg of a complex order or stock-option order, proposed Rule 6.25.07 will govern.

[9] Only the execution price on the leg (or legs) that qualifies as an obvious or catastrophic error pursuant to any portion of Proposed Rule 6.25.07 will be adjusted. The execution price of a leg (or legs) that does not qualify as an obvious or catastrophic error will not be adjusted.

[10] *See* Rule 6.25(b) (defining the manner in which Theoretical Price is determined).

[11] *See* Rule 6.25(a)(1) (defining Customer for purposes of Rule 6.25 as not including a broker-dealer, Professional Customer, or Voluntary Professional Customer).

execution may later be nullified (as opposed to the counterparty on single-legged order that is executed at an obvious error or catastrophic error price).

Paragraph (c)(4)(A) of the Current Rule mandates that if it is determined that an obvious error has occurred, the execution price of the transaction will be adjusted pursuant to the table set forth in (c)(4)(A). Although for simple orders paragraph (c)(4)(A) is only applicable when no party to the transaction is a Customer, for the purposes of complex orders paragraph (a) of Interpretation and Policy .07 will supersede that limitation; therefore, if it is determined that a leg (or legs) of a complex order is an obvious error, the leg (or legs) will be adjusted pursuant to (c)(4)(A), regardless of whether a party to the transaction is a Customer. The Size Adjustment Modifier defined in subparagraph (a)(4) will similarly apply (regardless of whether a Customer is on the transaction) by virtue of the application of paragraph (c)(4)(A).[12] The Exchange notes that adjusting all market participants is not unique or novel. When the Exchange determines that a simple order execution is a Catastrophic Error pursuant to the Current Rule, paragraph (d)(3) already provides for adjusting the execution price for all market participants, including Customers.

Furthermore, as with the Current Rule, Proposed Rule 6.25.07(a) provides protection for Customer orders, stating that where at least one party to a complex order transaction is a Customer, the transaction will be nullified if adjustment would result in an execution price higher (for buy transactions) or lower (for sell transactions) than the Customer's limit price on the complex order or individual leg(s). For example, assume Customer enters a complex order to buy leg 1 and leg 2.

- Assume the NBBO for leg 1 is $0.20–1.00 and the NBBO for leg 2 is $0.50–1.00 and that these have been the NBBOs since the market opened.
- A split-second prior to the execution of the complex order a Customer enters a simple order to sell the leg 1 options series at $1.30, and the simple order enters the Exchange's book so that the BBO is $.20–$1.30. The limit price on the simple order is $1.30.
- The complex order executes leg 1 against the Exchange's best offer of $1.30 and leg 2 at $1.00 for a net execution price of $2.30.
- However, leg 1 executed on a wide quote (the NBBO for leg 1 was $0.20–1.00 at the time of execution, which is wider than $0.75).[13] Leg 2 was not executed on a wide quote (the market for leg 2 was $0.50–1.00); thus, leg 2 execution price stands.
- The Exchange determines that the Theoretical Price for leg 1 is $1.00, which was the best offer prior to the execution. Leg 1 qualifies as an obvious error because the difference between the Theoretical Price ($1.00) and the execution price ($1.30) is larger than $0.25.[14]
- According to Proposed Rule 6.25.07(a) Customers will also be adjusted in accordance with Rule 6.25(c)(4)(A), which for a buy transaction under $3.00 calls for the Theoretical Price to by adjusted by adding $0.15 [15] to the Theoretical Price of $1.00. Thus, adjust execution price for leg 1 would be $1.15.
- However, adjusting the execution price of leg 1 to $1.15 violates the limit price of the Customer's sell order on the simple order book for leg 1, which was $1.30.
- Thus, the entire complex order transaction will be nullified [16] because the limit price of a Customer's sell order would be violated by the adjustment.[17]

As the above example demonstrates, incoming complex orders may execute against resting simple orders in the leg market. If a complex order leg is deemed to be an obvious error, adjusting the execution price of the leg may violate the limit price of the resting order, which will result in nullification if the resting order is for a Customer. In contrast, Interpretation and Policy .02 to Rule 6.25 provides that if an adjustment would result in an execution price that is higher than an erroneous buy transaction or lower than an erroneous sell transaction the execution will not be adjusted or nullified.[18] If the adjustment of a complex order would violate the complex order Customer's limit price, the transaction will be nullified.

As previously noted, paragraph (d)(3) of the Current Rule already mandates that if it is determined that a catastrophic error has occurred, the execution price of the transaction will be adjusted pursuant to the table set forth in (d)(3). For purposes of complex orders under Proposed Rule .07(a), if one of the legs of a complex orders is determined to be a Catastrophic Error under paragraph (d)(3), all market participants will be adjusted in accordance with the table set forth in (d)(3). Again, however, where at least one party to a complex order transaction is a Customer, the transaction will be nullified if adjustment would result in an execution price higher (for buy transactions) or lower (for sell transactions) than the Customer's limit price on the complex order or individual leg(s). Again, if any leg of a complex order is nullified, the entire transaction is nullified. Additionally, as is the case today, if an Official determines that a Catastrophic Error has not occurred, the Trading Permit Holder will be subject to a charge of $5,000.[19]

Other than honoring the limit prices established for Customer orders, the Exchange has proposed to treat Customers and non-Customers the same in the context of the complex orders that trade against the leg market. When complex orders trade against the leg market, it is possible that at least some of the legs will execute at prices that would not be deemed obvious or catastrophic errors, which gives the counterparty in such situations no indication that the execution will later by adjusted or nullified. The Exchange believes that treating Customers and non-Customers the same in this context will provide additional certainty to non-Customers (especially Market-Makers) with respect to their potential exposure and hedging activities, including comfort that even if a transaction is later adjusted, such transaction will not be fully nullified. However, as noted above, under the Proposed Rule where at least one party to the transaction is a Customer, the trade will be nullified if the adjustment would result in an execution price higher (for buy transactions) or lower (for sell transactions) than the Customer's limit price on the complex order or individual leg(s). The Exchange has retained the protection of a Customer's limit price in order to avoid a situation where the adjustment could be to a price that a Customer would not have expected, and market professionals such as non-Customers would be better prepared to recover in such situations. Therefore, adjustment for non-Customers is more appropriate.

[12] *See* Rule 6.25(c)(4)(A) (stating that any non-Customer Obvious Error exceeding 50 contracts will be subject to the Size Adjustment Modifier defined in sub-paragraph (a)(4)). The Size Adjustment Modifier may also apply to the option leg of a stock-option order that is adjusted pursuant to Proposed Rule 6.25.07(c).

[13] *See* Rule 6.25(b)(3).

[14] *See* Rule (c)(1).

[15] *See* Rule 6.25(c)(4)(A).

[16] If any leg of a complex order is nullified, the entire transaction is nullified. *See* Proposed Rule 6.25.07(a).

[17] The simple order in this example is not an erroneous sell transaction because the execution price was not erroneously low. *See* Rule 6.25(a)(2).

[18] *See* Rule 6.25.02.

[19] *See* Rule 6.25(d)(3).

Second, proposed Interpretation and Policy .07(b) governs the review of complex orders that are executed against other complex orders. Proposed Rule 6.25.07(b) provides:

> If a complex order executes against another complex order and at least one of the legs qualifies as an Obvious Error under paragraph (c)(1) or a Catastrophic Error under paragraph (d)(1), then the leg(s) that is an Obvious or Catastrophic Error will be adjusted or busted in accordance with paragraph (c)(4) or (d)(3), respectively, so long as either: (i) the width of the National Spread Market for the complex order strategy just prior to the erroneous transaction was equal to or greater than the amount set forth in the wide quote table of paragraph (b)(3) or (ii) the net execution price of the complex order is higher (lower) than the offer (bid) of the National Spread Market for the complex order strategy just prior to the erroneous transaction by an amount equal to at least the amount shown in the table in paragraph (c)(1). If any leg of a complex order is nullified, the entire transaction is nullified. For purposes of Rule 6.25, the National Spread Market for a complex order strategy is determined by the National Best Bid/Offer of the individual legs of the strategy.

As described above in relation to Proposed Rule 6.25.07(a), the first step is for the Exchange to review (upon receipt of a timely notification in accordance with paragraphs (c)(2) or (d)(2) of the Current Rule) the individual legs to determine whether a leg or legs qualifies as an obvious or catastrophic error. If no leg qualifies as an obvious or catastrophic error, the transaction stands—no adjustment and no nullification.

Unlike Proposed Rule 6.25.07(a), the Exchange is also proposing to compare the net execution price of the entire complex order package to the National Spread Market (''NSM'') for the complex order strategy.[20] Complex orders are exempt from the order protection rules of the options exchanges.[21] Thus, depending on the manner in which the systems of an options exchange are calibrated, a complex order can execute without regard to the prices offered in the complex order books or the leg markets of other options exchanges. In certain situations, reviewing the execution prices of the legs in a vacuum would make the leg appear to be an obvious or catastrophic error, even though the net execution price on the complex order is not an erroneous price. For example, assume the Exchange receives a complex order to buy ABC calls and sell ABC puts.

- If the BBO for the ABC calls is $5.50–7.50 and the BBO for ABC puts is $3.00–4.50, then the Exchange's spread market is $1.00–4.50.[22]
- If the NBBO for the ABC calls is $6.00–6.50 and the NBBO for the ABC puts is $3.50–4.00, then the NSM is $2.00–3.00.
- If the Customer buys the calls at $7.50 and sells the puts at $4.00, the complex order Customer receives a net execution price of $3.00 (debit), which is the expected net execution price as indicated by the NSM offer of $3.00.

If the exchange were to solely focus on the $7.50 execution price of the ABC calls or the $4.00 execution price of the ABC puts, the execution would qualify as an obvious or catastrophic error because the execution price on the legs was outside the NBBO, even though the net execution price is accurate. Thus, the additional review of the NSM to determine if the complex order was executed at a truly erroneous price is necessary. The same concern is not present when a complex order executes against the leg market under Rule 6.25.07(a) because the Exchange is modifying its system in order to ensure the leg will execute at or within the NBBO of the leg markets.[23]

In order to incorporate NSM, Rule 6.25.07(b) provides that if the Exchange determines that a leg or legs does qualify as on obvious or catastrophic error, the leg or legs will be adjusted or busted in accordance with paragraph (c)(4) or (d)(3) of the Current Rule, so long as either: (i) the width of the NSM for the complex order strategy just prior to the erroneous transaction was equal to or greater than the amount set forth in the wide quote table of paragraph (b)(3) of the Current Rule or (ii) the net execution price of the complex order is higher (lower) than the offer (bid) of the NSM for the complex order strategy just prior to the erroneous transaction by an amount equal to at least the amount shown in the table in paragraph (c)(1) of the Current Rule.

For example, assume an individual leg or legs qualifies as an obvious or catastrophic error and the width of the NSM of the complex order strategy just prior to the erroneous transaction is $6.00–9.00. The complex order will qualify to be adjusted or busted in accordance with paragraph (c)(4) of the Current Rule because the wide quote table of paragraph (b)(3) of the Current Rule indicates that the minimum amount is $1.50 for a bid price between $5.00 to $10.00. If the NSM were instead $6.00–7.00 the complex order strategy would not qualify to be adjusted or busted pursuant to .07(b)(i) because the width of the NSM is $1.00, which is less than the required $1.50. However, the execution may still qualify to be adjusted or busted in accordance with paragraph (c)(4) or (d)(3) of the Current Rule pursuant to .07(b)(ii). Focusing on the NSM in this manner will ensure that the obvious/catastrophic error review process focuses on the net execution price instead of the execution prices of the individual legs, which may have execution prices outside of the NBBO of the leg markets.

Again, assume an individual leg or legs qualifies as an obvious or catastrophic error as described above. If the NSM is $6.00–7.00 (not a wide quote pursuant to the wide quote table in paragraph (b)(3) of the Current Rule) but the execution price of the entire complex order package (*i.e.,* the net execution price) is higher (lower) than the offer (bid) of the NSM for the complex order strategy just prior to the erroneous transaction by an amount equal to at least the amount in the table in paragraph (c)(1) of the Current Rule, then the complex order qualifies to be adjusted or busted in accordance with paragraph (c)(4) or (d)(3) of the Current Rule. For example, if the NSM for the complex order strategy just prior to the erroneous transaction is $6.00–7.00 and the net execution price of the complex order transaction is $7.75, the complex order qualifies to be adjusted or busted in accordance with paragraph (c)(4) of the Current Rule because the execution price of $7.75 is more than $0.50 (*i.e.,* the minimum amount according to the table in paragraph (c)(1) when the price is above $5.00 but less than $10.01) from the NSM offer of $7.00. Focusing on the NSM in this manner will ensure that the obvious/catastrophic error review process focuses on the net execution price instead of the execution prices of the individual legs, which may have execution prices outside of the NBBO of the leg markets.

Although the Exchange believes adjusting execution prices is generally better for the marketplace than

[20] NSM is the derived net market for a complex order package. *See e.g.,* Rule 6.53C.04 (utilizing the term derived net market in the context of complex order strategies). For example, if the NBBO of Leg 1 is $1.00–2.00 and the NBBO of Leg 2 is $5.00–7.00, then the NSM for a complex order to buy Leg 1 and buy Leg 2 is $6.00–9.00.

[21] *See* Rule 6.81(b)(7). All options exchanges have the same order protection rule.

[22] The complex order is to buy ABC calls and sell ABC puts. The Exchange's best offer for ABC puts is $7.50 and Exchange's best bid for is $3.00. If the Customer were to buy the complex order strategy, the Customer would receive a debit of $4.50 (buy ABC calls for $7.50 minus selling ABC puts for $3.00). If the Customer were to sell the complex order strategy the Customer would receive a credit of $1.00 (selling the ABC calls for $5.50 minus buying the ABC puts for $4.50). Thus, the Exchange's spread market is $1.00–4.50.

[23] The proposed rule change to modify Exchange systems to ensure the legs of a complex order will execute against legs in the simple order market within the NBBO of the simple order market will be in a separate filing.

nullifying executions because liquidity providers often execute hedging transactions to offset options positions, the Exchange recognizes that complex orders executing against other complex orders is similar to simple orders executing against other simple orders because both parties are able to review the execution price to determine whether the transaction may have been executed at an erroneous price. Thus, for purposes of complex orders that meet the requirements of Rule 6.25.07(b), the Exchange proposes to apply the Current Rule and adjust or bust obvious errors in accordance with paragraph (c)(4) (as opposed to applying paragraph (c)(4)(A) as is the case under .07(a)) and catastrophic errors in accordance with (d)(3).

Therefore, for purposes of complex orders under Proposed Rule 6.25.07(b), if one of the legs is determined to be an obvious error under paragraph (c)(1), all Customer transactions will be nullified, unless a Trading Permit Holder (''TPH'') submits 200 or more Customer transactions for review in accordance with (c)(4)(C).[24] For purposes of complex orders under Proposed Rule 6.25.07(b), if one of the legs is determined to be a catastrophic error under paragraph (d)(3) and all of the other requirements of Rule 6.25.07(b) are met, all market participants will be adjusted in accordance with the table set forth in (d)(3). Again, however, pursuant to paragraph (d)(3) where at least one party to a complex order transaction is a Customer, the transaction will be nullified if adjustment would result in an execution price higher (for buy transactions) or lower (for sell transactions) than the Customer's limit price on the complex order or individual leg(s). Also, if any leg of a complex order is nullified, the entire transaction is nullified.

Third, proposed Interpretation and Policy .07(c) governs stock-option orders. Proposed Rule 6.25.07(c) provides:

> If the option leg of a stock-option order qualifies as an Obvious Error under paragraph (c)(1) or a Catastrophic Error under paragraph (d)(1), then the option leg that is an Obvious or Catastrophic Error will be adjusted in accordance with paragraph (c)(4)(A) or (d)(3), respectively, regardless of whether one of the parties is a Customer. However, the option leg of any Customer order subject to this paragraph (c) will be nullified if the adjustment would result in an execution price higher (for buy transactions) or lower (for sell transactions) than the Customer's limit price on the stock-option order, and the Exchange will attempt to nullify the stock leg. Whenever a stock trading venue nullifies the stock leg of a stock-option order or whenever the stock leg cannot be executed, the Exchange will nullify the option leg upon request of one of the parties to the transaction or in accordance with paragraph (c)(3).

Similar to proposed Interpretation and Policy .07(a), an options leg (or legs) of a stock-option order must qualify as an obvious or catastrophic error under the Current Rule in order for the stock-option order to qualify as an obvious or catastrophic error. Also similar to Proposed Rule 6.25.07(a), if an options leg (or legs) does qualify as an obvious or catastrophic error, the option leg (or legs) will be adjusted in accordance with paragraph (c)(4)(A) or (d)(3), respectively, regardless of whether one of the parties is a Customer. Again, as with Proposed Rule 6.25.07(a), where at least one party to a complex order transaction is a Customer, the Exchange will nullify the option leg and attempt to nullify the stock leg if adjustment would result in an execution price higher (for buy transactions) or lower (for sell transactions) than the Customer's limit price on the complex order or individual leg(s).

The stock leg of a stock-option order is not executed on the Exchange; rather, the stock leg is sent to a stock trading venue for execution. The Exchange is unaware of a mechanism by which the Exchange can guarantee that the stock leg will be nullified by the stock trading venue in the event of an obvious or catastrophic error on the Exchange. Thus, in the event of the nullification of the option leg pursuant to Proposed Rule 6.25.07(c), the Exchange will attempt to have the stock leg nullified by the stock trading venue by either contacting the stock trading venue or notifying the parties to the transaction that the option leg is being nullified. The party or parties to the transaction may ultimately need to contact the stock trading venue to have the stock portion nullified.

Finally, the Exchange proposes to provide guidance that whenever the stock trading venue nullifies the stock leg of a stock-option order, the option will be nullified upon request of one of the parties to the transaction or by an Official acting on their own motion in accordance with paragraph (c)(3). There are situations in which buyer and seller agree to trade a stock-option order, but the stock leg cannot be executed. The Exchange proposes to provide guidance that whenever the stock portion of a stock-option order cannot be executed, the Exchange will nullify the option leg upon request of one of the parties to the transaction or on an Official's own motion.

2. Statutory Basis

The Exchange believes that its proposal is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[25] Specifically, the proposal is consistent with Section 6(b)(5) of the Act[26] because it would promote just and equitable principles of trade, remove impediments to, and perfect the mechanism of, a free and open market and a national market system, and, in general, protect investors and the public interest.

As described above, the Exchange and other options exchanges are seeking to adopt harmonized rules related to the adjustment and nullification of erroneous options transactions. The Exchange believes that the Proposed Rule will provide greater transparency and clarity with respect to the adjustment and nullification of erroneous options transactions. Particularly, the proposed changes seek to achieve consistent results for participants across U.S. options exchanges while maintaining a fair and orderly market, protecting investors and protecting the public interest. Based on the foregoing, the Exchange believes that the proposal is consistent with Section 6(b)(5) of the Act[27] in that the Proposed Rule will foster cooperation and coordination with persons engaged in regulating and facilitating transactions.

The Exchange believes the various provisions allowing or dictating adjustment rather than nullification of a trade are necessary given the benefits of adjusting a trade price rather than nullifying the trade completely. Because options trades are used to hedge, or are hedged by, transactions in other markets, including securities and futures, many TPHs, and their customers, would rather adjust prices of executions rather than nullify the transactions and, thus, lose a hedge altogether. As such, the Exchange believes it is in the best interest of investors to allow for price adjustments as well as nullifications.

The Exchange does not believe that the proposal is unfairly discriminatory, even though it differentiates in many places between Customers and non-

[24] Rule 6.25(c)(4)(C) also requires the orders resulting in 200 or more Customer transactions to have been submitted during the course of 2 minutes or less.

[25] 15 U.S.C. 78f(b).

[26] 15 U.S.C. 78f(b)(5).

[27] 15 U.S.C. 78f(b)(5).

Customers. As with the Current Rule, Customers are treated differently, often affording them preferential treatment. This treatment is appropriate in light of the fact that Customers are not necessarily immersed in the day-to-day trading of the markets, are less likely to be watching trading activity in a particular option throughout the day, and may have limited funds in their trading accounts. At the same time, the Exchange reiterates that in the U.S. options markets generally there is significant retail customer participation that occurs directly on (and only on) options exchanges such as the Exchange. Accordingly, differentiating among market participants with respect to the adjustment and nullification of erroneous options transactions is not unfairly discriminatory because it is reasonable and fair to provide Customers with additional protections as compared to non-Customers.

The Exchange believes that its proposal to adopt the ability to adjust a Customer's execution price when a complex order is deemed to be an Obvious or Catastrophic Error is consistent with the Act. A complex order that executes against individual leg markets may receive an execution price on an individual leg that is not an Obvious or Catastrophic error but another leg of the transaction is an Obvious or Catastrophic Error. In such situations where the complex order is executing against at least one individual or firm that is not aware of the fact that they have executed against a complex order or that the complex order has been executed at an erroneous price, the Exchange believes it is more appropriate to adjust execution prices if possible because the derivative transactions are often hedged with other securities. Allowing adjustments instead of nullifying transactions in these limited situations will help to ensure that market participants are not left with a hedge that has no position to hedge against.

The Exchange also believes its proposal related to stock-option orders is consistent with the Act. Stock-option orders consist of an option component and a stock component. Due to the fact that the Exchange has no control over the venues on which the stock is executed the proposal focuses on the option component of the stock-option order by adjusting or nullifying the option in accordance with paragraph (c)(4)(A) or (d)(3). Also, nullifying the option component if the stock component cannot be executed ensures that market participants receive the execution for which they bargained. Stock-option orders are negotiated and agreed to as a package; thus, if for any reason the stock portion of a stock-option order cannot ultimately be executed, the parties should not be saddled with an options position sans stock.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Importantly, the Exchange believes the proposal will not impose a burden on intermarket competition but will rather alleviate any burden on competition because it is the result of a collaborative effort by all options exchanges to harmonize and improve the process related to the adjustment and nullification of erroneous options transactions. The Exchange does not believe that the rules applicable to such process is an area where options exchanges should compete, but rather, that all options exchanges should have consistent rules to the extent possible. Particularly where a market participant trades on several different exchanges and an erroneous trade may occur on multiple markets nearly simultaneously, the Exchange believes that a participant should have a consistent experience with respect to the nullification or adjustment of transactions. The Exchange understands that all other options exchanges that trade complex orders and/or stock-option orders intend to file proposals that are substantially similar to this proposal.

The Exchange does not believe that the proposed rule change imposes a burden on intramarket competition because the provisions apply to all market participants equally within each participant category (*i.e.,* Customers and non-Customers). With respect to competition between Customer and non-Customer market participants, the Exchange believes that the Proposed Rule acknowledges competing concerns and tries to strike the appropriate balance between such concerns. For instance, the Exchange believes that protection of Customers is important due to their direct participation in the options markets as well as the fact that they are not, by definition, market professionals. At the same time, the Exchange believes due to the quote-driven nature of the options markets, the importance of liquidity provision in such markets and the risk that liquidity providers bear when quoting a large breadth of products that are derivative of underlying securities, that the protection of liquidity providers and the practice of adjusting transactions rather than nullifying them is of critical importance. As described above, the Exchange will apply specific and objective criteria to determine whether an erroneous transaction has occurred and, if so, how to adjust or nullify a transaction.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

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 Exchange consents, the Commission will:

A. by order approve or disapprove such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2016–088 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2016–088. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements

with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2016–088, and should be submitted on or before January 24, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[28]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2016–31766 Filed 12–30–16; 8:45 am]

BILLING CODE 8011–01–P

[28] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79696; File No. SR–CBOE–2016–093]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 6.54

December 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 December 20, 2016, Chicago Board Options Exchange, Incorporated (the ''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend its program that allows transactions to take place at a price that is below $1 per option contract through March 5, 2018. The text of the proposed rule change is available on the Exchange's Web site (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

An ''accommodation'' or ''cabinet'' trade refers to trades in listed options on the Exchange that are worthless or not actively traded. Cabinet trading is generally conducted in accordance with the Exchange Rules, except as provided in Exchange Rule 6.54, *Accommodation Liquidations (Cabinet Trades),* which sets forth specific procedures for engaging in cabinet trades. Rule 6.54 currently provides for cabinet transactions to occur via open outcry at a cabinet price of $1 per option contract in any options series open for trading in the Exchange, except that the Rule is not applicable to trading in option classes participating in the Penny Pilot Program. Under the procedures, bids and offers (whether opening or closing a position) at a price of $1 per option contract may be represented in the trading crowd by a Floor Broker or by a Market-Maker or provided in response to a request by a PAR Official/OBO, a Floor Broker or a Market-Maker, but must yield priority to all resting orders in the PAR Official/OBO cabinet book (which resting cabinet book orders may be closing only). So long as both the buyer and the seller yield to orders resting in the cabinet book, opening cabinet bids can trade with opening cabinet offers at $1 per option contract.

The Exchange has temporarily amended the procedures through January 5, 2017 to allow transactions to take place in open outcry at a price of at least $0 but less than $1 per option contract.[3] These lower priced transactions are traded pursuant to the same procedures applicable to $1 cabinet trades, except that (i) bids and offers for opening transactions are only permitted to accommodate closing transactions in order to limit use of the procedure to liquidations of existing positions, and (ii) the procedures are also available for trading in option classes participating in the Penny Pilot Program.[4] The Exchange believes that allowing a price of at least $0 but less than $1 better accommodates the closing of options positions in series that are worthless or not actively traded, particularly due to market conditions which may result in a significant number of series being out-of-the-

[3] *See* Securities Exchange Act Release Nos. 59188 (December 30, 2008), 74 FR 480 (January 6, 2009) (SR–CBOE–2008–133) (adopting the amended procedures on a temporary basis through January 30, 2009), 59331 (January 30, 2009), 74 FR 6333 (February 6, 2009)(extending the amended procedures on a temporary basis through May 29, 2009), 60020 (June 1, 2009), 74 FR 27220 (June 8, 2009) (SR–CBOE–2009–034) (extending the amended procedures on a temporary basis through June 1, 2010), 62192 (May 28, 2010), 75 FR 31828(June 4, 2010) (SR–CBOE–2010–052) (extending the amended procedures on a temporary basis through June 1, 2011); 64403 (May 4, 2011), 76 FR 27110 (May 10, 2011) (SR–CBOE–2011–048) (extending the amended procedures on a temporary basis through December 30, 2011); 65872 (December 2, 2011), 76 FR 76788 (December 8, 2011) (SR–CBOE–2011–113) (extending the amended procedures on a temporary basis through June 29, 2012) 67144 (June 6, 2012), 77 FR 35095 (June 12, 2012) (SR–CBOE–2012–053) (extending the amended procedures on a temporary basis through June 28, 2013), and 69854 (June 25, 2013), 78 FR 39424 (July 1, 2013) (SR–CBOE–2013–063); 69893 (June 28, 2013), 78 FR 40539 (July 5, 2013) (both extending the amended procedures on a temporary basis through January 5, 2014), 71090 [sic] (December 17, 2013), 78 FR 77532 (December 23, 2013) (SR–CBOE–2013–118) (extending the amended procedures on a temporary basis through January 5, 2015), 73974 (December 31, 2014), 80 FR 911 (January 7, 2015) (SR–CBOE–2014–093) (extending the amended procedures on a temporary basis through January 5, 2016), and 76566 (December 7, 2015), 80 FR 77061 (December 11, 2015) (SR–CBOE–2015–108) (extending the amended procedures on a temporary basis through January 5, 2017).

[4] Currently the $1 cabinet trading procedures are limited to options classes traded in $0.05 or $0.10 standard increment. The $1 cabinet trading procedures are not available in Penny Pilot Program classes because in those classes an option series can trade in a standard increment as low as $0.01 per share (or $1.00 per option contract with a 100 share multiplier). Because the temporary procedures allow trading below $0.01 per share (or $1.00 per option contract with a 100 share multiplier), the procedures are available for all classes, including those classes participating in the Penny Pilot Program.

money. For example, a market participant might have a long position in a call series with a strike price of $100 and the underlying stock might now be trading at $30. In such an instance, there might not otherwise be a market for that person to close-out the position even at the $1 cabinet price (*e.g.,* the series might be quoted no bid).[5]

The purpose of the instant rule change is to extend the operation of these temporary procedures through March 5, 2018, so that the procedures can continue without interruption while CBOE considers whether to seek permanent approval of the temporary procedures.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[6] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[7] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[8] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that allowing for liquidations at a price less than $1 per option contract better facilitates the closing of options positions that are worthless or not actively trading. Further, the Exchange believes the proposal is consistent with the Act because the proposed extension is of appropriate length to allow the Exchange and the Commission to continue to assess the impact of the Exchange's authority to allow transactions to take place in open outcry at a price of at least $0 but less than $1 per option in accordance with its attendant obligations and conditions, including the process for submitting such transactions to OCC for clearing.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that allowing for liquidations at a price less than $1 per option contract better facilitates the closing of options positions that are worthless or not actively trading. The Exchange believes this promotes fair and orderly markets, as well as assists the Exchange in its ability to effectively attract order flow and liquidity to its market, and ultimately benefit all CBOE Trading Permit Holders (''TPHs'') and all investors.

The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed rule change does not make any changes to Exchange rules, but simply extends an existing temporary program. Further, the program is available to all market participants through CBOE TPHs. The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because, again, the proposed rule change does not make any changes to Exchange rules, but simply extends an existing temporary program. Moreover, to the extent that the program makes CBOE a more attractive marketplace, as noted above, the program is available to all market participants through CBOE TPHs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[9] and Rule 19b–4(f)(6) thereunder.[10]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days after the date of filing. However, Rule 19b–4(f)(6)(iii)[11] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. In its filing with the Commission, the Exchange requests that the Commission waive the 30-day operative delay so that the pilot may continue without interruption. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because it will allow the pilot to continue uninterrupted, avoiding any potential investor confusion that could result from a temporary interruption in the pilot and allowing members to continue to benefit from the program. Therefore, the Commission designates the proposed rule change operative upon filing.[12]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the

[5] As with other accommodation liquidations under Rule 6.54, transactions that occur for less than $1 are not be disseminated to the public on the consolidated tape. In addition, as with other accommodation liquidations under Rule 6.54, the transactions are exempt from the Consolidated Options Audit Trail (''COATS'') requirements of Exchange Rule 6.24, *Required Order Information.* However, the Exchange maintains quotation, order and transaction information for the transactions in the same format as the COATS data is maintained. In this regard, all transactions for less than $1 must be reported to the Exchange following the close of each business day. The rule also provides that transactions for less than $1 will be reported for clearing utilizing forms, formats and procedures established by the Exchange from time to time. In this regard, the Exchange initially intends to have clearing firms directly report the transactions to The Options Clearing Corporation (''OCC'') using OCC's position adjustment/transfer procedures. This manner of reporting transactions for clearing is similar to the procedure that CBOE currently employs for on-floor position transfer packages executed pursuant to Exchange Rule 6.49A, *Transfer of Positions.*

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] *Id.*

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[11] 17 CFR 240.19b–4(f)(6)(iii).

[12] For purposes only of waiving the operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2016–093 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2016–093. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2016–093 and should be submitted on or before January 24, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2016–31765 Filed 12–30–16; 8:45 am]

BILLING CODE 8011–01–P

[13] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice: 9833]

In the Matter of the Amendment of the Designation of Lashkar-e-Tayyiba and Other Aliases as a Specially Designated Global Terrorist Entity Pursuant to Executive Order 13224

Based upon a review of the administrative record assembled in this matter, and in consultation with the Attorney General and the Secretary of the Treasury, I have concluded that there is a sufficient factual basis to find that Lashkar-e-Tayyiba uses the additional aliases Al-Muhammadia Students, AMS, and Al-Muhammadia Students Pakistan. Therefore, pursuant to Section 1(b) of Executive Order 13224, I hereby amend the designation of Lashkar-e-Tayyiba as a Specially Designated Global Terrorist to include

Al-Muhammadia Students, AMS, and Al-Muhammadia Students Pakistan as aliases.

This determination shall be published in the **Federal Register**.

Dated: November 28, 2016.

John F. Kerry,

Secretary of State.

[FR Doc. 2016–31782 Filed 12–30–16; 8:45 am]

BILLING CODE 4710–10–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[U.S. DOT Docket No. NHTSA–2016–0119]

Reports, Forms, and Record Keeping Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), U.S. Department of Transportation.

ACTION: Request for public comment on proposed collection of information.

SUMMARY: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatement of previously approved collections. This document describes one collection of information for which NHTSA intends to seek OMB approval.

DATES: Comments must be received on or before March 6, 2017.

ADDRESSES: You may submit comments, identified by the docket number in the heading of this document, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the instructions for submitting comments on the electronic docket site by clicking on ''Help'' or ''FAQ.''
- *Hand Delivery:* 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, between 9 a.m. and 5 p.m. Eastern Time, Monday through Friday, except Federal holidays.
- *Fax:* 202–493–2251.

Regardless of how you submit comments, you should mention the docket number of this document.

You may call the Docket Management Facility at 202–366–9826.

Instructions: For detailed instructions on submitting comments and additional information on the rulemaking process, see the Public Participation heading of the **SUPPLEMENTARY INFORMATION** section of this document. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Privacy Act: Anyone is able to search the electronic form of 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) or you may visit *https://www.transportation.gov/privacy.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov,* or the street address listed above. Follow the online instructions for accessing the dockets.

FOR FURTHER INFORMATION CONTACT: Mike Joyce, Marketing Specialist, Office of Communications and Consumer Information (NCO–0200), National Highway Traffic Safety Administration, 1200 New Jersey Ave. SE., W52–238, Washington, DC, 20590. Mike Joyce's phone number is 202–366–5600 and his email address is *Mike.Joyce@dot.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed

collection of information to OMB for approval, it must first publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulation (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following:

(i) 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;

(ii) 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;

(iii) how to enhance the quality, utility, and clarity of the information to be collected;

(iv) how to 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, *e.g.* permitting electronic submission of responses.

In compliance with these requirements, NHTSA asks for public comments on the following proposed collection of information for which the agency is seeking approval from OMB:

Title: Safety Ratings and Advanced Crash Avoidance Technologies Consumer Research

Requested Expiration Date of Approval: Three years from approval date.

Abstract: The National Highway Traffic Safety Administration (NHTSA) was established by the Highway Safety Act of 1970 (23 U.S.C. 101) to carry out a Congressional mandate to reduce the mounting number of deaths, injuries, and economic losses resulting from motor vehicle crashes on the Nation's highways. In support of this mission, NHTSA previously conducted two comprehensive consumer research studies in 2012 and 2014 to better understand (1) the type of information consumers seek during their vehicle purchase decisions, (2) consumer comprehension of vehicle safety ratings, and (3) consumer knowledge and interest in advanced crash avoidance technologies in order to guide NHTSA communications. Building on that research, NHTSA proposes to conduct a quantitative online survey that draws from findings in the previous qualitative research studies to further explore consumer perception, interest and understanding of the 5-star safety ratings (including response to half stars), overall vehicle scores, and advanced crash avoidance technologies information to support the development of consumer communications.

Summary of the Collection of Information: In this collection of information, NHTSA is seeking approval to conduct an online survey with 1,500 consumer respondents. The survey will be used to further support findings from previous qualitative research studies and will achieve the following objectives:

(1) Confirm qualitative research findings with regard to vehicle purchase decision-making criteria;

(2) Identify and evaluate sources of vehicle safety information to help inform the development of a consumer education program;

(3) Understand consumer knowledge and interest in communications around safety ratings;

(4) Explore consumer knowledge, interest and engagement with advanced crash avoidance technologies;

(5) Assess consumer response to overall vehicle score; and,

(6) Evaluate consumer perception of the 5-Star safety ratings and its components (including incorporation of ½ star ratings).

Description of the Need for the Information and the Proposed Use of the Information: NHTSA will obtain critical information that will fulfill a congressional mandate to improve highway traffic safety. Specifically, the data from this collection will be used to enhance consumer understanding of NHTSA's safety ratings and advanced crash avoidance technologies and guide the development of communication materials that will help consumers as they factor this information into their vehicle purchase decisions. In addition, this data will be used to substantiate the effectiveness of communications approaches.

Affected Public: For this collection, NHTSA plans to conduct an online survey with 1,500 panel member respondents that will take approximately 20 minutes to complete. In order to identify 1,500 qualified respondents, approximately 20,000 respondents will be needed to complete a 1.5-minute screener. NHTSA plans to administer this study one time, amounting to 963 burden hours.

Prior to administering the online survey, NHTSA will administer a cognitive test of the survey instrument. For the cognitive test, a total of eight to 12 potential participants will be recruited via dialed telephone screening calls, which are estimated to take 10 minutes per response. The recruitment calls will utilize the screening section of the survey document to determine qualified respondents. NHTSA anticipates needing 45 minutes to allow respondents to navigate the survey while also discussing their feedback on survey questions. The Agency will conduct interviews with one respondent at a time.

Based on experience, it is prudent to recruit up to 12 people in order to help achieve at least eight participants showing up for the cognitive tests. Approximately 600 potential participants will complete a 1.5-minute pre-screen in order to identify a pool of potentially qualified respondents. Among the 12 selected qualified recruits, the total burden per participant is estimated to be 55 minutes (10 minutes for the screening/recruiting telephone call, plus 45 minutes for the interview).

Therefore, the total annual estimated burden imposed by this collection of information is approximately 989 hours.

Estimated Total Annual Burden: 989 hours.

Number of Respondents: 1,512.

The results of this research will be used to inform communications for the New Car Assessment Program's Government 5-Star Safety Ratings program.

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.

Issued on: December 27, 2016.

Susan Gorcowski,

Associate Administrator, NHTSA NCO–010.

[FR Doc. 2016–31820 Filed 12–30–16; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Sanctions Actions Pursuant to Executive Order 13224

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of two individuals whose property and interests in property are blocked pursuant to Executive Order 13224 of September 23, 2001, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten To Commit, or Support Terrorism.''

DATES: OFAC's actions described in this notice were effective on December 28, 2016.

FOR FURTHER INFORMATION CONTACT: Associate Director for Global Targeting, tel.: 202/622–2420, Assistant Director for Sanctions Compliance & Evaluation, tel.: 202/622–2490, Assistant Director for Licensing, tel.: 202/622–2480, Office of Foreign Assets Control, or Chief Counsel (Foreign Assets Control), tel.: 202/622–2410, Office of the General Counsel, Department of the Treasury (not toll free numbers).

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available from OFAC's Web site (*www.treas.gov/ofac*).

Notice of OFAC Actions

On December 28, 2016, OFAC blocked the property and interests in property of the following two individuals pursuant to E.O. 13224, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten To Commit, or Support Terrorism'':

Individuals

1. MAHMOOD, Shahid (a.k.a. AHMED, Shahid Mehmood Manzoor; a.k.a. MEHMOOD, Shaheed; a.k.a. MEHMOUD, Shahid; a.k.a. REHMATULLAH, Shahid Mahmood), Karachi, Pakistan; DOB 10 Apr 1980; POB Pakistan; nationality Pakistan; Gender Male (individual) [SDGT] (Linked To: LASHKAR E–TAYYIBA).

2. SARWAR, Muhammad (a.k.a. ABU ALI HASHIM; a.k.a. ABU HASHIM; a.k.a. ABU UL–HASHIM; a.k.a. HASHIM, Abdul; a.k.a. HASHIM, Abul; a.k.a. RABBANI, Abul Hashim), Lahore, Pakistan; DOB 01 Jan 1966 to 31 Dec 1968; POB Sheikhupura, Pakistan; nationality Pakistan; Gender Male; Passport AK5995921 (Pakistan) issued 24 Mar 2007 expires 22 Mar 2012 (individual) [SDGT] (Linked To: LASHKAR E–TAYYIBA).

Dated: December 28, 2016.

John E. Smith,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2016–31787 Filed 12–30–16; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Proposed Collection; Comment Request

December 28, 2016.

AGENCY: Departmental Offices, Treasury.

ACTION: Notice and request for comment.

SUMMARY: The U.S. Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other federal agencies to take this opportunity to comment on this continuing information collection, as required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A). The information collection under review is 1505–0230, Garnishment of Accounts Containing Federal Benefit Payments.

DATES: Written comments must be received on or before March 6, 2017.

ADDRESSES: Submit your comments via email to *PRACollection1505-0230@treasury.gov*.

FOR FURTHER INFORMATION CONTACT: Barbara Wiss, Office of the Fiscal Assistant Secretary, Department of the Treasury, 1500 Pennsylvania Avenue NW., Washington, DC 20220 or by telephone on 202–622–0886 or by email at *PRACollection1505-0230@treasury.gov*.

SUPPLEMENTARY INFORMATION:

OMB Number: 1505–0230.

Type of Review: Extension without change of an existing information collection.

Title: Garnishment of Accounts Containing Federal Benefit Payments.

Abstract: The regulations at 31 CFR part 212 establish procedures that financial institutions must follow when a garnishment order is received for an account into which federal benefit payments have been directly deposited. Financial institutions that comply with the required procedures are given a safe harbor under the rule. The regulations require a financial institution to review the account, to determine if any exempt benefit payments have been directly deposited within the 60 calendar days prior to the receipt of the garnishment order, and, if so, requires the financial institution to ensure that the account holder has access to a protected amount of funds in the account. Once the account review is completed the financial institution must notify the accountholder of the receipt of the garnishment order and provide certain additional information. In addition, a financial institution must maintain certain records of account activity and actions taken in response to garnishment orders sufficient to demonstrate compliance with the regulations.

Affected Public: Businesses or other for-profit institutions.

Estimated Total Annual Burden Hours: 24,167.

Request for Comments: Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services required to provide information.

Bob Faber,

Treasury PRA Clearance Officer.

[FR Doc. 2016–31839 Filed 12–30–16; 8:45 am]

BILLING CODE 4810–25–P

FEDERAL REGISTER

Vol. 82 Tuesday,

No. 1 January 3, 2017

Book 2 of 2 Books

Pages 179–710

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); Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 510 and 512

[CMS–5519–F]

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: Final rule.

SUMMARY: This final rule implements three new Medicare Parts A and B episode payment models, a Cardiac Rehabilitation (CR) Incentive Payment model and modifications to the existing Comprehensive Care for Joint Replacement model 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 these models will further our goals of improving the efficiency and quality of care for Medicare beneficiaries receiving care for these common clinical conditions and procedures.

DATES: *Effective dates:* This rule is effective February 18, 2017, except for the following amendatory instructions: number 3 amending 42 CFR 510.2; number 4 adding 42 CFR 510.110; number 6 amending 42 CFR 510.120; number 14 amending 42 CFR 510.405; number 15 42 CFR 510.410; number 16 revising 42 CFR 510.500; number 17 revising 42 CFR 510.505; number 18 adding 42 CFR 510.506; and number 19 amending 42 CFR 510.515, which are effective July 1, 2017.

Applicability date: The regulations at 42 CFR part 512 are applicable July 1, 2017.

FOR FURTHER INFORMATION CONTACT: For questions related to the EPMs: *EPMRULE@cms.hhs.gov*.

For questions related to the CJR model: *CJR@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through Federal Digital System (FDsys), a service of the U.S. Government Printing Office. This database can be accessed via the internet at *http://www.gpo.gov/fdsys/*.

Alphabetical List of Acronyms

Because of the many terms to which we refer by acronym, abbreviation, or short form in this final rule, we are listing the acronyms, abbreviations and short forms used and their corresponding terms in alphabetical order.

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
APRN Advanced Practice Registered Nurse
ASC QRP Ambulatory Surgical Center Quality Reporting Program
ASC Ambulatory Surgical Center
ASPE Assistant Secretary for Planning and Evaluation
BAA Business Associate Agreement
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
CEP Clinical Episode Payment
CFR Code of Federal Regulations
CHIP Children's Health Insurance Program
CJR Comprehensive Care for Joint Replacement
CMHC Community Mental Health Center
CMI Case Mix Index
CMP Civil monetary penalty
CQMC Core Quality Measure Collaborative
CMS Centers for Medicare & Medicaid Services
CoP Condition of Participation
CORF Comprehensive Outpatient Rehabilitation Facility
CPC Comprehensive Primary Care Initiative
CPT Current Procedural Terminology
CR Cardiac rehabilitation
CRNA Certified Registered Nurse Anesthetists
CSA Combined Statistical Area
CVICU Cardiovascular intensive care units
CY Calendar year
DES Drug-eluting stents
DME Durable medical equipment
DMEPOS Durable medical equipment, prosthetics, orthotics, and supplies
DR Downside Risk
DSH Disproportionate Share Hospital
DUA Data Use Agreement
ED Emergency Department
ECMO Extracorporeal membrane circulation
ECQM Electronic Clinical Quality Measures
EFT Electronic funds transfer
EGM Episode Grouper for Medicare
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
FFR Fractional Flow Reserve
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
HIPAA Health Insurance Portability and Accountability Act
HIQR Hospital Inpatient Quality Reporting
HIV Human Immunodeficiency Virus
Health IT Health Information Technology
HLM Hierarchical Logistic Regression model
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
ICD–9–CM International Classification of Diseases, 9th Revision, Clinical Modification
ICHOM International Consortium for Health Outcomes Measurement
IRFQR Inpatient Rehabilitation Facilities Quality Reporting
ICD Implantable Cardioverter Defibrillator
ICD–10–CM International Classification of Diseases, 10th Revision, Clinical Modification
ICR Intensive Cardiac Rehabilitation
I–I Inpatient to inpatient transfer
IME Indirect medical education
IP Inpatient
IPF Inpatient psychiatric facility
IPF QRP Inpatient Psychiatric Facility Quality Reporting Program
IPPS Inpatient Prospective Payment System
IRF Inpatient rehabilitation facility
IRF QRP Inpatient Rehabilitation Facility Quality Reporting Program
IVR Active Interactive Voice Recognition
KOOS Knee Injury and Osteoarthritis Outcome Score

LAN Healthcare Payment Learning and Action Network
LBBB Left bundled branch block
LEJR Lower-extremity joint replacement
LEP limited English proficiency
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
MA Medicare Advantage
MAC Medicare Administrative Contractor
MACRA Medicare Access and CHIP Reauthorization Act of 2015
MAP Measure Application Partnership
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
MDM Master Database Management
MedPAC Medicare Payment Advisory Commission
MIPS Merit-based Incentive Payment System
MP Malpractice
MSA Metropolitan Statistical Area
MS–DRG Medical Severity Diagnosis-Related Group
MSPB Medicare Spending Per Beneficiary
NHDS National Hospital Discharge Survey
NCDR National Cardiovascular Data Registry
NDR No Downside Risk
NPI National Provider Identifier
NPPGP Non-Physician Practitioner Group Practice
NPRA Net Payment Reconciliation Amount
NQF National Quality Forum
NSTEMI Non ST-elevation myocardial infarction
OCM Oncology Care Model
OIG Department of Health and Human Services' Office of the Inspector General
O–I Outpatient-to-inpatient transfer
OPPS Outpatient Prospective Payment System
OPT Outpatient Physical Therapist
OQR Outpatient Quality Reporting
PACE Program of All-Inclusive Care for the Elderly
PBPM Per-beneficiary per-month
PCI Percutaneous Coronary Intervention
PCMH Primary Care Medical Homes
PE Practice Expense
PEP Partial Episode Payment
PFS Physician Fee Schedule
PGP Physician group practice
PHA Partial hip arthroplasty
PQRS Physician Quality Reporting System
PPS Prospective Payment System
PRO Patient-Reported Outcome
PROMIS Patient-Reported Outcomes Measurement Information Systems
PROM Patient-Reported Outcome Performance Measure
PTAC Focused Payment Model Technical Advisory Committee
PTCA Percutaneous transluminal coronary angioplasty
PY Performance year
QCDR Qualified clinical data registries
QE Qualified Entity
QIO Quality Improvement Organization
QP Qualifying APM Participant
QPP Quality Payment Program
QRDA Quality Reporting Document Architecture
QRUR Quality and Resource Use Reports
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
SDS Socio-demographic Status
SFT Secure File Transfer
SHFFT Surgical hip/femur fracture treatment
SHIP State Health Insurance Assistance Programs
SILS2 Single Item Health Literacy Screening
SLA Service level agreement
SNF Skilled nursing facility
SNF–QRP QRP Skilled Nursing Facility Quality Reporting Program
SSDMF Social Security Death Master file
STEMI ST-elevation myocardial infarction
STS Society of Thoracic Surgeons
ST–T ST-segment-T wave
TEP Technical Expert Panel
TGP Therapy Group Practice
THA Total hip arthroplasty
TIN Taxpayer identification number
TJA Total joint arthroplasty
TKA Total knee arthroplasty
TP Target price
UHDDS Uniform Hospital Discharge Data Set
VAD Ventricular Assist Device
VBP Value Based Purchasing
VR–12 Veterans Rand 12 Item Health Survey

Table of Contents

I. Executive Summary
A. Purpose
B. Summary of the Major Provisions
1. Model Overview—EPM Episodes of Care
2. Model Scope
3. Payment
4. Similar, Previous, and Concurrent Models
5. Overlap With Ongoing CMS Efforts
6. Quality Measures and Reporting Requirements
7. Beneficiary Protections
8. Financial Arrangements
9. Data Sharing
10. Program Waivers
C. Summary of Economic Effects
II. Background
III. Episode Payment Models
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
b. SHFFT Model
c. AMI and CABG Models
2. Advanced Alternative Payment Model Considerations
a. Overview for the EPMs
b. EPM Participant Tracks
c. Clinician Financial Arrangements Lists Under the EPMs
d. Documentation Requirements
3. Future Directions for Episode Payment Models
a. Refinements to the BPCI Initiative Models
b. Potential Future Condition-Specific Episode Payment Models
c. Potential Future Event-Based Episode Payment Models for Procedures and Medical Conditions
d. Health Information Technology Readiness for Potential Future Episode Payment Models
B. Definition of the Episode Initiator and Selected Geographic Areas
1. Background
2. Definition of Episode Initiator
3. Financial Responsibility for Episode of Care
4. Geographic Unit of Selection and Exclusion of Selected Hospitals
5. Overview and Options for Geographic Area Selection for AMI and CABG Episodes
a. Exclusion of Certain MSAs
b. Selection Approach
(1) Factors Considered but Not Used
(2) Sample Size Calculations and the Number of Selected MSAs
(3) Method of Selecting MSAs
C. Episode Definition for EPMs
1. Background
2. Overview of Three New Episode Payment Models
3. Clinical Dimensions of AMI, CABG, and SHFFT Model Episodes
a. Definition of the Clinical Conditions Included in AMI, CABG, and SHFFT Model Episodes
(1) AMI (Medical Management and PCI) Model
(2) CABG Model
(3) SHFFT (Excludes Lower Extremity Joint Replacement) Model
b. Definition of the Related Services Included in EPM Episodes
4. EPM Episodes
a. Beneficiary Care Inclusion Criteria and Beginning of EPM Episodes
(1) General Beneficiary Care Inclusion Criteria
(2) Beginning AMI Episodes
(3) Beginning CABG Episodes
(4) Beginning SHFFT Episodes
(5) Special Policies for Hospital Transfers of Beneficiaries With AMI
b. Middle of EPM Episodes
c. End of EPM Episodes
(1) AMI and CABG Models
(2) SHFFT Model
D. Methodology for Setting EPM Episode Prices and Paying EPM Participants in the AMI, CABG, and SHFFT Models
1. Background
a. Overview
b. Key Terms for EPM Episode Pricing and Payment
2. Performance Years, Retrospective Episode Payments, and Two-Sided Risk EPMs
a. Performance Period
b. Retrospective Payment Methodology
c. Two-Sided Risk EPMs
3. Adjustments to Actual EPM Episode Payments and to Historical Episode Payments Used To Set Episode Prices

a. Overview
b. Special Payment Provisions
c. Services That Straddle Episodes
d. 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
4. EPM-Episode Price-Setting Methodologies
a. Overview
(1) AMI Model DRGs
(2) CABG Model DRGs
(3) SHFFT Model DRGs
b. EPM-Episode Benchmark and Quality-Adjusted Target Price Features
(1) Risk-Stratifying EPM-Episode Benchmark Prices Based on MS–DRG and Diagnosis
(2) Adjustments To Account for EPM-Episode Price Variation
(a) Adjustments for Certain AMI Model Episodes With Chained Anchor Hospitalizations
(b) Adjustments for CABG Model Episodes
(c) Adjustments for Certain AMI Model Episodes With CABG Readmissions
(d) Potential Future Approaches To Setting Target Prices for AMI and Hip Fracture Episodes
(e) Summary of Pricing Methodologies for AMI, CABG, and SHFFT Model Episode Scenarios
(3) 3 Years of Historical Data
(4) Trending Historical Data to the Most Recent Year
(5) Update Historical EPM-Episode Payments for Ongoing Payment System Updates
(6) Blend Hospital-Specific and Regional Historical Data
(7) Define Regions as U.S. Census Divisions
(8) Normalize for Provider-Specific Wage Adjustment Variations
(9) Combining Episodes To Set Stable Benchmark and Quality-Adjusted Target Prices
(10) Effective Discount Factor
c. Approach To Combine Pricing Features for all SHFFT Model Episodes and AMI Model Episodes Without CABG Readmissions
d. Approach To Combine Pricing Features for CABG Model Episodes
(1) Anchor Hospitalization Portion of CABG Model Episodes
(2) Approach To Combine Pricing Features for Post-Anchor Hospitalization Portion of CABG Model Episodes
(3) Combine CABG Anchor Hospitalization Benchmark Price and CABG Post-Anchor Hospitalization Benchmark Price
e. Approach To Combine Pricing Features for AMI Model Episodes With CABG Readmissions
5. Process for Reconciliation
a. Net Payment Reconciliation Amount (NPRA)
b. Payment Reconciliation
c. Reconciliation Report
6. Adjustments for Overlaps With Other Innovation Center Models and CMS Programs
a. Overview
b. Provider Overlap
(1) BPCI Participant Hospitals in Geographic Areas Selected for EPMs
(2) BPCI Physician Group Practice (PGP) Episode Initiators in Hospitals Participating in EPMs
c. Beneficiary Overlap
(1) Beneficiary Overlap With BPCI
(2) Beneficiary Overlap With the CJR Model and Other EPMs
(3) Beneficiary Overlap With Shared Savings Models and Programs
d. Payment Reconciliation of Overlap With Non-ACO CMS Models and Programs
7. Limits or Adjustments to EPM Participants' Financial Responsibility
a. Overview
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
(2) Limitation on Reconciliation Payments
c. Additional Protections for Certain EPM Participants
(1) Policies for Certain EPM Participants to Further Limit Repayment Responsibility
(2) Considerations for Hospitals Serving a High Percentage of Potentially Vulnerable Populations
d. Application of Stop-Gain and Stop-Loss Limits
e. EPM Participant Responsibility for Increased Post-Episode Payments
8. Appeals Process
a. Overview
b. Notice of Calculation Error (First Level Appeal)
c. Dispute Resolution Process (Second Level of Appeal)
d. Exception to the Notice of Calculation Error Process and Notice of Termination
e. Limitations on Review
E. EPM Quality Measures, Public Display, and Use of Quality Measures in the EPM Payment Methodology
1. Background
2. Selection of Quality Measures for the EPMs
a. Overview of Quality Measure Selection
b. AMI Model Quality Measures
c. CABG Model Quality Measures
d. SHFFT Model Quality Measures
3. Use of Quality Measures in the EPM Payment Methodologies
a. Overview of EPM Composite Quality Score Methodology
b. Determining Quality Measure Performance
c. Determining Quality Measure Improvement
d. Determining Successful Submission of Voluntary Data for AMI and SHFFT Models
(1) Hybrid AMI Mortality (NQF #2473) Voluntary Data
(2) Patient-Reported Outcomes and Limited Risk Variable Voluntary Data Following Elective Primary THA/TKA
e. Calculation of the EPM-Specific Composite Quality Score
(1) AMI Model Composite Quality Score
(2) CABG Model Composite Quality Score
(3) 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
(2) AMI and CABG Model Pay-for-Performance Methodology
(a) AMI Model Pay-for-Performance Methodology
(b) CABG Model Pay-for-Performance Methodology
(c) Alignment Between the AMI and CABG Model Methodologies
(3) 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
(b) Data Sources
(c) Cohort
(d) Inclusion and Exclusion Criteria
(e) Risk-Adjustment
(f) Calculating the Risk-Standardized Mortality Ratio (RSMR) and Performance Period
(2) Excess Days in Acute Care After Hospitalization for Acute Myocardial Infarction (AMI Excess Days)
(a) Background
(b) Data Sources
(c) Cohort
(d) Inclusion and Exclusion Criteria
(e) Risk-Adjustment
(f) Calculating the Rate and Performance Period
(3) Hybrid Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #2473) (Hybrid AMI Mortality)
(a) Background
(b) Data Sources
(c) Cohort
(d) Inclusion and Exclusion Criteria
(e) Risk-Adjustment
(f) Calculating the Risk-Standardized Mortality Ratio (RSMR) and Performance Period
(g) Requirements for Successful Submission of AMI Voluntary Data
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
(b) Data Source
(c) Cohort
(d) Inclusion and Exclusion Criteria
(e) Risk-Adjustment
(f) Calculating the Risk-Standardized Mortality Ratio (RSMR) and Performance Period
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
(b) Data Sources

(c) Cohort
(d) Inclusion and Exclusion Criteria
(e) Risk Adjustment
(f) Calculating the Risk Standardized Complication Rate and Performance Period
(2) Hospital-Level Performance Measure(s) of Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty
(a) Background
(b) Data Sources
(c) Cohort
(d) Inclusion and Exclusion Criteria
(e) Outcome
(f) Risk Adjustment (If Applicable)
(g) Calculating the Risk Standardized Rate
(h) Performance Period for Successful Submission of THA/TKA Patient-Reported Outcome-Based Voluntary Data
(i) Requirements for Successful Submission of THA/TKA Patient-Reported-Outcome-Based Voluntary Data
d. Measure Used for All EPMs
(1) Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey (NQF #0166)
(a) Background
(b) Data Sources
(c) Cohort
(d) Inclusion and Exclusion Criteria
(e) Case-Mix Adjustment
(f) HCAHPS Scoring
(g) Calculating the Rate and Performance Period
e. Potential Future Measures
5. Form, Manner, and Timing of Quality Measure Data Submission
6. Display of Quality Measures and Availability of Information for the Public From the AMI, CABG, and SHFFT Models
F. Compliance Enforcement and Termination of an Episode Payment Model
1. Overview and Background
2. Compliance Enforcement for EPMs
3. Termination of an Episode Payment Model
G. Monitoring and Beneficiary Protection
1. Introduction and Summary
2. Beneficiary Choice
3. Beneficiary Notification
4. Monitoring for Access To Care
5. Monitoring for Quality of Care
6. Monitoring for Delayed Care
H. Access to Records and Record Retention
I. Financial Arrangements Under EPM
1. Background
2. Overview of the EPM Financial Arrangements
3. EPM Collaborators
4. Sharing Arrangements Under EPM
a. General
b. Requirements
c. Gainsharing Payment, Alignment Payment, and Internal Cost Savings Conditions and Restrictions
d. Documentation Requirements
5. Distribution Arrangements Under the EPM
a. General
b. Requirements
6. Downstream Distribution Arrangements Under the EPM
a. General
b. Requirements
7. Summary of Proposals for Sharing, Distribution, and Downstream Distribution Arrangements Under the EPM
8. Enforcement Authority
9. Beneficiary Engagement Incentives Under the EPM
a. General
b. Technology Provided to an EPM Beneficiary
c. Clinical Goals of the EPM
d. Documentation of Beneficiary Incentives
10. Compliance With Fraud and Abuse Laws
J. Waivers of Medicare Program Requirements
1. Overview
2. Summary of Waivers Adopted Under the CJR Model
3. Analysis of Current Model Data
a. Analysis of Waiver Usage
b. Analysis of Discharge Destination—Post-Acute Care Usage
c. Analysis of Hospital Mean Length of Stay Data
4. Post-Discharge Home Visits
a. AMI Model
b. CABG Model
c. SHFFT Model
5. Billing and Payment for Telehealth Services
6. SNF 3-Day Rule
a. Waiver of SNF 3-Day Rule
b. Additional Beneficiary Protections Under the SNF 3-Day Stay Rule Waiver
7. Waivers of Medicare Program Rules To Allow Reconciliation Payment or Repayment Actions Resulting From the Net Payment Reconciliation Amount
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
K. Data Sharing
1. Overview
2. Beneficiary Claims Data
3. Aggregate Regional Data
4. Timing and Period of Baseline Data
5. Frequency and Period of Claims Data Updates for Sharing Beneficiary-Identifiable Claims Data During the Performance Period
6. Legal Permission To Share Beneficiary-Identifiable Data
7. Data Considerations With Respect to EPM and CJR Collaborators
L. Coordination With Other Agencies
IV. Evaluation Approach
A. Background
B. Design and Evaluation Methods
C. Data Collection Methods
D. Key Evaluation Research Questions
E. Evaluation Period and Anticipated Reports
V. Comprehensive Care for Joint Replacement Model
A. Participant Hospitals in the CJR Model
B. Inclusion of Reconciliation and Repayment Amounts When Updating Data for Quality-Adjusted Target Prices
C. Quality-Adjusted Target Price
D. Reconciliation
1. Hospital Responsibility for Increased Post-Episode Payments
2. ACO Overlap and Subsequent Reconciliation Calculation
3. Stop-Loss and Stop-Gain Limits
4. Modifications to Reconciliation Process
E. Use of Quality Measures and the Composite Quality Score
1. Hospitals Included in Quality Performance Distribution
2. Quality Improvement Points
3. Relationship of Composite Quality Score to Quality Categories
4. Maximum Composite Quality Score
5. Acknowledgement of Voluntary Data Submission
6. Calculation of the HCAHPS Linear Mean Roll-Up (HLMR) Score
F. Accounting for Overlap With CMS ACO Models and the Medicare Shared Savings Program
G. Appeals Process
H. Beneficiary Notification
I. Compliance Enforcement
1. Failure To Comply
J. Financial Arrangements Under the CJR Model
1. Definitions Related to Financial Arrangements
a. Addition to the Definition of CJR Collaborators
b. Deleting the Term Collaborator Agreements
c. Addition of CJR Activities
2. Sharing Arrangements
a. General
b. Requirements
c. Gainsharing Payment, Alignment Payment, and Internal Cost Savings Conditions and Restrictions
d. Documentation
3. Distribution Arrangements
a. General
b. Requirements
4. Downstream Distribution Arrangements Under the CJR Model
a. General
b. Requirements
5. Summary of Proposals for Sharing, Distribution, and Downstream Distribution Arrangements Under the CJR Model
K. Beneficiary Incentives Under the CJR Model
L. Access to Records and Record Retention
M. Waivers of Medicare Program Rules To Allow Reconciliation Payment or Repayment Actions Resulting From the Net Payment Reconciliation Amount
N. SNF 3-Day Waiver Beneficiary Protections
O. Advanced Alternative Payment Model Considerations
1. Overview for CJR
2. CJR Participant Hospital Track
3. Clinician Financial Arrangements Lists Under the CJR Model
4. Documentation Requirements
VI. Cardiac Rehabilitation Incentive Payment Model
A. Background
B. Overview of the CR Incentive Payment Model
1. Rationale for the CR Incentive Payment Model
2. General Design of the CR Incentive Payment Model
C. CR Incentive Payment Model Participants

D. CR/ICR Services That Count Towards CR Incentive Payments
E. Determination of CR Incentive Payments
1. Determination of CR Amounts That Sum To Determine a CR Incentive Payment
2. Relation of CR Incentive Payments to EPM Pricing and Payment Policies and Sharing Arrangements for EPM–CR Participants
3. CR Incentive Payment Report
4. Timing for Making CR Incentive Payments
F. Provisions for FFS–CR Participants
1. Access to Records and Retention for FFS–CR Participants
2. Appeals Process for FFS–CR Participants
a. Overview
b. Notice of Calculation Error (First Level Appeal)
c. Dispute Resolution Process (Second Level of Appeal)
d. Exception to the Notice of Calculation Error Process and Notice of Termination
e. Limitations on Review
3. Data Sharing for FFS–CR Participants
a. Overview
b. Data Sharing With CR Participants
4. Compliance Enforcement for FFS–CR Participants and Termination of the CR Incentive Payment Model
5. Enforcement Authority for FFS–CR Participants
6. Beneficiary Engagement Incentives for FFS–CR Participants
7. Waiver of Physician Definition for FFS–CR Participants Furnishing CR and ICR Services
a. Overview of Program Rule Waivers Under an EPM
b. General Physician Requirements for Furnishing CR/ICR Services
c. Waiver of Physician Definition For EPM–CR Participants Furnishing CR and ICR Services
d. Waiver of Physician Definition For FFS–CR Participants Furnishing CR and ICR Services
G. Considerations Regarding Financial Arrangements Under the CR Incentive Payment Model
VII. Collection of Information Requirements
VIII. Regulatory Impact Analysis
A. Statement of Need
1. Need for EPM Final Rule
2. Need for CJR Modifications
3. Need for CR Incentive Payment Model
4. Aggregate Impact of EPMs, CJR, and CR Incentive Payment Model
B. Overall Impact
C. Anticipated Effects
1. Overall Magnitude of the Model and Its Effects on the Market
a. EPMs
b. CJR
c. CR Incentive Payment Model
d. Aggregate Effects on the Market
2. Effects on the Medicare Program
a. EPMs
(1) Assumptions and Uncertainties
(2) Analyses
(3) Uncertainties
b. CJR
(1) Assumptions and Uncertainties
(2) Analyses
c. CR Incentive Payment Model
(1) Assumptions and Uncertainties
(2) Analysis
d. Further Consideration
3. Effects on Beneficiaries
4. Effects on Small Rural Hospitals
5. Effects on Small Entities
6. Effects on Collection of Information
7. Unfunded Mandates
D. Alternatives Considered
E. Accounting Statement and Table
F. Conclusion
Regulations Text

I. Executive Summary

A. Purpose

The purpose of this final rule—Advancing Care Coordination through Episode Payment Models is to implement 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 (''the Innovation Center''), as well as to implement several modifications to the Comprehensive Care for Joint Replacement model. 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 (CHIP) 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 EPMs is to improve the quality of care provided to beneficiaries in an applicable episode while reducing episode spending through financial accountability.[1] The EPMs 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 this final 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 that the finalized models will 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 efficient service delivery, and incentivizing higher-value care across the inpatient and post-acute care spectrum. We proposed on August 2, 2016 to test the proposed EPMs for 5 performance years, beginning July 1, 2017, and ending December 31, 2021 (81 FR 50799) and we are finalizing those dates as proposed in this final rule.

Within this final rule, we discuss three distinct EPMs focused on episodes of care for AMI, CABG, and SHFFT episodes. We chose these episodes for the models because, as discussed in depth in section III.A. of this final rule and as stated in the proposed rule, we believe hospitals would have a significant opportunity to redesign care and to improve the quality of care furnished during the applicable episode. The EPMs will 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 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 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

[1] In this final 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 final rule.

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 EPMs will 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 a hospitalization for one of the procedures or clinical conditions included in these EPMs will 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 will also 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 AMI, CABG, and SHFFT models will require the participation of hospitals in multiple geographic areas that might not otherwise participate in testing episode payment for the 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 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 proposed (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 EPMs, CMS will test episode payment for certain cardiac conditions and procedures, as well as SHFFT. We expect the patient population included in these episodes will 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 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 hospitalization, with the majority of spending following discharge from the 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 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.[2] 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 in this rule 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 this final rule.

These models will also allow CMS to gain additional experience with episode-payment based 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 EPMs by a large number of hospitals with diverse characteristics will result in a robust data set for evaluating this payment approach and will stimulate the rapid development of new evidence-based knowledge. Testing the EPMs in this manner will 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 could potentially inform future Medicare payment policies.

We proposed the CR incentive payment model to test the effects on

[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.

[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).

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 sought public comment on the proposals contained in the proposed rule (81 FR 50794) published on August 2, 2016, and also on any alternatives considered. Public comment and our responses to those comments follow under the applicable sections. The applicable sections contain our proposed policy changes, commenters' reactions, and our responses.

We received approximately 175 timely pieces of correspondence containing multiple comments on the EPM proposed rule. We note that some of these public comments were outside of the scope of the proposed rule. These out-of-scope public comments are mentioned in this section but are not addressed with the policy responses in this final rule. The following is a summary of the comments received on the proposed model as a whole, including the authority for the model and general comments on CMS' implementation of the EPM model at this time and our responses.

Comment: Some commenters expressed support for the proposed EPMs and for requiring participation from specific hospitals in the selected geographic regions. Other commenters requested whether CMS has the authority under section 1115A of the Social Security Act (the Act) to implement the EPMs as proposed, while others stated specifically that they believe CMS cannot compel provider participation and further stated that they did not believe Congress intended to delegate its authority to make permanent changes to the Medicare program to the Secretary through the Innovation Center.

Many commenters raised concerns that interpreting section 1115A to mean that requiring participation in models is permissible under statute holds significant implications for the patients and providers included in the proposed EPMs, as required models could negatively impact the Medicare Shared Savings Program (Shared Savings Program) and/or Accountable Care Organizations (ACOs).

Response: While we appreciate the support expressed by some commenters, we disagree with the contention that the Innovation Center lacks the authority to test models under section 1115A of the Act in which participation is required. Section 1115A of the Act authorizes the Secretary to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program (CHIP) beneficiaries, and section 1115A of the Act does not specify that participation in models must be voluntary. As discussed in section IV. of this final rule, one of the reasons that we have determined it is necessary to test the EPM models by requiring the participation of certain hospitals is to obtain more generalizable evaluation results.

Moreover, the Secretary has authority to establish regulations to carry out the administration of Medicare. Specifically, the Secretary has authority under both sections 1102 and 1871 of the Act to implement regulations as necessary to administer Medicare, including testing these Medicare payment and service delivery models. We note that the EPMs will test different methods for delivering and paying for services covered under the Medicare program, which the Secretary has clear legal authority to regulate.

To be clear, we did not propose, and are not finalizing, permanent changes to Medicare, but rather are testing payment and service delivery models under section 1115A(b) of the Act. While the EPMs require the participation of certain participant hospitals, the EPMs are not permanent changes to the Medicare program. We acknowledge the importance of examining the impact of the EPMs as this test will implement models at the geographic regional level. The EPMs are thus intended to enable CMS to test and evaluate the effects of episode payment approaches on a broader range of Medicare providers and suppliers than would choose to participate in an alternative payment model. More specifically, the evaluation is to conduct a multifaceted and multi-pronged examination of issues of quality, access, and consequences. Randomized evaluation designs of this kind helps to reduce the systematic differences among hospitals that are and are not participating in the EPMs, which helps to ensure that, on average, differences in outcomes between participating and non-participating hospitals reflect the impact of the model. Testing these models in this manner also allows us to learn more about patterns of inefficient utilization of health care services and how to incentivize the improvement of quality for AMI, CABG, and SHFFT procedure/diagnosis episodes. This learning can potentially inform future Medicare payment policy.

We do not believe the EPMs will harm the continuation of a permanent Medicare program such as the Shared Savings Program, We continue to believe that while we test the EPMs, ACOs will still work towards the goals of the Shared Savings Program. These goals have been previously described (76 FR 67801) and include ensuring the coordination of care for beneficiaries, regardless of the time or place of that care, being innovative in service delivery by drawing upon the best, most advanced models of care, and using modern technologies, including telehealth and electronic health records, and other tools to continually reinvent care in the modern age.

We refer to our discussion about ACO overlap with the proposed EPMs that was included in the proposed rule (81 FR 50870) and acknowledge the concerns expressed by some ACOs that the current CJR and BPCI ACO overlap

[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.

policies deprive them of a key source of savings. Because ACOs in certain types of 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 such 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. Furthermore, it is more operationally feasible to identify and exclude beneficiaries who are prospectively aligned to ACOs.

Comment: One commenter believed that the EPMs did not satisfy the requirement that the model address ''a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable costs'' as is required by section 1115A(b)(2)(A) of the Act.

Response: Models tested under section 1115A of the Act must address a defined population for which there are either deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. As discussed in section III.C. of the proposed rule (81 FR 50829–50843) and section III.C. of this final rule, these models satisfy the requirements of section 1115A(b) of the Act, as the EPMs address defined populations (FFS Medicare beneficiaries experiencing acute myocardial infarctions, coronary artery bypass grafting procedures and/or surgical hip/femur fracture treatment) for which there are potentially avoidable expenditure because there are no strong incentives for coordinated care, which can lead to suboptimal care. As discussed in section IV. of this final rule, one of the reasons that we have determined it is necessary to require the participation of hospitals in multiple geographic areas that might not otherwise participate in testing episode payment for the episodes of care is to provide more generalizable evaluation results of the impacts of these models.

Comment: A few commenters asserted that the SHFFT model is equivalent to an expansion of the CJR model under section 1115A(c) of the Act. The same commenters stated that the SHFFT EPM model test should not be finalized in this rule as the CJR model has not yet satisfied the requirements of section 1115A(c) of the Act. One commenter stated that before implementing the SHFFT EPM, CMS must first complete the evaluation of the CJR model required under section 1115A(b)(4) of the Act; make the determinations required under section 1115A(c)(1) and (3) of the Act; and receive the certification from the Chief Actuary required under section 1115A(c)(2) of the Act.

Response: Regarding the commenters' assertion that the proposed SHFFT model expands the CJR model prior to the CJR evaluation, we note that this is not the case. We agree that section 1115A of the Act establishes the necessary criteria for the Secretary to expand payment and service delivery models. However, the SHFFT model we are finalizing in this rule is not an expansion of the CJR model under section 1115A(c) of the Act. Rather, the SHFFT EPM model is a new model test under section 1115A(b) of the Act. The CJR model is still at the initial model test stage, and we will not make any determinations about continuing the CJR model test through expansion under section 1115A(c) of the Act until there is sufficient information from evaluation(s) to assess its potential for expansion. While the SHFFT EPM model test complements the CJR model test, it is a separate and distinct model test. Specifically, the SHFFT model differs from the CJR model in that the CJR model is largely for planned admissions for hip and knee replacements and the episode of care begins with an admission to a participant hospital of a beneficiary who is ultimately discharged under MS–DRG 469 (Major joint replacement or reattachment of lower extremity with major complications or comorbidities) or 470 (Major joint replacement or reattachment of lower extremity without major complications or comorbidities). In contrast, the SHFFT model tests a hospital payment for hip fixation and the episode of care eventually results from a discharge paid under MS–DRG 480 (Hip and femur procedures except major joint with major complication or comorbidity—CC), MS–DRG 481 (Hip and femur procedures except major joint with complication or comorbidity—MCC), or MS–DRG 482 (Hip and femur procedures except major joint without CC or MCC). Therefore, the interventions under each model test would not overlap. Further, the SHFFT model test would give hospitals already participating in the CJR model different experience in managing care for hip and femur fracture cases that typically present emergently, rather than the planned, elective surgery that is most common for lower extremity joint replacement. Despite this geographic overlap, beneficiaries who initiate an episode in either the SHFFT or CJR model remain in that initial model and are precluded from initiating a simultaneous episode in the CJR or SHFFT models respectively. As a result, the evaluations of the CJR model and the SHFFT model will assess the effect of discrete episodes.

Comment: Some commenters expressed support for the intended goals of the EPMs, and stated they want to contribute to moving our health care system to a value-based system. However, many commenters disagreed with the process used by CMS to achieve this goal. Specifically, commenters stated that CMS moved too fast and too soon in implementing these models. Furthermore, commenters believe that the breadth and speed of the CMS models expanded exponentially. Commenters stated that in situations when multiple initiatives are being implemented simultaneously, for example Meaningful Use, new conditions of participation for emergency preparedness, multiple clinical and payment changes to the existing fee-for-service payment systems, performance requirements of payment reforms such as the MACRA, and state regulatory changes to health care, commenters stated that hospitals may have little time or resources available for thoughtful care redesigns to be applied to the proposed model. A few commenters noted that the insurance marketplace in general remains volatile, adding further complication to the health care landscape, while others believe generally that CMS is putting the existing initiatives' success at risk as a result of the proposed pace of implementation of new programs and models.

Commenters raised concerns that they were unable to submit informed comments on the proposed rule because they did not have sufficient data on the CJR model, making it difficult to assess even early experience with the process of implementation of models that require participation. Other commenters submitted statements of experience related to implementation of the CJR model, specifically that implementation was administratively challenging due to the need to first develop a process of care redesign and then implement operational changes related to efficiency as well as specific provisions of the model, including but not limited to collaboration agreements, provisions for beneficiary notifications, and data analysis. As a result of this experience, commenters requested that CMS delay the implementation time line of the EPMs. The alternative time lines proposed by commenters varied. A few commenters stated that it would be unreasonable to implement a new episode payment model before

evaluation of the outcomes and processes of existing bundled payment models. Other commenters suggested that CMS generally delay implementation until the agency can address concerns related to risk adjustment, minimum volume thresholds, comprehensiveness of payment, and episode definitions. Commenters believed that launching the proposed models simultaneously will require an incredible administrative effort, which may hinder the ability to effectively direct clinical resources towards best practices for success. To this end, commenters also suggested alternative proposals, including but not limited to reconsideration of implementing cardiac EPMs; delay, pilot, or narrow the scope of the proposed SHFFT model; delay the start date of the proposed EPMs until no earlier than January 1, 2018; provide hospitals with at least 12 months of preparation time from the date the final rule is finalized. Other commenters believed hospitals should not be subject to downside risk for at least 12 months from the implementation date of the final rule, and other commenters suggested that CMS delay the onset of downside risk beyond the first quarter of performance year 2. Commenters suggested CMS delay implementation to allow both CMS and EPM participants to prepare to be successful during testing of the model. Specifically, commenters stated that CMS should use the delay to establish a dialogue with hospitals to improve the existing bundled payment experience, perform outcomes studies on existing models and programs, analyze the existing CJR model to determine the model's impact to beneficiaries' outcomes and longer term well-being, and create infrastructure to more easily attribute patients to the EPMs. Commenters also stated that such a delay would allow time for EPM participants to better understand the clinical and financial risk of their patient populations, to establish collaborator relationships and to create the internal organization structure to manage payment bundles. A few commenters specifically suggested changes in payment once the risk-bearing phase begins, to allow a prospective payment to the EPM participants upon determination of an eligible diagnosis, as this change could permit all collaborating providers to share in both the upside and downside financial risk, and not be constrained by what Medicare pays for services during the episode. Overall, most commenters requested that CMS generally apply a more strategic process to achieve the intended goals by building on the experience to date to set the health care system on a pathway to success rather than rolling out new models before anything concrete is gleaned from existing models.

Response: We appreciate the comments we received in support of our proposed performance period and start date. We also appreciate comments expressing concerns around the timing of this model. Although we believe that it is important to initiate these EPMs now since they are different than CJR and BPCI and will provide essential information about the potential for episode payment to improve care and lower spending, we are sensitive to commenters' concerns that our proposed date to implement downside risk may not provide sufficient time for participants to implement the kinds of changes needed to successfully participate in the model, particularly given the availability of baseline data. Accordingly, this final rule will increase available preparation time by not implementing downside risk for all participants in the EPMs until October 1, 2018. Downside risk for EPM episodes will be applied to episodes ending on or after January 1, 2019. As discussed in detail in section III.D. of this final rule, participants who are interested in taking on downside risk earlier can choose to begin downside risk for episodes ending on or after January 1, 2018. Additionally, specific amendments to the regulations regarding the CJR model access to records and records retention policy, compliance enforcement policy, and waiver of the SNF 3 day rule will take effect July 1, 2017. We refer readers to sections V.H., V.I., and V.L. of the final rule for discussions of our final decisions. We believe that these changes will both facilitate participants' abilities to be successful under these models and allow for a more gradual transition to full financial responsibility under the models. CMS will also continue to work internally to determine the extent to which the suggestions submitted by commenters, including performing education and outreach activities or outcomes studies on existing models, will impact the implementation of the EPMs. The EPMs will only include a limited number of episode types, and as such we believe it is reasonable for hospitals to begin to analyze data and identify care patterns and opportunities for care redesign for these episodes prior to assuming financial responsibility for spending for episode beginning after October 1, 2018. We also note that due to the gradual implementation of financial responsibility that was proposed and that will still be incorporated in the models even given the start of the phased-in downside risk that we are finalizing in this rule, we expect that hospitals will spend the first performance year of the model analyzing data, identifying care pathways, forming clinical and financial relationships with other providers and suppliers, and assessing opportunities for savings under the model, utilizing in part the claims data we provide to them. As a result of these changes, we do not believe that further changes are needed to the start date of implementation. We also do not agree with commenters that implementation of the model is premature or that it should not be implemented until results for CJR or other episode-based payment models are available. While we anticipate that these models will offer valuable information that should assist CMS in developing future episode payment models, the EPMs will offer additional insights that are not available under the CJR model; in particular, insights with respect to episode payment models on a distinct set of episodes for participants that would not otherwise participate under a model such as BPCI.

Likewise, we do not agree that the models should be implemented after certain other actions have occurred or because of the multiple competing mandates faced by hospitals and other providers. Since the Medicare program's inception, providers have and will continue to contend with constantly evolving statutory and administrative requirements that often require them to make concurrent changes in their practices and procedures. We do not believe the EPMs are dissimilar to those requirements.

Also as discussed earlier in this section, some commenters pointed to the potential for unintended consequences that could result from our proposed start date, including impediments to beneficiary access and reduced quality of care. As discussed in section III.E. of this final rule, we are including quality measures for purposes of evaluating hospitals' performance both individually and in aggregate across the models. Also, as discussed in section III.F. of this final rule, we are making final policies and actions to monitor both care access and quality. We believe these features will help ensure that beneficiary access to high quality care is not compromised under the EPMs.

Comment: Commenters raised specific concerns that the proposed EPMs' emphasis on cost-savings could incentivize hospitals to use the least

costly post-acute alternative rather than the option that is most appropriate for the beneficiary. Furthermore, commenters stated that under an episode payment structure, EPM participants that admit healthier patients would have better financial results. Some commenters believe this design will consequently impact Medicare beneficiaries and the Medicare Trust Fund by increasing the frequency of Medicare payments from participants initiating a higher volume of episodes in a healthier population of beneficiaries. Other commenters believed that the proposed regulation would have serious negative impacts on Medicare beneficiaries by encouraging unnecessary surgeries and on health care stakeholders by discouraging innovation. One commenter encouraged us to create a patient advisory panel so that beneficiary viewpoints could be incorporated into model planning for the EPMs and any other Innovation Center bundled payment models.

Response: We appreciate the commenters' concerns regarding the quality of care for Medicare beneficiaries. Improving the quality of care is a central goal of the Innovation Center's work to test new payment and service delivery models. We disagree with commenters that the models will negatively impact the quality of care for beneficiaries in these models and we refer readers to the monitoring and beneficiary protections discussion in section III.G. of this final rule which we believe will address the commenters' concerns about care stinting. We emphasize that care stinting or denying the provision of medically necessary care is not permitted under the EPMs. Medicare beneficiaries in the EPMs will retain the right to obtain health services from any individual or organization qualified to participate in the Medicare program, and EPM participants are required 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 disagree with commenters that the EPMs will stifle innovation for care furnished during an EPM episode. We proposed, and are finalizing in this final rule, a payment methodology that will account for changes in care patterns and utilization trends for EPM episodes as described in section III.D. of this final rule and will have a monitoring contractor actively reviewing claims and monitoring behavior of participant providers to ensure beneficiary choice and care are not compromised by the EPMs. The Federal Government has long recognized the important role of the public in developing effective policies. Advisory committees are a way of ensuring public and expert involvement and advice in federal decision-making. In compliance with the Federal Advisory Committee Act (FACA) the number of advisory committees is carefully managed and committee memberships reflect a balance of viewpoints, education, and experience. Although the establishment of a Patient Advisory Committee for all Innovation Center models is beyond the scope of this rule, we believe that stakeholder engagement is essential to the success of these models and our learning and monitoring contractors as well as our evaluation contractor will be soliciting beneficiary feedback on their experiences with the EPMs.

Comment: While some commenters appreciated the approach of CMS to implement episode-based payment models for a select group of clinical scenarios, others suggested that participation be voluntary, in order to allow hospitals and providers implementing other payment reforms like the MACRA a more gradual adoption process of EPMs. An additional voluntary component to the proposed EPMs, commenters stated, would also permit additional participants who are interested in the models but not located in the MSAs in which the models will be tested to volunteer for participation. Still, other commenters stated that single-episode initiatives fail to encourage systemic change within organizations, and may hinder competition if implemented. Commenters stated that as a result of mandated participation, many surgeons who and facilities which lack familiarity, experience, or proper infrastructure to support care redesign efforts will hamper provider participation, bias model performance evaluation, and negatively affect patient care. One commenter suggested that the nature of the models will provide information about how many organizations, and which organizations, fail. Other commenters commended CMS for the episode payment models. The commenters believed that this overall strategy will motivate hospitals to work more closely with other members of the patient's care team, which could reduce avoidable complications after surgery and decrease the risk of additional hospitalizations.

Response: We thank the commenters for their feedback, but disagree with the suggestion to finalize the proposed EPMs as a voluntary initiative. The EPMs will give CMS the ability to test how an episode payment model might function among participants that would otherwise not participate in such a model. As such, we expect the results from these models will produce data that are more broadly representative than what might be achieved under a voluntary model. Also, these models test a regional target pricing approach to consider a participant hospital's performance relative to its regional peers. As part of this test, we will learn whether our alternative pricing approach in these models will better incentivize participants who are already delivering high quality and efficient care while still incentivizing historically less efficient providers to improve. We would not be able to test such a regional pricing approach under a purely voluntary model, nor could the appropriate evaluation approach be implemented if participants could volunteer, because it is likely that only the already high quality and efficient providers would sign up.

Comment: Many commenters supported our use of notice and comment rulemaking for the EPMs and encouraged us to continue to use the notice and comment rulemaking process to facilitate a robust public dialogue on important issues related to the EPMs and the CR incentive payment model. These commenters generally agreed with the proposed EPM episodes. A few commenters were concerned that we would avoid notice and comment rulemaking requirements.

Response: We appreciate the commenters' support for the use of notice and comment rule-making for the EPM models. The EPMs are intended to enable CMS to better understand the effects of payment models on a broader range of Medicare providers than what is currently being tested under the BPCI initiative. To this end, testing the EPMs in the proposed manner will also allow us to learn more about patterns of inefficient utilization of health care services and how to incentivize improvement in quality for common AMI episodes.

We respectfully disagree that we are avoiding notice and comment rulemaking. We note that the proposed rule (81 FR 50794), promulgated in accordance with the requirements of 5 U.S.C. 553, went into great detail about the provisions of the proposed EPMs, enabling the public to fully understand and comment on how the proposed models were designed and could apply to those affected providers and beneficiaries. In this final rule, which is also being promulgated in accordance with the requirements of 5 U.S.C. 553,

we respond to the public comments received on our proposals, and after considering them, we are finalizing our proposals with some modifications.

Comment: Commenters questioned the extent to which EPM participants would have the knowledge, skills, and experience to successfully drive improvements in care delivery and health outcomes. Many commenters asserted they do not have enough experience to even know where the efficiencies in care delivery are available to take advantage of them, which limits the ability of the EPMs' potential success. Another commenter recommended CMS inform the participants that will be in these episode payment models as early as possible. To this end, many commenters recommended that CMS implement a broad-based education campaign regarding the new EPMs that uses all of CMS' communication channels to reach hospitals, post-acute care providers, physicians, and community-based providers of long term services and supports.

There were many unique suggestions by commenters to appropriately communicate the proposed EPMs to affected stakeholders. A few commenters were generally uncertain where CMS could articulate its vision for innovative payment models. A few other commenters believed CMS should explain in detail the applicable EPMs, provide contact information and a publicly accessible list of all the providers that are part of the model in each region. Other commenters requested more opportunity to analyze the lessons learned from Health Care Payment Learning and Action Network (HCP–LAN), Clinical Episode Payment (CEP) work group, and BPCI so they can be broadly applied to care redesigns as part of the proposed EPMs. To support learning efforts, some commenters recommended CMS to include in final regulations a requirement that participating hospitals must develop, have approved by CMS, and implement a comprehensive, effective clinical care model and leadership structure for coordinating care and managing implementation of the EPMs. A few suggested that CMS assign a Medicare Project Officer to assist CJR and EPM participants. One commenter suggested that CMS provide advanced education and clinical-financial tools attainable through a blend of registries, databases and CMS claims data. Other commenters supported the intention of CMS to establish a learning and diffusion program.

Response: We agree with commenters regarding the need to continually improve stakeholder outreach for models to succeed and we intend to do as much as we can to work to design and deploy a helpful learning and diffusion program. CMS is committed to continuing to facilitate performance improvement by identifying areas of excellence for the purposes of extrapolating best practices. CMS encourages collaboration amongst organizations and can provide guidance on the development and implementation of specific learning systems. We currently deploy the expertise and experience of The Innovation Center's Learning and Diffusion Group to facilitate learning within models by disseminating the lessons learned across models so that participants can benefit from the experiences of other models, and are always looking for better ways to educate and assist participants in knowledge sharing. For example, BPCI includes a shared learning network that brings experienced stakeholders together for knowledge sharing, collaboration, and peer-to-peer learning. We continue to believe that these efforts contribute to reducing the administrative burden on the health care delivery system and will be responsive to commenters' concerns.

Comment: One commenter stated that they believe CMS should engage in models which enhance sharing of best practices rather than financial incentives.

Response: We appreciate the commenter's submission and agree with the sentiment that providers of care in the EPMs should ensure quality of care is maintained or improved. The design of the episode-based payments directly corresponds with CMS' stated goal of decreasing costs while maintaining or improving quality. Within this framework, we anticipate best practices naturally evolving as participants explore care redesign to achieve efficiencies in the episode.

Comment: Many commenters applauded many of the design features in the new proposed models—suggesting that the proposed rule outlined the framework for models that could become very successful at reducing Medicare spending and improving patient care. One commenter suggested that CMS develop accreditation standards for participation and only select accredited EPM participants. Another commenter suggested considering Quality Improvement Organizations (QIOs) as participants, or that QIOs be more centrally involved in such models to continue to recognize the importance of care transitions.

Response: We thank commenters for their support of the proposed design features in the new proposed models. The QIO Care Transitions Project [7] previously tested the extent to which QIOs lead improvements in care transitions. Research found reduced rates of 30-day re-hospitalization and all-cause hospitalization per 1,000, however the reduced rate of all-cause 30-day re-hospitalization as a percentage of hospital discharges was not statistically significant. We will continue to work internally to evaluate the extent to which QIOs complement the operations of the EPMs. We disagree with the suggestion to develop accreditation standards, as such actions are distinct from testing of EPMs, and the proposal to define EPM episode initiators as only those accredited EPM participants. The definition of the episode initiator is discussed further in section III.B of this final rule.

As discussed in more detail in section V. of this final rule, we proposed numerous modifications to the CJR model, which began on April 1, 2016. Section V. of this final rule contains our proposed policy changes, commenters' reactions, and our responses. We discuss here comments we received on the CJR model as a whole, including several comments pertaining to model policies for which we did not propose any changes, as well as our responses.

Comment: In general, commenters expressed support for the CJR model. One commenter suggested that CMS extend the model on a voluntary basis after the conclusion of the model's 5 performance years, to allow for successful participants to continue under CJR. The commenter also suggested that in such a scenario, CMS allow for convening organizations to participate (as is the case currently under the BPCI initiative) and modify the model design to include features such as financial risk for the post-acute care period only. The commenter noted that such flexibility would encourage participation in alternative payment models.

Another commenter expressed support for the CJR model but noted the significant time and effort required for hospitals to implement the model. Commenters also requested several policy changes out of scope for this rulemaking, including: Additional relaxation of regulatory barriers to integration between hospitals and other stakeholders, removal of fractures in

[7] Brock J, et al., Association between quality improvement for care transitions in communities and rehospitalizations among Medicare beneficiaries. JAMA. 2013 Jan 23;309(4):381–91.

their entirety from this episode payment model, additional waivers of Medicare program rules, additional quality measures, policies that would encourage use of specific medical devices associated with lower revision rates, and modifications to the pricing methodology that would include comprehensive risk adjustment. Finally, one commenter requested that data be provided on a more frequent basis.

Response: We thank the commenters for their support of the CJR model. With regard to the CJR model policies for which we did not propose any changes, we will continue to consider the issues commenters brought forward and if warranted, would address any changes through future rulemaking as necessary. In addition, we note that while currently we provide CJR hospitals with episode data on a quarterly basis, we may begin to consider providing such data on a monthly basis when practicable.

Comment: A few commenters supported CMS' pursuit of opportunities to spread value-based payment to more providers through additional episode payment models beyond lower extremity joint replacement.

Response: We acknowledge and appreciate the commenters' remarks.

Comment: A few commenters addressed issues on the following subject-matter areas: Alternative administration of medications, non-medically directed anesthesia delivery, remote patient monitoring, data collection for global surgical services, and the long term care hospital certification program.

Response: These comments pertain to issues for which we did not include any proposals in the proposed rule. Therefore, we believe these comments are outside the scope of the proposed rule, and we are not addressing them in this final rule. After carefully considering all of the comments we received on the proposed model, including those discussed previously and within the following pages, for the reasons described elsewhere in this rule, we have concluded that we can successfully test the Episode Payment Models with several modifications and timing changes. The final model design we are implementing includes additional lead time for participants prior to the onset of downside risk to ensure that the models have time to incorporate risk adjustment into pricing, a commitment to conduct public listening sessions on risk adjustment during the 2017 calendar year and rulemaking during the 2018 calendar year on risk adjustment methods, an exemption for the Medicare Shared Savings Program Track 3 ACOs from participation in the EPMs and adjustments to the AMI transfer policy and the CABG quality measures. All of these changes are discussed in detail in this final rule.

B. Summary of the Major Provisions

1. Model Overview—EPM Episodes of Care

The EPMs, as described further in section III.B.2. of this final rule, are an AMI, CABG, or SHFFT model episode that will 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 will 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 EPMs' episodes will 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 proposed 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 proposed to require all hospitals to participate 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 proposed to select geographic areas through a random sampling methodology.

For the CR incentive payment model, we proposed 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 proposed to provide a CR incentive payment specifically to selected hospitals that are not AMI or CABG model participants (hereinafter FFS–CR participants).

Our geographic-area selection process is detailed further in section III.B.4. of this final rule.

3. Payment

We will test the AMI, CABG, and SHFFT EPMs for 5 performance years. The first performance year would begin July 1, 2017. During these performance years we will continue paying hospitals and other providers and suppliers according to the appropriate Medicare FFS payment systems. However, after the completion of a performance year, the Medicare claims payments for services furnished to an eligible beneficiary during an episode, based on claims data, will be combined to calculate an actual episode payment. The actual episode payment will then be reconciled against an established EPM quality adjusted target price. The amount of this calculation, if positive, will be paid to the EPM participant as a ''reconciliation payment'' provided they had achieved a quality category of ''acceptable'' or higher. If the amount of this calculation is negative, we will require a ''Medicare repayment'' from the participant hospital beginning with episodes ending in performance year 3 of the EPMs. We had proposed to phase in the requirement that participants whose actual episode payments exceed the quality adjusted target price pay the difference back to Medicare beginning in the second quarter of performance year 2, and under this proposal, CMS would not require a Medicare repayment from hospitals for actual episode payments that exceed their target price in performance year 1 and the first quarter of performance year 2. Our final rule implements the requirement for Medicare repayments during performance year 3 and includes

an applicable discount factor that would be used for calculating repayment amounts for performance years 3 and 4. Also, participants may elect to assume downside risk for performance year 2, which would also include an applicable discount factor for calculating repayment amounts.

In contrast to the CJR model, due to the clinical characteristics and common patterns of care in AMI episodes, we proposed 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 sections III.D.4.b.(1). through III.D.4.b.(2).(a). of the proposed and this final rule. We did not finalize one of these proposals—a payment adjustment for AMI episodes involving an inpatient-to-inpatient transfer or what we referred to as a chained anchor hospitalization. We also proposed payment adjustments for CABG model episodes, which we are finalizing in this rule. We proposed and are making final with modification limits on how much a hospital can gain or lose based on its actual episode payments relative to quality adjusted target prices, including policies to further limit the risk of high payment cases for special categories of participants as described in sections III.D.7.a. through III.D.7.d. of this final rule. In response to comments, we are finalizing a policy to extend separate financial loss protections to participants with a low volume of episodes under a model, which we refer to as EPM volume protection hospitals.

In addition to the EPMs, we proposed to test a CR incentive payment model (81 FR 50800) to encourage the utilization of CR/ICR services for beneficiaries hospitalized for treatment of AMI or CABG. To determine the CR incentive payment, we proposed 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 will 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 final rule. The CR performance years would be the same as the performance years for the EPMs in section III.D.2.a. of this final rule. Further details about the payment structure and design of the CR incentive payment model can be found in section VI. of this final rule.

4. Similar, Previous, and Concurrent Models

The EPMs are informed by other models and demonstrations currently and previously conducted by CMS, and will 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.[8]

The Innovation Center previously tested innovative episode payment approaches in the Medicare Acute Care Episode (ACE) demonstration,[9] and, as described in this final rule, currently is testing additional approaches under the BPCI initiative and the CJR model. The ACE demonstration tested an alternative 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.

Currently, we are testing the BPCI initiative, which is composed of 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.[10] Our experience testing BPCI Model 2 informed the design of the three 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 the AMI, CABG, and SHFFT models. These clinical episodes are being tested by over 1,200 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

[8] More information on the OCM can be found on the Innovation Center's Web site at *http://innovation.cms.gov/initiatives/Oncology-Care/*.

[9] Information on the ACE Demonstration can be found on the Innovation Center's Web site at *http://innovation.cms.gov/initiatives/ACE/*.

[10] 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/*.

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 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 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 on why specific elements of the models and initiatives were incorporated into the EPMs' designs is discussed later in this final rule.

5. Overlap With Ongoing CMS Efforts

We proposed 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 proposed to exclude from EPMs beneficiaries prospectively aligned to Innovation Center ACO models which had downside financial risk such as the Next Generation ACO and the Comprehensive ESRD Care models. We also sought comment regarding whether this exclusion should be extended to include beneficiaries assigned to Track 3 Shared Savings Program ACOs as these ACOs also have prospective assignment and downside financial risk. As discussed in the proposed rule, other CMS programs, such as the Shared Savings Program (Tracks 1 and 2) and other accountable care organization (ACO) or total cost of care initiatives will remain eligible for EPM episode initiation. We proposed 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. Specifically, as with CJR, we have proposed to give precedence to existing BPCI models when a beneficiary is admitted to an acute care hospital for what would otherwise be a covered EPM episode but that acute care hospital or the treating physician is participating in BPCI and the admission would meet the criteria to be covered under BPCI. In addition, as with CJR, an EPM episode will be cancelled if a beneficiary whose hospitalization initiates an EPM episode receives treatment during the post discharge period that would also result in the episode being covered under BPCI. Based on the comments received, we are finalizing these proposals with the modification that we will exclude from EPMs not only those beneficiaries prospectively assigned to the Next Generation ACO and the Comprehensive ESRD Care models which also share in downside risk with CMS, but also those beneficiaries prospectively assigned to Track 3 Shared Savings Program ACOs. More detail on our policies for accounting for provider- and beneficiary-level overlap is discussed in section III.D.6. of this final 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 finalized by CMS in the Quality Payment Program final rule with comment period (81 FR 77008 through 77831). 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 sufficient participation in Advanced APMs, eligible clinicians can become Qualifying APM Participants (QPs) for a payment year beginning with CY 2019 and potentially 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 in the Quality Payment Program final rule with comment period, we proposed 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 proposed 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 final rule with comment period. We also made similar proposals with respect to CJR.

We proposed to implement two different tracks within the EPMs whereby EPM participants that meet 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 criteria in the Quality Payment Program final rule with comment period. We made similar proposals with respect to CJR. We considered 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 how EPMs and CJR could qualify as Advanced APMs, and how eligible clinicians participating in the EPMs and CJR will be identified and affected, can be found in sections III.A.2 and V.O. of this final rule.

Comment: One commenter suggested that the most relevant definition of CEHRT to the EPM is found at § 495.4.

Response: The definition at 42 FR 495.4 relates to Medicaid eligible professionals, eligible hospitals, and CAHs, as defined for the EHR Incentive Programs. The definition at 45 FR 414.1305 relates to Medicare eligible clinicians and groups participating as defined for the CMS Quality Payment Program. These two definitions are substantively the same; however, we refer readers to the definition at 42 FR 495.4 as this most closely relates to the eligibility status of EPM participants. We have updated and finalized this technical correction.

6. Quality Measures and Reporting Requirements

Similar to the quality measures selected for the CJR model, we proposed to use established measures used in other CMS quality-reporting programs for the proposed EPMs' episodes. We proposed 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 proposed applying the same quality measures selected for the CJR model.

The quality measures for SHFFT episodes are as follows:

- 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.

The measures for the AMI model are as follows:

- 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.

The measures for the CABG model are as follows:

- 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.

We proposed and requested 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. Public comment and our responses to those comments follow under the applicable sections in section III. of this final rule.

We are finalizing as proposed the following quality measures for SHFFT episodes:

- 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 are finalizing as proposed 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 are finalizing as proposed 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.

In addition, after consideration of comments received, we are finalizing an additional measure for the CABG model. Successful voluntary reporting of the Society of Thoracic Surgeons (STS) CABG composite score (NQF #0696) is a comprehensive NQF-endorsed composite measure and will be weighted at 10 percent of the composite quality score for those hospitals that report this voluntary measure.

Additionally, similar to the CJR model, we proposed 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 EPM 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 EPM participants would not have the option to opt out of inclusion in the applicable model. We proposed to require EPM 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 will make a robust effort to reach out to beneficiaries and their advocates to help them understand the models. We also proposed to use our existing authority, if necessary, to audit participant hospitals if claims analysis indicates an inappropriate change in furnished services. Beneficiary protections are discussed in greater depth in section III.G. of this final rule.

8. Financial Arrangements

We proposed a regulatory structure for financial relationships under the EPM to advance the goals of improving the quality and efficiency of model episodes, which also included program integrity safeguards to protect against abuse under the financial relationships permitted for the EPM. Our EPM proposals reflected changes from the current CJR model regulations that generally fell into the following four categories: (1) Removing duplication of requirements in similar provisions; (2) streamlining and reorganizing the provisions for clarity and consistency; (3) providing additional flexibility in response to feedback from CJR participant hospitals and other stakeholders; and (4) expanding the scope of financial arrangements under the EPM. In addition to the collaborators permitted under the CJR model, we proposed to add hospitals and critical access hospitals (CAHs) 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 specifically proposed that ACOs 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 made additional proposals that would allow ACOs to enter into financial arrangements under the EPM with ACO participants and ACO providers/suppliers and to allow physicians group practices (PGPs) that are ACO participants in an ACO that is an EPM collaborator to enter into financial

arrangements under the EPM with PGP members.

As discussed in section III.I. of this final rule, after consideration of the public comments received we are finalizing the proposed structure for financial arrangements under the EPM, including that EPM participants may enter into sharing arrangements with EPM collaborators, EPM collaborators may enter into distribution arrangements with collaboration agents, and collaboration agents may enter into downstream distribution arrangements with downstream collaboration agents, subject to the requirements specific to each type of arrangement. Our final policies also include modifications to specify individually based on their enrollment in Medicare the specific providers and suppliers of outpatient therapy services that may be EPM collaborators. We also make modifications to clarify that groups of nonphysician practitioners and groups of therapists (physical therapy, occupational therapy, and speech-language pathology) enrolled in Medicare may be EPM collaborators and may enter into distribution arrangements or downstream distribution arrangements under the EPM that are similar to those we are finalizing for PGPs and their members.

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 proposed 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 proposed 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 proposed 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 will 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 final rule, we will 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 $159 million over the 5 performance years of the models. 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 models, we estimate a Medicare cost of approximately $10 million, as hospitals will not be subject to downside risk in the first performance year of the models. In performance year 2 of the models, we estimate a Medicare cost of approximately $25 million, as some hospitals will voluntarily assume downside risk in the second performance year of the models and some hospitals will receive payments made by CMS. As we introduce downside risk beginning in performance year 3 of the models, we estimate Medicare savings of approximately $34 million. In performance years 4 and 5 of the models, 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 $49 million and $112 million, respectively.

As a result, we estimate the net savings to Medicare to be $159 million over the 5 performance years of the models. 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 $29 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 final 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 $4 million in spending. The total estimated net financial impact to the Medicare program from both the modifications in the final rule and revised assumptions are $26 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 a model it is determined that termination or modification is necessary, such actions will be undertaken through rulemaking.

II. Background

This final rule finalizes 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 proposed 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. Critical Access Hospitals (CAHs) acting as EPM collaborators would continue to receive payment via the usual cost-based reimbursement system. 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 proposed the CR incentive payment model to test the effects on quality of care and Medicare expenditures of providing explicit financial incentives to a subset of EPM participants and selected hospitals that are not AMI or CABG model 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. We believe the models will further our goals of improving the efficiency and quality of care for Medicare beneficiaries for these medical conditions and procedures.

III. Episode Payment Models

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

We have 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 October 1, 2016, the BPCI initiative has 1,403 participants in the risk-bearing phase, comprised of 297 Awardees and 1,107 Episode Initiators. The breakdown of BPCI participants by provider type is as follows: Acute care hospitals (354); skilled nursing facilities (642); physician group practices (257); home health agencies (81); and inpatient rehabilitation facilities (9).[11] 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.[12]

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-based payment model 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 CJR 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 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 the BPCI initiative and the CJR model are focused on care that is related to an inpatient hospitalization, with CJR model and BPCI Model 2 episodes beginning with an inpatient hospitalization (anchor hospitalization) and extending up to 90 days post-hospital discharge.

In the proposed rule (81 FR 50805), we proposed 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 proposed EPMs would be AMI, CABG, and SHFFT excluding lower extremity joint replacement. The proposed AMI model included beneficiaries discharged under AMI MS–DRGs (280–282), representing IPPS admissions for AMI that are treated with medical management. The proposed AMI model also included 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 included beneficiaries discharged under CABG MS–DRGs (231–236), representing IPPS admissions for this coronary revascularization procedure irrespective of AMI diagnosis. The proposed SHFFT model included 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 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.[13] The total annual Medicare spending for these historical episodes was approximately $4.1 billion, $2.3 billion, and $4.7 billion, respectively.[14] 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 the CJR model, which are predominantly elective and during which hospital readmissions are rare

[11] *https://innovation.cms.gov/initiatives/bundled-payments/.*

[12] *https://innovation.cms.gov/Files/x/bpcianalyticfile.xlsx.*

[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 the proposed 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 the proposed rule that began in CY 2012–2014.

and substantial post-acute care provider utilization is common, the proposed AMI, CABG, and SHFFT 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 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.[15] 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.[16] Pay-for-performance episode payment models, such as the three EPMs proposed in the proposed 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 anticipated 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 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 proposed 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 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.

The following is a summary of the comments received on our overall proposal of three new EPMs in which participation would be required and our responses.

Comment: Many commenters commended CMS for its continued commitment to testing episode-based payments demonstrated through the proposal to implement three new EPMs. MedPAC identified conditions with high post-acute care use as an appropriate setting to test bundled payments that would offer ample opportunities to improve care and lower spending. MedPAC also suggested that another consideration for bundled payments is whether the condition has a relatively uniform clinical pathway that simplifies the rules defining and pricing the bundle. In addition, MedPAC emphasized that conditions that lend themselves to patient selection should be avoided in bundled payment models, at least in the near term, to limit the undesirable provider responses to financial incentives that may occur. Other commenters expressed appreciation for the opportunity to test innovative care models under the Innovation Center authority. They stated that EPMs could hold significant promise for furthering the Triple Aim goals of providing high quality care at lower cost to produce better outcomes and advance population health.

However, some commenters expressed concern about the pace of changes proposed by CMS through its models and the associated expectation and burden that rapid changes in the delivery system and related payment structure place on hospitals and providers. Some commenters noted that CMS has been swift in releasing rules aimed at improving the quality of care delivered, reducing the cost of care, and coordinating patient care across multiple settings. The commenters pointed out the large volume of significant requirements announced by CMS over the last 2 years, including MACRA, the CJR model, and the proposed Part B drug payment model, as well as alternative payment models and programs, including the Shared Savings Program, Next Generation ACOs, BPCI initiative, and OCM, coupled with state level initiatives. The commenters believe the breadth and amount of new activities make it difficult to understand how the various models and program will interact with each other and impact individual delivery systems. While directed toward laudable goals, the commenters encouraged CMS to be vigilant in its review and analysis of these models and programs and to consider the impact and burden on hospitals as it continues to release models and programs impacting the hospital community. The commenters believe it is in everyone's best interest that these models are successful, yet the pace and complexity of implementation likely will be a critical factor in the achievement of these goals. Therefore, they encouraged CMS to slow the pace of EPM implementation to establish ''proof of concept'' through the CJR model and BPCI Model 2 results before implementing new EPMs where participation is required. Without adequate time to understand the appropriate role these payment innovations play in transforming care delivery and build upon lessons learned and best practices, the commenters

[15] 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 the proposed rule that end in CY 2014.

[16] Sylvia Mathews Burwell, HHS Secretary, Progress Towards Achieving Better Care, Smarter Spending, Healthier People, *http://www.hhs.gov/blog/2015/01/26/progress-towards-better-care-smarter-spending-healthier-people.html* (January 26, 2015).

concluded that both CMS and the provider community would miss an important opportunity to create programs that will advance patient care and successfully transform systems of care.

The commenters recommended that CMS establish a solid framework upon which to build payment initiatives and transform care. Before finalizing any more bundled payment initiatives, some commenters believe that CMS should articulate its vision and set a clear path for innovative payment models, establishing a consistent, predictable and transparent framework, giving providers the necessary tools to succeed in creating a higher-quality, more efficient health care system. The commenters suggested that the framework should include tools such as incorporating a predictable pricing trend factor so that participants can make decisions about investing in care design in the context of stable future prices; providing necessary risk adjustment methodologies; releasing consistent quality measures and reporting requirements and reliable target pricing; and holding fast to the principle of attributing no more than one patient to one bundled payment initiative at a time.

A few commenters expressed concerns about CMS' proposal to test three new bundled payment models. The commenters contended that the proposed EPMs would make treatment more difficult to access for high need patients; discourage truly innovative approaches to managing underlying health problems; encourage unnecessary surgeries; encourage further consolidation in the health care industry; provide fewer choices for consumers; and result in higher prices for private payers. One commenter requested that CMS present a much more comprehensive analytic work to understand the prevalence and needs of the beneficiaries who have serious illness or disabilities prior to and during the episode and who therefore require substantial attention to the elements of comprehensive care and quality measurement that are tailored for these beneficiaries prior to implementing the EPMs. Several commenters recommended CMS not to limit alternative payment models to episode payment approaches because for many types of patients, the biggest opportunity for improving quality and achieving savings is avoiding unnecessary episodes and events, and not simply paying differently for episodes and events when they occur. Some commenters strongly cautioned against EPMs that may subordinate future provider-led models. Other commenters recommended CMS to develop and implement payment reform models that incorporate population-based models, rather than look exclusively at episode payment models which can hamper growth of population-based models by limiting their financial opportunity.

Response: We appreciate the support of many commenters for CMS' continued development of new episode payment models and agree with these commenters that episode payment models provide substantial opportunity to improve the quality and efficiency of care for specific clinical conditions. We also agree that bundled payment models are just one strategy to incentivize the health care system moving toward the provision of more accountable, coordinated, high-value care, while provider-led and population-based models, as well as other types of payment reform models, play complementary roles. The Innovation Center is continuing to develop, implement, and evaluate a variety of different types of models that test different approaches to achieving better care, lower costs, and improved health. The three EPMs are part of that portfolio of models. Issues of concern raised by some of the commenters about the proposed EPMs, including the implementation timeline, are discussed in the specific sections of this final rule that address the relevant policies.

b. SHFFT Model

The SHFFT model was selected to complement the CJR model. We proposed to test the SHFFT model in most of the same hospitals participating in the CJR model as discussed in section III.B.4. of the proposed rule (81 FR 50794), 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.[17] 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.[18] Mortality associated with hip fracture is 5–10 percent after 1 month and approximately 33 percent at 1 year.[19] Hip arthroplasty and hip fixation, or ''hip pinning,'' represent the two broad surgical options for treating hip fractures.[20] The CJR 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 test an additional 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.

The following is a summary of the comments received and our responses.

Comment: Some commenters expressed support for the SHFFT model, which CMS proposed to implement in the same MSAs as the CJR model, which was implemented beginning in April 2016, and in particular expressed appreciation for the design consistency proposed for the SHFFT model with the CJR model and the two proposed cardiac EPMs. Analysis by MedPAC found that most SHFFT episodes include at least some post-acute care services use and that the spending on post-acute care services comprises a sizable share of total episode spending, about one-third. MedPAC concluded that SHFFT was a good candidate for bundled payment. MedPAC also reasoned that the SHFFT episode would give hospitals already participating in the CJR model the experience of managing care for hip and femur fracture cases that typically present emergently, rather than as the planned, elective surgery that is most common for lower extremity joint replacement. MedPAC, which recommended proceeding only with the SHFFT model in the context of CMS' proposal for three new EPMs, maintained that this

[17] Smith et al. Increase in Disability Prevalence Before Hip Fracture. J Am Geriatr Soc. 2015 Oct;63(10):2029–35.

[18] 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.

[19] Parker et al. Hip Fracture. BMJ. 2006 Jul 1;333(7557):27–30.

[20] American Academy of Orthopaedic Surgeons, OrthoInfo: Hip Fractures, *http://orthoinfo.aaos.org* (April 12, 2016).

would simplify the set of models that providers are adapting to and simplify the administrative requirements for CMS because CMS would not need to select new markets for testing the cardiac EPMs. Other commenters found it positive that CMS noted that there are differences between CJR and SHFFT beneficiaries, notably the latter being more likely to have multiple chronic conditions and frailty.

However, many commenters opposed CMS' proposal for the SHFFT model, encouraging CMS either to abandon the model altogether or to substantially delay implementation pending additional CJR model experience and evaluation results from BPCI Model 2 regarding SHFFT episodes. These commenters recommended that CMS proceed at a more deliberate pace and simplify the proposed rule for the three different EPMs by eliminating the SHFFT model because CMS is already testing an episode payment model that requires participation through the CJR model. Therefore, they believe that CMS should test only a cardiac bundled payment model in a different clinical area as a next step in required bundled payment models. The commenters stated that the SHFFT model would be overly burdensome to providers who just began participating in the CJR model in April 2016 and had insufficient financial safeguards for hospitals and quality safeguards for beneficiaries, including no quality measures specific to SHFFT model beneficiaries, to substantially improve beneficiaries' care experience through successful surgery and recovery. Several commenters stated that the proposed SHFFT model was not a true value-based payment model because the clinical outcome quality measures that were proposed did not capture hip fracture patients. Given CMS' proposal to implement the SHFFT model in the same MSAs as the CJR model, the commenters stated that due to limited implementation time of the CJR model, it would be inappropriate to add the very sick and frail SHFFT cohort to the relatively stable CJR model cohort without substantial investigation as to how to proceed with adequate monitoring against harm. They also recommended not proceeding without risk adjustment to account for variable costs experienced by hospitals treating different populations of SHFFT model beneficiaries. Several commenters claimed that because SHFFT beneficiaries would receive emergency care, care coordination would be less predictable and no planning would be possible prior to hospital admission, so the burden on potential family caregivers would be escalated in comparison to the CJR model if there was only a short hospital and/or SNF stay. The commenters stated that in comparison with beneficiaries undergoing elective LEJR, those with hip fracture require more time and resources from providers to optimize planning and rehabilitation and, therefore, limited efficiencies would be possible for SHFFT model beneficiaries without significant risk to the quality of care.

Response: We appreciate the perspective of some commenters that the opportunities for care redesign to improve quality and reduce spending are substantial for Medicare beneficiaries undergoing SHFFT procedures. We agree with those commenters about the potential value of the SHFFT model for beneficiaries, providers, and CMS to complement the CJR model by testing bundled payment for beneficiaries requiring emergency lower extremity joint surgery compared to testing episode payment for lower extremity surgeries that are mainly elective. We also acknowledge the concerns of the commenters around various proposed design elements of the SHFFT model, specifically the lack of risk adjustment to protect SHFFT model participants from undue financial risk for complex beneficiaries and the lack of quality measures that are specific to SHFFT beneficiaries in the pay-for-performance methodology to reward SHFFT model participants that improve quality for these beneficiaries and protect SHFFT beneficiaries from harm due to the model. We refer to sections III.D.4.b.(2) and III.E.2.d. of this final rule for further discussion of the comments on these issues and our responses.

We also appreciate the concerns of commenters regarding the proposed implementation of the SHFFT model in the same MSAs as CJR participant hospitals, and the additional responsibilities this model would place on participants early in their CJR model implementation experience. However, we continue to believe that there are efficiencies in care redesign that can be achieved by testing the models concurrently at the same hospitals. We note that those commenters opposing CMS' proposal to implement the SHFFT model did not dispute the care redesign opportunities identified by CMS for such a model. We refer to section III.D.2.a. of this final rule for a discussion of the comments on the proposed implementation timeline for the SHFFT model and our responses.

Final Decision: After consideration of the public comments received, we are finalizing the proposal to implement the SHFFT model, with modifications to specific policies as described throughout this final rule. We refer to section III.D.2.a. of this final rule for the implementation timeline that applies to the SHFFT model.

c. AMI and CABG Models

The AMI and CABG models, which we proposed to be tested at a single set of hospitals as discussed in section III.B.5. of the proposed rule (81 FR 50794), 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 (the part of an electrocardiogram between the QRS complex and the T wave) 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 multivessel disease with complex lesions; and for patients with clinically significant CAD in at least one vessel and refractory symptoms despite medical therapy and PCI.[21] 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.[22] 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

[21] Alexander JH, Smith PK. Coronary-Artery Bypass Grafting. N Engl J Med. 2016 May 19;374(2):1954–1964.

[22] 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.

therapy than among those who received medical therapy alone.[23] While about 30 percent of CABGs are performed during the care of AMIs, we proposed 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.[24]

We proposed AMI as the episode for an EPM because we recognized 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, extend following hospital discharge, and are addressed in clinical guidelines.[25] [26] 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.[27] AMI remains 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.[28] [29] In 2013, AMI was the sixth most common principal discharge diagnosis for hospitalized Medicare FFS beneficiaries, constituting 2.9 percent of discharges.[30] 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.[31] An additional 3 percent of beneficiaries were in MS–DRGs 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.[32] 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 while 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 proposed to test a condition-specific EPM that was 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.[33] From the AMI model, we expect to better understand the impact that 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 AMI and CABG models will all have CAD. In 2010 in the U.S., the prevalence of CAD in the population 65 years and older was about 20 percent.[34] Patients with CAD also often experience other significant health conditions, 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 proposed 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

[23] Velazquez et al. Coronary Artery Bypass Surgery in Patients with Ischemic Cardiomyopathy. N Engl J Med. 2016 Apr 3.

[24] 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 the proposed rule that end in CY 2014.

[25] 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.

[26] 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:

[27] 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 statistics—2016 update: a report from the American Heart Association. Circulation. 2016 Jan 26; 133(4):447–54.

[28] 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.

[29] 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.

[30] 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.

[31] 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.

[32] Epstein et al. JAMA. 2011 May 4; 305(17):1769–1776.

[33] 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 the proposed rule that began in CYs 2012–2014.

[34] National Center for Chronic Disease Prevention and Health Promotion, Division for Heart Disease and Stroke Prevention, August 10, 2015.

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 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 lays 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 episode itself, as discussed in sections III.E.2.b. and c. of the proposed rule (81 FR 50794), although we were interested in comments about potential future measures that could incorporate longer-term outcomes. Moreover, as discussed in section VI. of the proposed rule (81 FR 50794), we also proposed 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 proposed to 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.

The following is a summary of the comments received and our responses.

Comment: A number of commenters expressed support for the proposed AMI and CABG models, characterizing the proposals as a good first step toward achieving greater focus not only on cardiac care quality improvement but also care coordination for the anchor admission through post-acute care management of patients and families. Several commenters believe that CMS' proposal to implement separate models for beneficiaries undergoing treatment for AMI versus CABG surgery was sensible given the typical recovery pathways experienced by beneficiaries. One commenter noted that while the majority of beneficiaries with AMI or CABG have CAD, not all will have this condition as CMS stated in the proposed rule (81 FR 50807).

Several commenters commended CMS for developing a clinically appropriate definition for AMI because AMI is a condition that can require a range of treatments, including both medical treatments and PCI. The commenters observed that the combination of AMI medical management and PCI into a single AMI episode is likely to present AMI model participants with greater opportunity than if the hospital managed just one of the MS–DRG groupings. They stated that the proposal to include both medical and PCI MS–DRG groupings in the AMI model would increase each hospital's AMI episode volume relative to a single MS–DRG grouping, and further noted that sufficient volume in any bundled payment model is key to ensuring that financial results are not primarily driven by random variation.

Several commenters observed that the proposed AMI model would be the first Innovation Center bundled payment model to combine medical and procedural care in a single episode and that the majority of beneficiaries in the AMI model would be experiencing a life-threatening emergency. These commenters believe the proposed AMI model has the potential for patient harm and serious unintended consequences and recommended CMS to maintain a dialogue with practicing clinicians from medical specialty and subspecialty societies so that unintended consequences are caught early. One commenter recommended that CMS refocus the proposed AMI model to be treatment-based, separating beneficiaries with AMI into two different treatment-based EPMs based on medical management or PCI. The commenter contended that this approach would be more straightforward for model participants and allow CMS to conduct longer-term analyses of BPCI-like models in a more representative cross-section of hospitals.

Other commenters recommended that CMS pursue only the CABG model, arguing that the proposed AMI model, with complex, care pathway-dependent prices and transfer pathways, would influence attribution and result in serious uncertainties for AMI model participants. One commenter reasoned that isolated CABG procedures are particularly well-positioned for a bundled payment model that requires participation because, despite the availability of robust clinical guidelines, variability in the costs and outcomes of CABG persist. The commenter noted that other entities, such as Arkansas and Tennessee Medicaid, Washington State's Bree Collaborative, and commercial payers, have seen the potential to improve the cost and quality of CABG through the implementation of bundled payments. Several commenters stated that initial implementation of the CABG model alone would allow CABG model participants to focus efforts on a specific population that includes the opportunity to excel in the care of CAD and gain some experience in the care of emergent patients. This limited implementation strategy would allow model participants to start to develop systems and models of care that address the unique needs of these populations in a value-driven equation. The commenters added that as hospitals work through implementation and gain experience with the CABG model, CMS could then phase in the inclusion of the much more complicated AMI model, which would introduce a myriad of factors that would add to the complexity of EPMs in which the hospital was a participant.

Another commenter who did not favor implementation of the proposed AMI model reasoned that, in addition to the built-in incentives of MS–DRGs that currently reward hospitals and physicians for complications that occur during the beneficiary's hospitalization by providing a higher IPPS payment for beneficiaries with complications, the proposed AMI model lacked incentives to manage beneficiaries to reduce CAD complications such as AMI. Instead, the commenter stated that the proposed AMI model would incentivize admitting patients who are marginally symptomatic for AMI that is a complication of CAD, contrary to the overall goals of EPMs to lower the incidence of complications. The commenter cited a body of research that has shown that optimal management of CAD can significantly lower the incidence of AMI. The commenter recommended CMS to move toward condition-specific episode payment defined by diagnosis codes, and to halt implementation of an event-based EPM for AMI that is, in itself, a complication from the lack of optimal management of CAD. The commenter also stated that CMS should implement site-agnostic

PCI episodes so the incentives under the model would be to provide care in the place of service best suited for the patient. Another commenter expressed concerns about bundling AMI care, as it encompasses a broad spectrum of many different complex illnesses. Several commenters observed that while some AMI patients require less complex care, other patients are admitted with multiple comorbidities and require a higher intensity of care, which may involve multiple organs and a variety of care resources. Other commenters believe that if CMS implements the AMI model as proposed, more beneficiaries would move into the CABG model because of the AMI model financial incentives, which would not be in the best interests of beneficiaries.

While some commenters recommended a short implementation delay for the AMI and/or CABG models, several other commenters recommended that CMS delay the AMI and CABG models, with recommendations ranging from 6 to 36 months. These commenters believe this delay would provide sufficient time for CMS to incorporate known best practices from the Healthcare Payment Learning and Action Network (LAN) Clinical Episode Payment (CEP) Work Group and lessons learned from both the BPCI and CJR models into the design of the cardiac EPMs. Otherwise, the commenters were concerned that the cardiac EPMs would both put beneficiaries at risk and disadvantage providers, as the episodes would be built using designs that were not supported by CMS' own panel of industry experts.

Some commenters expressed concern about expanding EPMs to complex conditions such as AMI and CABG, where treatment can follow multiple evidence-based care pathways. One commenter pointed out that the proposed AMI and CABG models would generally include beneficiaries receiving unplanned care due to an acute event, making the population's care difficult to manage. The commenter requested that CMS not implement the proposed cardiac EPMs. Several commenters stated that the complexity of the proposed cardiac EPMs was so great that CMS had essentially proposed a completely different payment system for cardiac care and would provide EPM participants with little time to prepare and plan for implementation. The commenters believe that decisions about appropriate care should be made by physicians and their patients and should be based on each patient's medical necessity and care preferences. They stated that bundling clinically complex episodes with multiple care pathways may lead to factors other than medical necessity and care preferences influencing the decisions that providers make, and that such decisions could have a long-term impact on a patient's health and well-being and may increase costs in the long run while achieving the short-term goal of reducing episodic costs. The commenters believe that this potentially serious issue warranted immediate attention by CMS, given the lack of evidence on the impact of the EPMs on key patient-centered outcomes, and concluded that the proposed EPMs require further consideration and study before additional bundling initiatives are implemented.

MedPAC stated that the proposed AMI episodes did not appear to be a promising place to further test bundled payment because AMI episodes have relatively low post-acute care use and the associated post-acute care spending makes up a small share of total episode spending. They concluded that savings opportunities for participating providers would be smaller compared with other conditions. Consistent with the observations of a few other commenters, MedPAC stated that complex medical conditions such as AMI do not involve a single clinical pathway but rather can involve patient transfers to hospitals with more intensive cardiac capabilities and subsequent readmissions for CABG. While MedPAC acknowledged that CMS' proposed rule addressed these issues, they noted that if the benchmark prices are not accurate, the prices could inadvertently shape clinical practice or encourage selective admissions. Instead of an EPM, MedPAC suggested that CMS consider allowing hospitals to share savings with physicians as a way to focus physicians on reducing the cost of the inpatient stay for AMI care.

MedPAC further concluded that CABG was also not an ideal condition for testing bundled payment models because, although the majority of beneficiaries undergoing CABG go on to use post-acute care services, the spending on post-acute care services is relatively low compared to other clinical conditions. They noted that with the inpatient stay comprising the vast majority of total episode spending, the opportunities to realize savings by changing clinical practice would be small. MedPAC presented an additional concern regarding the potential for undesirable provider responses to financial incentives, including patient selection, in the proposed CABG model. They claimed that providers of cardiac care have been shown to engage in patient selection and expressed concern that, with larger savings at stake, these behaviors could increase. They recommended that CMS delay testing the CABG model until the benefits of episode efficiency outweigh the concerns about patient selection.

Response: We appreciate the support of some of the commenters for our proposal to implement the AMI and CABG models. The proposed cardiac models represent clinical conditions that result in a significant burden of morbidity and expenditures in the Medicare population. However, we acknowledge the great diversity of views about the AMI and CABG models reflected in the comments.

We proposed AMI as the episode for an EPM because we recognized 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. As commenters observed, 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. In this sense the AMI model is a condition-specific EPM, although it is not focused on the underlying CAD condition that puts some beneficiaries at risk for the AMI but rather on the AMI itself. While we recognize that AMI may be a complication of care from inadequately managed CAD, we continue to believe that there is an important role for the AMI model in testing bundled payment for beneficiaries with AMI who follow a variety of clinical pathways because AMI is a sentinel event indicating the need for an increased focus on condition-specific management. The proposed 90 day post-discharge episode duration would provide a springboard to heighten the focus on CAD-specific management. While future models may focus on CAD management itself, including reducing the risk of AMI, in addition to the current Million Hearts® Cardiovascular Risk Reduction Model, we believe that the proposed AMI model also plays an important role in testing an EPM for this clinical condition which is not always avoidable even in the context of the best practices to manage CAD on an ongoing basis.[35]

We believe that it is important to test EPMs like the AMI model where

[35] Million Hearts®: Cardiovascular Disease Risk Reduction Model. *https://innovation.cms.gov/initiatives/Million-Hearts-CVDRRM/.*

beneficiaries can follow multiple clinical pathways, including transfers among hospitals with different cardiac care capacity because, more commonly than not, beneficiaries who are hospitalized for an emergent clinical condition do not constitute as homogeneous a group as those who choose to undergo elective surgery. However, there likely are significant opportunities to improve the quality and efficiency of episode care through care redesign that improves care coordination and management for beneficiaries unexpectedly hospitalized for treatment following a cardiac event. We disagree with the commenter who recommended that we create two treatment-based EPMs, AMI medical management and PCI, because, in the context of our proposed pricing methodology that sets MS–DRG-specific EPM-episode benchmark prices and quality-adjusted target prices as discussed in section III.D.4.b.(1). of this final rule, we believe we can appropriately include beneficiaries following the two different treatment approaches in the same EPM without concern that the financial incentives of the EPM are influencing the treatment choice for beneficiaries.

We appreciate the support of many commenters for the proposed CABG model. We believe that CABG may play a role for some beneficiaries with symptomatic CAD, either with or without AMI, because CABG is associated with lower longer-term rates of major adverse cardiac and cerebrovascular events in comparison to PCI for certain groups of patients. As a number of commenters pointed out, multiple other entities, including states, are testing CABG bundled payment models due to the variability in costs and outcomes despite robust clinical guidelines.

In response to those commenters who recommended that the AMI and CABG models be delayed in order to incorporate known best practices from the LAN CEP Work Group, we note that the LAN is a public-private partnership established by the U.S. Department of Health and Human Services (HHS) to increase the adoption of APMs that promote better care, smarter spending, and healthier people. The LAN has a voluntary collaborative structure and its consensus recommendations do not necessarily reflect the views of its individual participants. Representatives from CMS, along with representatives from states, purchasers, providers, commercial payers, and consumers, were active participants in the CEP Work Group and developed, with input from the broader LAN network, a set of recommendations that reflect a consensus view, balancing innovation with current practice to move the health care delivery system forward. The CEP Work Group full recommendations have not yet been tested in the market. The LAN CEP Work Group recommendations and the proposed CMS CABG and AMI EPMs, although incorporating different design features, both support the implementation of episode-based payment models for cardiac care. We anticipate that both the LAN recommendations and the CMS AMI and CABG models will expand provider experience and expertise regarding the necessary resources and most effective strategies for providing high quality, efficient care through episode-based payment models and will help prepare the market for further adoption of innovative payment models in the future. Therefore, we believe that best practices for episode payment models are continuously being identified and refined based on providers' actual implementation experiences with episode payment models of various designs. Rather than redesigning the proposed cardiac care models to conform to the LAN CEP Work Group recommendations, we look forward to testing the AMI and CABG models based on the policies included in this final rule and sharing our evaluation findings with stakeholders to inform other episode payment models for cardiac care.

We do not agree with MedPAC's conclusion that the proposed AMI and CABG models do not hold promise because of limited post-acute care spending in AMI episodes and the high percentage of CABG episode spending due to the anchor hospitalization in CABG episodes coupled with the risk of patient selection due to the financial incentives of the CABG model. While care redesign to improve the efficiency of post-acute care use may be an obvious strategy to address variation in episode spending for those episodes, such as SHFFT and LEJR episodes with high utilization of post-acute care services, AMI and CABG beneficiaries have substantial episode spending during 90 days post-discharge from the anchor hospitalization as a result of complications, further treatment, and ongoing care management of their underlying chronic conditions. We believe that increased efficiencies in the post-discharge care and improved care coordination represent a significant opportunity to improve the quality and reduce the cost of AMI and CABG episodes.

As commenters pointed out, the cardiac EPMs create some risks of harm to beneficiaries from patient selection and different treatment choices EPM participants could adopt based on the financial incentives under the EPMs, although we believe these concerns are generally present for every episode payment model that sets a price that Medicare pays for an episode-of-care. As discussed further in sections III.G.4. through 6. of this final rule, we will take steps to prevent potential harm by monitoring for access to care, quality of care, and delayed care under the EPMs and may take remedial action against EPM participants if we find evidence that supports concerns in these areas. In addition, the evaluation as discussed in section IV. of this final rule will analyze beneficiary outcomes and their relationship to clinical pathways under the EPMs.

We refer to section III.D.2.a. of this final rule for a discussion of the comments on the proposed implementation timeline for the AMI and CABG models and our responses.

Final Decision: After consideration of the public comments received, we are finalizing the proposal to implement the AMI and CABG models, with modifications to specific policies as described throughout this final rule. We refer to section III.D.2.a. of this final rule for the implementation timeline that applies to the AMI and CABG models.

2. Advanced Alternative Payment Model Considerations

For ease of reading the subsequent sections regarding our proposals and our final policies around the EPMs as Advanced APMs, we first present the proposals outlined in the Quality Payment Program proposed rule (81 FR 28161) followed by the policies outlined in the Quality Payment Program final rule with comment period (81 FR 77008).

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 performance category described in section 1848(q)(2)(B)(i) of the Act,

which is the MIPS quality performance category. We interpret this criterion to require the APM to incorporate quality measure results as a factor when determining payment to participants under the terms of the APM. 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 the proposed rule (81 FR 50794), we proposed 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 proposed 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 the proposed rule (81 FR 50794), 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 was proposed for the AMI model, is not currently NQF-endorsed, but was reviewed, recommended for endorsement, and is expected to be formally endorsed within the first quarter of 2017. 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 included one outcome measure that is NQF-endorsed, has an evidence-based focus, and is reliable and valid. The EPM quality measures were discussed in detail in section III.E. of the proposed rule (81 FR 50794), where we assigned the quality measures to quality domains. For the AMI model, we proposed 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 proposed 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 proposed 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 believed 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, we proposed that 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 the proposed rule (81 FR 50794). 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 believed 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. We proposed that 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 the proposed rule (81 FR 50794). Therefore, in the proposed rule, we stated our belief that the total proposed 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 was greater than the value of at least 4 percent of expected expenditures.

We note that we proposed 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 the proposed rule (81 FR 50794). Because 3 percent was 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 recognized 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. In the proposed rule, we explained our belief that 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 sought 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 noted 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 would be 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 proposed 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 proposed that Track 1 EPM participants must use certified health IT functions, in accordance with the definition of CEHRT under our regulation at § 414.1305 (81 FR 77537), 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 believed 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, non-physician 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 made 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 sought 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.

For ease of reading the subsequent sections regarding our proposals and final policies for the EPMs as Advanced APMs, we present the following definitions from § 414.1305 that have now been finalized in the Quality Payment Program final rule with comment period (81 FR 77008).

Alternative Payment Model (APM) means any of the following: (1) A model under section 1115A of the Act (other than a health care innovation award); (2) The shared savings program under section 1899 of the Act; or (3) A demonstration under section 1866C of the Act. (4) A demonstration required by federal law.

Episode payment model means an APM or other payer arrangement designed to improve the efficiency and quality of care for an episode of care by bundling payment for services furnished to an individual over a defined period of time for a specific clinical condition or conditions.

APM Entity means an entity that participates in an APM or payment arrangement with a non-Medicare payer through a direct agreement or through Federal or State law or regulation.

Advanced Alternative Payment Model (Advanced APM) means an APM that CMS determines meets the criteria set forth in § 414.1415.

Advanced APM Entity means an APM Entity that participates in an Advanced APM or Other Payer Advanced APM.

Participation List means the list of participants in an APM Entity that is compiled from a CMS-maintained list.

Eligible Clinician means ''eligible professional'' as defined in section 1848(k)(3) of the Act, as identified by a unique TIN and NPI combination and, includes any of the following: (1) A physician; (2) A practitioner described in section 1842(b)(18)(C) of the Act; (3) A physical or occupational therapist or a qualified speech language pathologist; or (4) A qualified audiologist (as defined in section 1861(ll)(3)(B) of the Act).

Affiliated Practitioner means an eligible clinician identified by a unique APM participant identifier on a CMS-maintained list who has a contractual relationship with the Advanced APM Entity for the purposes of supporting the Advanced APM Entity's quality or cost goals under the Advanced APM.

Affiliated Practitioner List means the list of Affiliated Practitioners of an APM Entity that is compiled from a CMS-maintained list.

Qualifying APM Participant (QP) means an eligible clinician determined by CMS to have met or exceeded the relevant QP payment amount or QP patient count threshold under § 414.1430(a)(1), (a)(3), (b)(1), or (b)(3) for a year based on participation in an Advanced APM Entity.

QP Patient Count Threshold means the minimum threshold score specified in § 414.1430(a)(3) and (b)(3) that an eligible clinician must attain through a patient count methodology described in §§ 414.1435(b) and 414.1440(c) to become a QP for a year.

QP Payment Amount Threshold means the minimum threshold score specified in § 414.1430(a)(1) and (b)(1) that an eligible clinician must attain through the payment amount methodology described in

§§ 414.1435(a) and 414.1440(b) to become a QP for a year.

Threshold Score means the percentage value that CMS determines for an eligible clinician based on the calculations described in § 414.1435 or § 414.1440.

Merit-based Incentive Payment System (MIPS) means the program required by section 1848(q) of the Act.

MIPS APM means an APM that meets the criteria specified under § 414.1370(b).

Improvement Activities means an activity that relevant MIPS eligible clinicians, organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes.

Based on the proposals for Advanced APM criteria in the Quality Payment Program proposed rule (81 FR 28161), we sought to align the design of the proposed EPM Advanced APM track with the proposed Advanced APM criteria and enable CMS to have the necessary information on Eligible Clinicians to make the requisite QP determinations. As detailed in the Quality Payment Program final rule with comment period, QP 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 77013). Eligible clinicians seeking QP determinations as early as performance year 2 would need to meet the QP threshold under the Medicare Option. The three criteria for an Advanced APM were finalized in the Quality Payment Program final rule with comment period (81 FR 77008), and we continue to align the design of the finalized EPMs with the finalized Advanced APM criteria so that EPM participants who choose to use and attest to use of CEHRT may participate in an EPM that meets the criteria of an Advanced APM. To be determined to be an advanced APM, an APM must meet three Advanced APM criteria identified in § 414.1415 and discussed specifically later in this section.

First, 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 (81 FR 77406). Specifically, where the APM participants are hospitals, the APM must require each hospital to use CEHRT. As addressed in the Quality Payment Program final rule with comment period, 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 now finalized in the Quality Payment Program final rule with comment period, so that the EPMs may meet the finalized criteria to be Advanced APMs, we proposed that those EPM participants who choose to participate in Track 1 of the EPMs 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. We believe that this proposal set forth in the EPM proposed rule would allow EPM participants who use and attest to use of CEHRT to be in an EPM that meets the first finalized Advanced APM criterion.

Second, the APM must provide for payment to participants based on performance 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. We interpret this criterion to require the APM to incorporate quality measure results as a factor when determining payment to participants under the terms of the APM as described in the Quality Payment Program final rule with comment period (81 FR 77414). In order to align the EPMs with the Quality Payment Program final rule with comment period, the quality measures on which the Advanced APM bases payment to participants 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 77418):

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 final rule with comment period, because the statute identifies outcome measures as a priority measure type and we want to encourage the use of outcome measures for quality performance assessment in APMs, we further finalized 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 77418). Therefore, according to the requirements finalized in the Quality Payment Program final rule with comment period and the quality measures finalized in section III.E of this final rule that are the proposed EPM quality measures with an additional voluntary measure for the CABG model, the EPMs will meet the second finalized criterion of the Advanced APM criteria.

Third, the Quality Payment Program final rule with comment period requires that for an APM to meet the Advanced APM criteria, 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. For the purposes of the EPM, the generally applicable nominal amount standard for an Advanced APM in the Quality Payment Program final rule with comment period (81 FR 77425) means the total amount an APM Entity potentially owes CMS or foregoes under an APM must be at least equal to 3 percent of the expected expenditures for which an APM Entity is responsible under the APM. The generally applicable financial risk standard (81 FR 77422) means when an APM Entity's actual expenditures for which the APM Entity is responsible under the APM exceed expected expenditures during a specified QP Performance Period, the APM Entity is required to owe payment(s) to CMS. We refer to the Quality Payment Program final rule with comment period for a discussion regarding why we did not finalize the specific level of marginal risk or minimum loss rate (81 FR 77426). However, consistent with the commitments we made to adhere to the proposed marginal risk and minimum loss rate requirements in the Quality Payment Program proposed rule, we note that the financial risk in this final rule when the EPMs involve downside risk exceeds the proposed marginal risk and minimum loss rate requirements proposed for the Quality Payment Program. As discussed in sections III.D.7.b. and c. and displayed in Table 12 of this final rule, the final total initial risk of expected expenditures for EPM participants of 5 percent, and 3 percent for rural hospitals, SCHs, MDHs, RRCs,

and EPM volume protection hospitals subject to separate stop-loss protections, beginning in performance year 3 when downside risk for all participants first applies, would meet the total potential risk element of the nominal risk amount standard for Advanced APMs finalized in the Quality Payment Program final rule with comment period (81 FR 77427) because they are greater than or equal to the value of at least 3 percent of expected expenditures. Those EPM participants who elect voluntary downside risk beginning in performance year 2 will be subject to the same total risk of expected expenditures in performance year 2 and, therefore, will be in an EPM that meets the total potential risk element of the nominal risk amount standard for Advanced APMs beginning in performance year 2. Therefore, according to the requirements finalized in the Quality Payment Program final rule with comment period and the payment methodology for EPM participants finalized in section III.D of this final rule, those EPM participants who voluntarily elect downside risk for EPM episodes ending on or after January 1, 2018 will be in an EPM that meets the third finalized criterion of the Advanced APM criteria in performance year 2. All other EPM participants will be in an EPM that meets the third finalized criterion of the Advanced APM criteria in performance year 3.

Finally, we finalized in the Quality Payment Program final rule with comment period (81 FR 77442) that for Advanced APMs, such as episode payment models, in which there are some Advanced APM Entities that include Eligible Clinicians on a Participation List and other Advanced APM Entities that identify Eligible Clinicians only on an Affiliated Practitioner List, we will identify Eligible Clinicians for QP determinations based on the composition of the Advanced APM Entity. In the scenario that applies to the EPM which includes only hospitals as Advanced APM Entities on the Participation List, for those Advanced APM Entities where there is an Affiliated Practitioner List that identifies Eligible Clinicians, that Affiliated Practitioner List will be used to identify the Eligible Clinicians for purposes of QP determinations, and those Eligible Clinicians will be assessed individually. Thus, to operationalize the EPM as an Advanced APM, our proposal for the EPM to identify Eligible Clinicians on a clinician financial arrangements list to construct the Affiliated Practitioner list would identify those Eligible Clinicians for purposes of QP determination, consistent with the policies finalized in the Quality Payment Program final rule with comment period.

We received a number of public comments on our proposals for the EPMs as Advanced APMs. A few commenters requested changes to the policies proposed by CMS in the Quality Payment Program proposed rule and not to specific proposals for the EPMs set forth in the EPM proposed rule. These comments are out of scope for this rulemaking and no responses are provided in this final rule. Nevertheless, we have summarized this feedback related to the Quality Payment Program proposed rule, as CMS will continue work to improve the Quality Payment Program in part through future notice and comment rulemaking.

One commenter requested change to the definition of Affiliated Practitioner to include rehabilitation therapists. Many commenters requested changes to the definitions of the Affiliated Practitioner List and/or Participation List to identify Eligible Clinicians for the purposes of Advanced APMs, MIPS APMs, and the assignment by CMS of an Improvement Activities score, which fulfills one of four categories for MIPS assessment of cost and quality. Another commenter requested changes to the performance period or the December 31 date by which an Eligible Clinician could qualify for automatic credit for incentive payment and/or clinical Improvement Activities performance. This commenter reasoned that such changes would permit more Eligible Clinicians to receive a QP determination, which may qualify them for an APM incentive payment under MACRA. One commenter expressed uncertainty regarding the process by which Eligible Clinicians could receive a QP determination for the efforts of the EPM participant, and requested that CMS clarify on the pathway for participating physicians to be in an Advanced APM generally. Another commenter suggested CMS replace the QP determination with the proposal that, for EPM providers who meet the CEHRT use requirement and have 50 or more Medicare beneficiaries attributed to these EPMs, the threshold for Advanced APMs would be met automatically. A few commenters wanted CMS to use the Meaningful Use program to gather attestation to CEHRT use from hospitals. A few commenters strongly recommended CMS lower the patient count and payment revenue thresholds used in the calculation of the Threshold Score to meet QP Threshold Status as specified in the Quality Payment Program proposed rule. Many commenters urged CMS to work closely with the affected professional organizations and/or physician specialty societies to design QP thresholds. One commenter requested changes to the APM Entity such that the APM Entity lose the right to all or part of otherwise guaranteed payment or payments as one of the options if the APM Entity's actual aggregate expenditures exceed expected aggregate expenditures. A few commenters requested changes to the categorical exclusion that Medicare Advantage (MA) and other private plans paid to act as insurers on the Medicare program's behalf are not Advanced APMs, in light of the amount of risk taken by physicians in MA. Finally, one commenter requested changes to the allow Independence at Home participants who use CEHRT to qualify for Advanced APM incentive payments.

The following is a summary of the comments received on our proposals and our responses.

Comment: MedPAC commented that the EPM and CJR models should not be considered Advanced APMs for the purposes of MACRA. MedPAC stated they believe the following six principles should apply to Advanced APMs: the Advanced APM entity should assume the financial risk and enroll clinicians; be at financial risk for total Part A and Part B spending; be responsible for a beneficiary population sufficiently large to detect changes in spending and quality; have the ability to share savings with beneficiaries; be provided certain regulatory relief by CMS; and the enrolled clinicians should receive an incentive payment only if the Advanced APM entity in which they participate is successful in controlling cost, improving quality, or both. Under the proposed EPMs, MedPAC believes the proposed rule contemplates large, loosely connected groups of clinicians who may have very little involvement with the beneficiaries in EPMs and hence have little reason to change their practice patterns or reduce inappropriate episodes. If CMS intends for clinicians to bear risk, MedPAC made the alternative proposal that they could do so directly without having the hospital as the intermediary.

Response: While we appreciate the principles for Advanced APMs offered by MedPAC, we note that according to the Advanced APM definition in the Quality Payment Program final rule with comment period (81 FR 77008), the Track 1 EPMs that we proposed qualify as Advanced EPMs as discussed previously in this section.

While we recognize EPM participants are the participating APM Entities for

the purposes of the Quality Payment Program, CMS will consider participation of Eligible Clinicians in the Track 1 EPMs through collection of identifying information from Track 1 EPM participants on clinician financial arrangements lists as discussed in section III.A.2.c. of this final rule who would then be included on the Affiliated Practitioner List as defined in the Quality Payment Program final rule with comment period at § 414.1305 (81 FR 77537), in order to determine who could be considered a QP. The requirements for Eligible Clinicians to be reported on the clinician financial arrangements lists help ensure that these clinicians have specific involvement in caring for EPM beneficiaries and advancing the goals of the EPMs to improve the quality and reduce the cost of care. Finally, Eligible Clinicians can only be considered Qualifying Professionals or Partial Qualifying Professionals and, therefore, potentially be exempt from MIPS, if the Eligible Clinician meets the QP threshold or partial QP threshold as described in the Quality Payment Program final rule with comment period (81 FR 77433). Additionally, while we recognize the concerns with EPM participants or CJR participant hospitals intermediating the APM incentive payments, we believe that the QP threshold incentivizes Eligible Clinicians to work with such participants to improve health care delivery for Medicare beneficiaries.

The qualification of the CJR model as an Advanced APM is discussed in section V.O. of this final rule.

Comment: Many commenters expressed support for all organizations to have the opportunities to participate as Advanced APMs and noted that as proposed, rural hospitals, SCHs, MDHs, and RRCs that are EPM participants would not potentially qualify for participation in an Advanced APM until performance year 3 due to the proposed lower stop-loss limits for these hospitals under the EPMs. Additionally, one commenter recommended that a distinct CEHRT program be developed and funding be allocated for non-physician and non-prescribing professionals as soon as possible, as the cost of acquisition, implementation, and maintenance of an EHR is a significant barrier to adoption, particularly for small practices. One commenter observed this proposal as an important illustration of why CMS must be flexible in its definition of nominal risk, and how nominal will not mean the same thing for every provider. As such, commenters supported retention of the proposed stop-loss limits under the EPMs as the default rule for these hospitals, thus enabling them to meet the nominal financial risk standard for Track 1 EPMs (Advanced APMs) in performance year 3 rather than performance year 2 when other EPM participants would be eligible for Track 1 EPMs. However, commenters also believe CMS should also explore options to allow these hospitals with additional stop-loss protection under the EPMs to voluntarily elect a higher stop-loss limit in order to participate in Track 1 EPMs in performance year 2.

Response: The Quality Payment Program final rule with comment period (81 FR 77427) finalized the policy that an APM would meet the nominal amount standard for an Advanced APM if, under the terms of the APM, the total annual amount that an APM Entity potentially owes us or foregoes is equal to at least 3 percent of the expected expenditures for which an APM Entity is responsible under the APM. Therefore, rural hospitals, SCHs, MDHs, RRCs, as well as EPM volume protection hospitals as discussed in section III.D.7.c of this final rule, that are EPM participants with special stop-loss limits could potentially qualify as being in an Advanced APM as participants in a Track 1 EPM in performance year 3, along the same timeframe as all other EPM participants when downside risk for all participants is implemented, or in performance year 2 when voluntary downside risk may be elected by EPM participants (section III.D.2.c. of this final rule), based on the stop-loss limits finalized in this rule for these hospitals as discussed in section III.D.7.c. of this final rule.

Comment: Commenters proposed alternative processes by which a QP determination could be made, including collective assessment of QP status across both the AMI and CABG models, so as not to create siloed EPMs. In cases where there is an overlap of beneficiaries in more than one CMS model or program, other commenters proposed that beneficiaries should be counted toward a physician's QP Threshold Score (a part of a QP determination) if a beneficiary would have been assigned to a particular model if it were not for the fact that a different model that has required participation overlapped.

Response: The QP determination discussed in the Quality Payment Program final rule with comment period depends on the level of payments or patients furnished services through an Advanced APM based on the calculations described in § 414.1435 and § 414.1440, as applicable. Under certain Advanced APMs such as a Track 1 EPM, the responsibility of cost and quality measurement and reporting is with EPM participants that are hospitals rather than Eligible Clinicians. However, we have specified that Eligible Clinicians who are on Affiliated Practitioner Lists may also be assessed for a QP determination based on their Affiliated Practitioner status if there are no eligible clinicians on an Advanced APM's Participation List. Therefore, as finalized in the Quality Payment Program final rule with comment period (81 FR 77443), if an Eligible Clinician participates in multiple Advanced APM Entities during a QP Performance Period, and is not determined to be a QP based on participation in any of those Advanced APM Entities, then we will assess the Eligible Clinician individually using combined information for services associated with that individual's NPI and furnished through all the Eligible Clinician's Advanced APM Entities during the QP Performance Period. This includes all Advanced APM Entities for which the Eligible Clinician is represented on either a Participation List or Affiliated Practitioner List that CMS uses for QP determinations. We will make adjustments to ensure that patients and payments for services that may be counted in the QP calculations for multiple Advanced APM Entities (for example, payments for services furnished to a beneficiary attributed to an ACO that are also part of an episode in an episode payment model) are not double-counted for the individual. We believe that this policy maintains the general principles behind Advanced APM Entity-level QP determinations, while acknowledging the broader commitment of individual Eligible Clinicians who are participating in multiple Advanced APMs. We believe considering these Eligible Clinicians individually is the most reasonable approach to capturing the multiple potential permutations of participation in Advanced APMs and providing Eligible Clinicians an equitable opportunity to become a QP.

Thus, with respect to the commenters' concerns that CMS would only make a model-specific QP determination for the Track 1 AMI model and Track 1 CABG model and not a collective determination across the two models, for Advanced APMs for which there is not a Participation List that identifies eligible clinicians and there is an Affiliated Practitioner List that identifies eligible clinicians, the Quality Payment Program final rule with comment period (81 FR 77442) notes that Affiliated Practitioner List will be

used to identify the eligible clinicians for purposes of QP determinations. Eligible clinicians on an Affiliated Practitioner List will be assessed individually, unlike eligible clinicians on a Participation List who are assessed as a group. Thus, we could make a determination across the two models if an Eligible Clinician was not determined to be a QP based on participation in any one of the Track 1 EPMs. Finally, as specified in the Quality Payment Program final rule with comment period (81 FR 77013), QPs are Eligible Clinicians in an Advanced APM who have a certain percentage of their patients or payments through an Advanced APM. Thus, we will only count beneficiaries attributed to an Advanced APM Entity toward a clinician's QP Threshold Score and will not count those beneficiaries who would have been attributed to an Advanced APM Entity if it were not for the fact that a different model overlapped. Beneficiary attribution is further discussed in the Quality Payment Program final rule with comment period (81 FR 77436)

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 proposed 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 (81 FR 77537) 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 voluntary selection by EPM participants to elect downside risk for EPM episodes ending on or after January 1, 2018, and 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 EPM participants in the Track 1 EPM 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 were included in proposed § 512.120(a). We sought comment on our proposals for EPM participant CEHRT use requirements.

The following is a summary of the comments received and our responses.

Comment: Commenters expressed appreciation for CMS' efforts to expand the Advanced APM participation opportunities as they commented that the 5 percent Advanced APM incentive payment is time-limited under current law. They applauded the proposal to expand the list of eligible Advanced APMs through Track 1 EPMs as it provides an incentive for physicians to collaborate with hospital participants in the EPM and could provide specialists, who otherwise may have limited avenues, to participate in an Advanced APM. Other commenters requested specifically that CMS clarify the steps necessary when a provider group wishes to change from Track 2 to Track 1 in the EPMs.

Response: We appreciate the commenters' support for our proposal of the Track 1 EPMs as Advanced APMs and agree that providing greater opportunities for physician participation in Advanced APMs is an important goal that can be advanced through our proposal. We remind commenters that only the EPM participant can choose to participate in a Track 1 EPM by using and attesting to use of CEHRT. If Eligible Clinicians enter into a financial arrangement associated with a Track 1 EPM participant, then the EPM participant must submit a clinician financial arrangements list that determines the Eligible Clinicians to be included on the Affiliated Practitioner List for the purposes of the Track 1 EPM that is an Advanced APM. Therefore, a provider group interested in their members becoming Affiliated Practitioners with an Advanced EPM Entity in an Advanced APM could work with a Track 1 EPM participant to enter into a financial arrangement with that EPM participant so that the members of the provider group could be included in the clinician financial arrangements list submitted by the Track 1 EPM participant to CMS.

Comment: While commenters appreciated the proposal to include two tracks for EPM participants and CJR participant hospitals, other commenters made additional proposals to CMS to help operationalize these tracks. A few commenters urged CMS to go further to align the EPMs and the CJR model with the proposed Quality Payment Program and configure Track 2 (the Non-Advanced APM) so that it could qualify as a MIPS APM. In addition to the request that CMS reconfigure Track 2, commenters also proposed that Track 2 EPM participants must also submit a clinician financial arrangements list, so that Eligible Clinicians could receive credit for Improvement Activities under MIPS and/or satisfy criteria to be considered participants in MIPS APMs, for which the Quality Payment Program applies unique scoring rules. One commenter believes that the multiple options due to the proposed tracks increases the level of complexity and administrative burden on the hospitals for activities such as record keeping.

Response: We disagree that the presence of two EPM tracks increases administrative burden as we continue to believe that the proposed tracks allow flexibility for EPM participants to choose to participate in an Advanced APM. While a Track 1 EPM participant needs to attest to CEHRT and submit a clinician financial arrangements list to meet the requirements for participation in an Advanced APM and allow us to operationalize the Track 1 EPM as an Advanced APM, we do not believe that these additional requirements create significantly increased administrative burden on the Track 1 EPM participant versus a Track 2 EPM participant in view of the documentation and record access and retention requirements for all EPM participants, which require EPM participants to maintain a subset of that list that constitutes the Eligible Clinicians, nor that the requirements to identify and maintain related lists regarding collaboration agents and downstream collaboration agents is a substantial burden. Beyond these additional activities for Track 1 EPM participants, the policies of the EPMs are the same for Track 1 and Track 2 EPM participants.

In addition, we disagree with the suggestion by commenters that we add the requirement for Track 2 EPM participants to submit to CMS clinician financial arrangements lists, information that we did not propose to require Track 2 EPM participants to submit to us. Submission of clinician financial arrangements lists is not necessary for

implementation of the Track 2 EPMs, and Track 2 EPM participants do not meet the definition of Advanced APM Entities in the Quality Payment Program final rule with comment period at § 414.1305 (81 FR 77537). To require Track 2 EPM participants to submit such a list would create unnecessary additional administrative burden on these participants. Furthermore, a Track 2 EPM does not meet the criteria of a MIPS APM in § 414.1370(b) of the Quality Payment Program final rule with comment period. Specifically, the MIPS APM criteria requires at least one Eligible Clinician on a Participation List for the APM, while currently all EPM and CJR participants are hospitals. Thus, the EPM and CJR Participation Lists do not include Eligible Clinicians and, therefore, a Track 2 EPM and the Track 2 CJR model are not MIPS APMs. As a result, EPM or CJR collaborators, collaboration agents, and downstream collaboration agents are not engaged with Track 2 EPM participants or Track 2 CJR participant hospitals in a MIPS APM. Therefore, we will not adopt a requirement in regulation for Track 2 EPM participants or Track 2 CJR participant hospitals to submit clinician financial arrangements lists at this time.

We agree with commenters that we should continue to consider whether there are opportunities for additional APMs, including episode payment models, to become MIPS APMs. We will continue to consider the balance in models between the most appropriate, streamlined model design for the intended model participants to advance the goals of the model and the requirements for models to be MIPS APMs or Advanced APMs as we strive to create more opportunities for Eligible Clinicians to participate in MIPS APMs and Advanced APMs.

Comment: Commenters urged CMS to consider reversing the proposed Track 1 and Track 2 designations to represent an APM and Advanced APM, respectively, or identifying an alternative naming convention as the term ''tracks'' are already used in the Shared Savings Program.

Response: We appreciate the perspective of the commenters but believe that our proposed designations of a Track 1 EPM as an Advanced APM and a Track 2 EPM as a Non-Advanced APM under the EPMs are straightforward and appropriate for the distinctions we make between Advanced and Non-Advanced EPMs. The track designations for the EPMs are relevant to the EPM participants in the specific track of the EPM and the individuals and entities that have financial arrangements under the EPMs. We never intend to refer solely to the term Track 1 or Track 2 in the context of the EPMs but always in combination with the term EPM as a Track 1 EPM or Track 2 EPM. Therefore, we do not believe that Track 1 EPMs or Track 2 EPMs will be confused with tracks in the Shared Savings Program. We will be working closely with EPM participants and other stakeholders during EPM implementation to explain the various requirements of the EPMs in general and the tracks of the EPMs in particular.

Comment: Additional proposals were submitted by commenters that encouraged CMS to work further by creating additional tracks, including a MIPS APM track and accommodating those that may wish to accept financial risk sooner in order to qualify as an Advanced APM. Commenters believe CMS should continue to develop pathways and provide assistance to organizations who wish to develop or become participants in Advanced APMs; and to expand beyond the current inpatient-based episode payment model tracks to include not only a physician-focus but also a focus that meaningfully incorporates additional roles and activities, for example, specialty service providers, rehabilitation therapy providers, BPCI early adopters, home health care, and transitional care.

Response: We appreciate the suggestions of commenters. We respond earlier in this section on requests for additional MIPs APMs and for voluntary election of early increased downside risk to allow rural hospitals, SCHs, MDHs, and RRCs with special stop-loss limits under the EPMs to be in a Track 1 EPM at the same time as other EPM participants without special stop-loss limits under the EPM. We will continue our efforts to develop pathways and provide assistance to organizations who wish to develop or become participants in Advanced APMs. We refer the commenters to section III.A.3 of this final rule for additional considerations for future EPMs.

Comment: Commenters expressed appreciation for the proposed alignment resulting from use of the same definition of CEHRT across the EPM and Quality Payment Program, and acknowledged that CMS' proposal to permit those EPM participants who do not use CEHRT to be in a different track of the EPM offers appropriate flexibility. A few commenters requested that CMS consider using a process through the Medicare EHR Incentive Program to gather the attestations from the hospitals.

Response: We appreciate the recognition from commenters of CMS' efforts to utilize the flexibilities of the Quality Payment Program for Eligible Clinicians to link quality to payments through meaningful participation in an Advanced APM.

We also appreciate the suggestions by the commenters about existing processes and information CMS might use to streamline CEHRT use attestation for EPM participants in Track 1 EPMs. We reiterate that EPM participants choose to attest to CEHRT use and submit a clinician financial arrangements list beginning in performance year 3 and, therefore, be a Track 1 EPM participant (or elect voluntary downside risk in performance year 2, attest to CEHRT use, and submit a clinician financial arrangements list, and therefore, be a Track 1 EPM participant beginning in performance year 2), or choose not to attest to CEHRT use and be a Track 2 EPM participant. We will consider the feedback from commenters on CEHRT attestation methodologies as we develop the operational information for EPM participants about EPM processes and procedures. We further note that CMS and ONC also offer continued support and guidance through educational resources to support participating in and reporting CEHRT use to CMS models and programs, such as the EHR Incentive Program. We will communicate closely with EPM participants about the form and manner of attestation to CEHRT use for Track 1 EPMs early in the process of EPM implementation.

Comment: Many commenters urged CMS to consider the significant upfront investments in health IT infrastructure that providers must make to participate and be successful in the Quality Payment Program and EPMs or CJR model, given that, as one commenter stated, this investment exists even in upside-only models. As a result, these commenters recommended that CMS consider permitting EPM participants to be Advanced APM Entities in performance year 1 and/or that entry into Track 1 for EPM participants and CJR participant hospitals begin as soon as possible. Other commenters pointed out the lack of resources/support for Eligible Clinicians, such as therapists, to adopt EHRs. The commenters believe that Eligible Clinicians participating in an Advanced APM where the Advanced APM Entity is a hospital must also use and attest to use of CEHRT, and further stated that such a requirement would put these professionals at a significant disadvantage. To this end, a few commenters requested that CMS clarify whether the CEHRT requirement only applies to the hospitals that are EPM

participants and whether Eligible Clinicians who have entered into sharing arrangements as EPM collaborators will potentially meet the requirements to attest to use of CEHRT for participating in an Advanced APM under the Quality Payment Program.

Response: Like the commenters, we appreciate the important role health IT may play in meeting the goals of Advanced APMs, including Track 1 EPMs, to improve the quality and reduce the cost of care. As a result of the Quality Payment Program final rule with comment period (81 FR 28306), in order for an APM to be considered an Advanced APM, 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. As a result of this final rule, a Track 1 CJR participant hospital will be considered to be participating in an Advanced APM, and could qualify as an Advanced APM Entity beginning in performance year 2 for episodes ending on or after January 1, 2017, the time at which CJR participant hospitals would begin to bear downside risk for excess actual CJR episode spending above the quality-adjusted target price. Track 1 EPM participants will be considered to be participating in an Advanced APM, and could qualify as an Advanced APM Entity beginning in performance year 2 for episodes ending on or after January 1, 2018, the time at which EPM participants in performance year 2 would begin to bear downside risk for excess actual episode spending above the quality-adjusted target price.

The Advanced APM criteria established in the Quality Payment Program final rule with comment period at § 414.1415 (81 FR 77549) require that for APMs in which hospitals are the APM Entities, such as the EPMs, each hospital must use CEHRT to document and communicate clinical care to their patients or other health care providers to meet the CEHRT use requirement for Advanced APMs. Thus, there is no requirement that Eligible Clinicians who would be included on an Affiliated Practitioner List for Track 1 EPMs attest to CEHRT use and, therefore, we will not develop CEHRT attestation processes for Eligible Clinicians in Track 1 EPMs nor will we provide funds to support EHR adoption. In addition, we encourage participants to consider utilizing any shared savings obtained as part of the model to invest in health IT infrastructure that can help EPM collaborators improve care coordination for beneficiaries.

Final Decision: After consideration of the public comments received, we are finalizing the proposal to include in § 512.120(a) the CEHRT use and attestation for EPM participants, with modification to specify that the policy applies for performance year 2 if the EPM participant elects downside risk, and to use the term ''specified'' for consistency with CEHRT attestation in other CMS programs.

For performance year 2 if the EPM participant elects downside risk and for performance years 3 through 5, EPM participants choose either of the following:

- CEHRT use. EPM participants attest in a form and manner specified 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.
- No CEHRT use. EPM participants do not attest in a form and manner specified 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.

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 final 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 final 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 proposed 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). The Quality Payment Program final rule with comment period (81 FR 77444) modified this process to identify eligible clinicians on the Affiliated Practitioner List for QP determinations at any one of three snapshots. The first snapshot will be on March 31 of the QP Performance Period, the second snapshot will be on June 30 of the QP Performance Period, and the third snapshot will be on August 31, which will be the last day of the QP Performance Period.

We noted that while the required submission of this information might create some additional administrative requirements for certain EPM participants, we expected that EPM participants in a Track 1 EPM 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 EPM was included in § 512.120(b). We sought comments on the proposal for submission of this information. We were 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.

The following is a summary of the comments received and our responses.

Comment: While some commenters supported CMS' plans to recognize Eligible Clinicians who participate in APMs from an Affiliated Practitioner List, others raised concerns about the means to identify Eligible Clinicians as Affiliated Practitioners of Advanced APMs. A few commenters disagreed with the development of an Affiliated Practitioner List from a clinician financial arrangements list. Some commenters believe that to assume risk-taking threatens the financial viability of most physician-led entities. Other commenters expressed concern that the definition of such an agreement suggests that risk must be shifted to the clinicians to achieve QP status. These commenters agreed that the clinicians must support the cost or quality goals of the Advanced APM, but do not believe that to be included on the Affiliated Practitioner List the clinician must take risk. Other commenters assumed that Eligible Clinicians must assume risk under the EPM to qualify for QP incentive payment under the Quality Payment Program, and suggested that CMS base the risk requirements on physician practice or APM organization revenues. One commenter noted that not all physicians bound contractually to the requirements of the EPMs would be captured on clinician financial arrangements lists, as hospitals may have agreements with their employed physicians that cascade the programmatic requirements of the EPMs, but do not necessarily alter their underlying compensation or include gainsharing/risk-sharing/internal cost savings parameters. Instead, commenters offered alternatives to the submission of clinician financial arrangements lists, including such proposals as modeling the EPM along the lines of the Medical Home Model standard and using claims data to identify and attribute Eligible Clinicians to populate the EPM Affiliated Practitioner List for the purposes of the Quality Payment Program.

Response: Under Track 1 EPMs, the Advanced APM Entity is always a hospital, and no physicians are EPM participants. As we discussed in the Quality Payment Program final rule with comment period (81 FR 77442), for Advanced APMs, such as episode payment models, in which there are some Advanced APM Entities that include Eligible Clinicians on a Participation List and other Advanced APM Entities that identify Eligible Clinicians only on an Affiliated Practitioner List, we will identify Eligible Clinicians for QP determination based on the composition of the Advanced APM Entity: (1) For Advanced APM Entities that include and identify Eligible Clinicians on a Participation List, that Participation List will be used to define the Advanced APM Entity group, regardless of whether or not there is also an Affiliated Practitioner List or other list of Eligible Clinicians, and those Eligible Clinicians will be assessed as a group; (2) for Advanced APM Entities that do not include and identify Eligible Clinicians on a Participation List and there is an Affiliated Practitioner List that identifies Eligible Clinicians, that Affiliated Practitioner List will be used to identify the Eligible Clinicians for purposes of QP determinations, and those Eligible Clinicians will be assessed individually. Track 1 EPMs fall into the second category because the EPMs do not include and identify Eligible Clinicians on a Participation List so, therefore, we will use an Affiliated Practitioner List for Track 1 EPMs to identify Eligible Clinicians for purposes of QP determinations.

In the Quality Payment Program final rule with comment period in § 414.1305 (81 FR 77537), an Affiliated Practitioner is defined as an Eligible Clinician identified by a unique APM participant identifier on a CMS-maintained list who has a contractual relationship with the Advanced APM Entity for the purposes of supporting the Advanced APM Entity's quality or cost goals under the Advanced APM. Furthermore, in the Quality Payment Program final rule with comment period (81 FR 77440), we provided the example that an Affiliated Practitioner List comprised of gainsharers under an APM might include Eligible Clinicians whereas a Participation List may only include hospitals. We believe this example applies to the Track 1 EPMs.

We believe that constructing the Affiliated Practitioner List from the list of clinicians with financial arrangements submitted by each EPM participant that chooses to use and attest to use of CEHRT allows us to appropriately identify clinicians for the Affiliated Practitioner List under the EPMs. All of these clinicians have contractual relationships under the EPMs, and because the determination of the amount of gainsharing payment, distribution payment, or downstream distribution payment under their arrangement is required to be substantially based on quality of care and the provision of EPM activities (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), we believe that their contractual relationship supports the cost and quality goals of the Track 1 EPM participant and, therefore, that they meet the definition of Affiliated Practitioner.

Regarding those commenters who were concerned that constructing the Affiliated Practitioner List in this way would shift the financial risk of the APM Entity (Track 1 EPM participant) to the clinician in order for the clinician to be eligible for a QP determination, we want to emphasize that distribution arrangements and downstream distribution arrangements allow only distribution of payments that may be comprised of hospital internal cost savings and/or reconciliation payments for savings beyond the quality-adjusted target price under the EPMs, without allowing the collaboration agent or downstream collaboration agents to assume any downside risk. Sharing arrangements may include the sharing of upside and downside risk with EPM collaborators, but we note that in our experience with other bundled payment models, sharing with individual physicians has generally been upside risk only. We understand that the Quality Payment Program final rule with comment period does not require that an Affiliated Practitioner take on upside or downside risk to be eligible for a QP determination, while our proposed methodology to identify Eligible Clinicians for the EPM Affiliated Practitioner List requires those clinicians to have a financial arrangement under the EPM. However, we based our proposal on the most streamlined approach to identifying Eligible Clinicians under the Track 1 EPM who meet the definition of Affiliated Practitioner to build off policies that apply across the EPMs in general, in order to limit any additional administrative burden on EPM participants for Track 1 participation. Under the EPMs, the only contractual relationships for which we specify requirements as part of the model design for all participants and which ensure the Eligible Clinicians meet the Affiliated Practitioner definition are financial arrangements. Therefore, under our proposal for identifying Eligible Clinicians for each EPM participant that chooses to use and attest to use of CEHRT we would use the clinician financial arrangements list submitted to us to construct the EPM Affiliated Practitioner List.

In terms of constructing the Affiliated Practitioner List from claims data based on those clinicians furnishing services to EPM beneficiaries, we would not be able to know if such physicians, nonphysician practitioners, or therapists had a contractual relationship with the EPM participant to support the EPM participant's cost or quality goals under the Track 1 EPM (the requirement for Affiliated Practitioners), so we are unable to adopt this suggestion by the commenters. Moreover, we believe we can only know the information about contractual relationships between an EPM participant and an Eligible Clinician if the EPM participant reports this to us as we do not otherwise require such reporting under the EPMs.

We understand that there are circumstances where an EPM participant might want to enter into a contract with a clinician to support the cost or quality goals of the EPM. At this point, EPM participants that choose to use and attest to use of CEHRT may not report these clinicians to us through the clinician financial arrangements list for inclusion on the Affiliated Practitioner List because we made no specific proposals about what such contractual relationships would entail. As discussed previously in this section, MedPAC expressed concern that the EPMs contemplate large, loosely connected groups of clinicians who may have very little involvement with the beneficiaries in EPMs and hence have little reason to change their practice patterns or reduce inappropriate episodes. Thus, in order to identify the circumstances in which Eligible Clinicians without financial arrangements under a Track 1 EPM participant could meet the definition of Affiliated Practitioner, we will further consider the scenarios raised by the commenters and intend to propose an additional methodology for EPM participants to identify other Eligible Clinicians who may be included on the Affiliated Practitioner List in future rulemaking. This additional methodology would be targeted for implementation in performance year 3 when downside risk for all participants under the EPMs applies.

We are finalizing our proposal to construct the EPM's Affiliated Practitioner List from the clinician financial arrangements lists submitted by those EPM participants that attest to CEHRT use.

Comment: Several commenters urged CMS to identify Eligible Clinicians through a streamlined reporting process, and ensure that a minimum burden is applied to EPM participants when providing lists. To this end, the commenters proposed alterations to the proposed contents of the clinician financial arrangements list, including the recommendation that CMS require EPM participants or CJR participant hospitals to submit an electronic form listing all collaborators, collaboration agents, and downstream collaboration agents and their tax identification numbers (TIN) on a yearly basis. Finally, some commenters requested that CMS enable more frequent updates to the list.

Response: We appreciate the interest of the commenters in creating the minimal necessary reporting burden on EPM participants and CJR participant hospitals. For those EPM participants that choose to use and attest to use of CEHRT and are required to submit a clinician financial arrangements list, we agree with the commenters that the most streamlined process that provides us with the timely, necessary information is desirable. We proposed that the submission must occur on a no more than quarterly basis and we continue to believe that this timing is the most appropriate. It establishes the maximum required submission burden on EPM participants of quarterly in view of the three planned ''snapshots'' of the Affiliated Practitioner List each year (81 FR 77444) to capture timely new Affiliated Practitioners that were not previously identified for the EPM participant, while allowing us the flexibility to determine a lower reporting periodicity for EPM participants whose list does not change during the EPM performance year. We also note that while under our proposal we could not require submission of the list more than quarterly, the submission timing requirement does not preclude us from accepting more frequent than quarterly voluntary updates to the list if EPM participants have more frequent changes to their list of clinicians with financial arrangements under the EPM.

We proposed that Eligible Clinicians on the clinician financial arrangements list that we would use to construct an Affiliated Practitioner List would be EPM collaborators who are physicians, nonphysician practitioners, and providers of outpatient therapy services engaged in sharing arrangements with an EPM participant; PGP members who are physicians and nonphysician practitioners who are collaboration agents engaged in distribution arrangements with a PGP that is an EPM collaborator; and PGP members who are physicians and nonphysician practitioners 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. To reflect our final policies for financial arrangements discussed in section III.I. of this final rule, and taking into consideration the issues discussed later in this section, we are revising the categories of individuals who qualify as Eligible Clinicians and clarifying the information to be reported on the clinician financial arrangements list in this final rule. It was our intention in

the proposed rule and our policy in this final rule that the full complement of physicians, nonphysician practitioners, and therapists who have financial arrangements under the EPMs be reported on the EPM participant's clinician financial arrangements list. We see no reason to treat physicians, nonphysician practitioners, or therapists differently for purposes of being considered Eligible Clinicians based on their specific type of financial arrangement under the EPM as the requirements for each type of contractual relationship are aligned with the cost and quality goals of the EPM.

We proposed that providers of outpatient therapy services that are EPM collaborators be reported on the clinician financial arrangements list, although the term provider of outpatient therapy services also encompassed entities that were not individual therapists and that, therefore, could not be Eligible Clinicians. However, as discussed in section III.I.3. of this final rule we are adopting the specific term therapist in private practice for those individual therapists who are EPM collaborators. Thus, we are refining the reporting of EPM collaborators on the clinician financial arrangements list to include physicians, nonphysician practitioners, and therapists in private practice to focus on individual therapists in private practice, who may be Eligible Clinicians under the provisions of the Quality Payment Program final rule with comment period, rather than all providers of outpatient therapy services.

In addition, our proposal did not identify as Eligible Clinicians therapists who are collaboration agents and downstream collaboration agents as members of PGPs or ACO providers/suppliers who are physicians, nonphysician practitioners, or therapists who are collaboration agents. While we did not propose that therapists who are collaboration agents or downstream collaboration agents as members of PGPs be reported on the clinician financial arrangements list, we did propose that a therapist could be a PGP member and we note that therapists can also be Eligible Clinicians under the provisions of the Quality Payment Program final rule with comment period. We also did not identify in our proposal that physicians, nonphysician practitioners, and therapists who are collaboration agents and ACO providers/suppliers in an ACO that is an EPM collaborator would be Eligible Clinicians on the clinician financial arrangements list. This was an oversight as we intended to include all collaboration agents who are physicians, nonphysician practitioners, and therapists on the clinician financial arrangements list, regardless of the entity that is their associated EPM collaborator. Moreover, our proposal did not take into account the provisions of this final rule that allow NPPGPs and TGPs to be EPM collaborators or collaboration agents and, therefore, we did not propose that the nonphysician practitioners and therapists who have financial arrangements with these entities would also be Eligible Clinicians on the clinician financial arrangements list. Therefore, in this final rule we are clarifying that all physicians, nonphysician practitioners, and therapists who are collaboration agents or downstream collaboration agents are reported on the clinician financial arrangements list, without regard to the type of entity that is the associated party with which the collaboration agent or downstream collaboration agent has his or her distribution arrangement or downstream distribution arrangement. We note that we proposed to require that physicians and nonphysician practitioners who are members of a PGP that is an EPM collaborator or members of a PGP that is also an ACO participant in an ACO that is an EPM collaborator and that have a distribution arrangement or downstream distribution arrangement, respectively, with the PGP be reported on the list. Therefore, we believe there is only a small additional burden on EPM participants to report on the list all collaboration agents or downstream collaboration agents that are physicians, nonphysician practitioners, or therapists with distribution arrangements or downstream distribution arrangements, in order to ensure that the clinician financial arrangements list reports all Eligible Clinicians with financial arrangements under the EPM.

We proposed that the information to be reported on the clinician financial arrangements list would include the name and NPI and, in some cases the TIN, of the Eligible Clinician with the financial arrangement under the EPM. We also proposed to collect the TIN of the PGP that is an EPM collaborator or collaboration agent and with which the physician or nonphysician practitioner reported on the list has a financial relationship, which would have provided us with information for purposes of monitoring and compliance on some of the entities related to the contracts of those physicians or nonphysician practitioners under the EPM. While we did not propose to similarly require information be submitted on the ACO that would be an EPM collaborator for those Eligible Clinicians that are collaboration agents or downstream collaboration agents, in this final rule, we are clarifying that the name and NPI of the entity (that is, the PGP, NPPGP, TGP, or ACO) that is an EPM collaborator and the entity (that is, the PGP, NPPGP, or TGP) that is a collaboration agent, if applicable, must also be reported on the clinician financial arrangements list for each Eligible Clinician who is a collaboration agent or downstream collaboration agent. Thus, the final requirements provide us with sufficient information to monitor the full series of related financial relationships under the EPM that result in the reporting of an Eligible Clinician on the clinician financial arrangements list. Because we do not expect that EPM participants will enter into sharing arrangements with many ACOs, due to the limited number of ACOs to which beneficiaries are typically assigned in a given geographic area, we do not believe that requiring the reporting of the name and TIN of the ACO that is an EPM collaborator is a significant additional burden on the EPM participant submitting the list to CMS.

In summary, based on the previous discussion, for purposes of clarity and consistency we are streamlining the requirements for reporting information on the clinician financial arrangements list. For each physician, nonphysician practitioner, or therapist that is an EPM collaborator, collaboration agent, or downstream collaboration agent, we require the name, TIN, and NPI to be reported, in addition to the start date and, if applicable, end date, for the individual's sharing arrangement, distribution arrangement, or downstream distribution arrangement. We further require for a collaboration agent that the name and TIN of the EPM collaborator be reported and that for a downstream collaboration agent the name and TIN of the EPM collaborator and the name and TIN of the collaboration agent be reported.

We will be working closely with EPM participants on the format and process for submission of clinician financial arrangements lists, including the potential for electronic submission of the required information, during the early phases of EPM implementation, seeking to ensure that the format and process is as streamlined as possible for EPM participants that choose to use and attest to use of CEHRT, while meeting CMS' need to maintain an EPM Affiliated Practitioner List that can be used to identify Eligible Clinicians for a QP determination.

Final Decision: After consideration of the public comments received, we are finalizing the proposal in § 512.120(b) for EPM participants that use and attest to use of CEHRT to submit to CMS a clinician financial arrangements list on a no more than quarterly basis, with modification to include on that list information on all physicians, nonphysician practitioners, and therapists with financial arrangements under the EPM and, if applicable, identifying information for the related parties with sharing arrangements, distribution arrangements, and downstream distribution arrangements under the EPM as finalized in section III.I. of this final rule.

Each EPM participant that chooses CEHRT use 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 and entities for the period of the EPM performance year specified by CMS:

• EPM collaborators. For each physician, nonphysician practitioner, or therapist in private practice who is an EPM collaborator during the period of the EPM performance year specified by CMS:

++ The name, TIN, and 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.

Collaboration agents. For each physician, nonphysician practitioner, or therapist who is a collaboration agent during the period of the EPM performance year specified by CMS:

++ The name and TIN of the EPM collaborator and the name, TIN, and NPI of the collaboration agent.

++ The start date and, if applicable, end date, for the distribution arrangement between the EPM collaborator and the collaboration agent.

• Downstream collaboration agents. For each physician, nonphysician practitioner, or therapist who is a downstream collaboration agent during the period of the EPM performance year specified by CMS:

++ The name and TIN of the EPM collaborator, the name and TIN of the collaboration agent and the name, TIN, and NPI of the downstream collaboration agent.

++ The start date and, if applicable, end date, for the downstream distribution arrangement between the collaboration agent and the downstream collaboration agent

• 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.

d. Documentation Requirements

For each EPM participant that chooses to meet and attest to CEHRT use, we proposed 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 proposed 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 was included in § 512.120(c). We sought comment on this proposal for required documentation.

Final Decision: We did not receive comments pertaining to § 512.120(c). Therefore, we are finalizing the proposal, without modification, for EPM participant documentation of attestation to CEHRT use and clinician financial arrangements lists submitted to CMS.

The following documentation requirements apply to EPM participants choosing to use and attest to use of CEHRT.

• Each EPM participant that chooses CEHRT use must maintain documentation of their attestation to CEHRT use and clinician financial arrangements lists.

• The EPM participant must retain and provide access to the required documentation in accordance with § 512.110.

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 two of the Advanced APM criteria in the Quality Payment Program (QPP) final rule with comment period (81 FR 77008), payment based on quality measures and CEHRT use. 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 new bundled payment model for CY 2018 where the model(s) would be designed to meet the criteria to be an Advanced APM.

The following is a summary of the comments received and our responses.

Comment: A number of commenters expressed support for a new voluntary bundled payment model in CY 2018. Specifically, commenters expected any new design to include the ability of the BPCI Initiative to qualify as meeting the requirements for an advanced APM under the QPP. Commenters also requested that data be provided by CMS on a monthly basis with quarterly reconciliation reports to allow participants to meaningfully engage in reforms to the delivery of health care. Consistent with the existing BPCI model, CMS was encouraged by commenters to continue assigning precedence to self-selected model participants over participants in assigned models. Additional recommended features included financial stop-gain and stop-loss limits and the incorporation of composite quality score similar to that used in the CJR model. Other specific features included recommendations for additional post-acute care bundles and the exclusion of ACOs.

More broadly, CMS received several recommendations calling for increased stakeholder input in the design, implementation, and evaluation of new voluntary bundled payment models. Commenters requested that hospitals currently participating in BPCI should be allowed to test additional episodes, and new hospitals should be allowed to enter the program. While ranging in degree, most commenters highlighted a need for input from external clinical experts in addition to consumers, patients, and purchasers as well as institutional stakeholders such as QIOs. To better align with other available EHR incentive payments, several commenters stated a need for future bundled payment models to include CEHRT measures.

Response: We appreciate these considerations as we design a new voluntary bundled payment model.

Comment: A few commenters suggested that since post-acute care

providers are the predominant care provider for LEJR patients, post-acute care should play a more prominent role in the BPCI initiative.

Response: CMS thanks the commenters for this suggestion.

Comment: One commenter recommended CMS use a consistent policy to address overlap of all Medicare bundled payment initiatives and population-based payment models. The commenter raised concerns with respect to overlap of beneficiaries in the EPMs, CJR model, and BPCI initiative, and suggested that, in a future BPCI initiative, beneficiaries should be excluded from bundled payments unless a collaborative agreement exists between an ACO and a hospital that is not a participant in that ACO. The commenter also had concerns for the extent to which Medicare beneficiaries benefit from allowing private for-profit awardee conveners to absorb the risk for providers. Therefore, the commenter recommended also that CMS exclude for-profit risk-taking conveners which do not provide patient care.

Response: We acknowledge and appreciate all comments, and specifically recognize the shared interest in improving Medicare for its beneficiaries.

Comment: A few commenters requested that CMS take into consideration several additional pricing flexibilities and regulatory waivers for a new voluntary bundled payment model. Specifically, commenters believed that reducing costs and increasing shared savings could be difficult, therefore, participants should have the flexibility in a new voluntary bundled payment model to modify practice or utilization patterns by reducing length of stay or intensity of services. Commenters stated that the next iteration of BPCI should feature program elements such as caps on total losses that gradually increase over time, variable discounts based on quality scoring, and elimination of financial responsibility for payments above a threshold. Other commenters proposed that CMS adopt a method of population risk stratification, as this could provide incentive to providers by reimbursing more for greater comorbidities. Finally, in setting the bundled payment amounts, commenters recommended that CMS incorporate clinical practice guidelines and appropriate use criteria to ensure that patients are not receiving inadequate care. One commenter suggested that CMS provide patient navigators to Medicare beneficiaries receiving items or services paid under an EPM. Additionally, the regulatory waivers requested included the home health homebound requirement, the IRF 60 percent rule, the IRF 3-hour therapy intensity rule, and the LTCH 25 day average length of stay restriction. One commenter suggested that occupational therapy be recognized as a ''qualifying service'' under the Medicare home health care benefit and occupational therapists could, in future APMs be permitted to open 'therapy only' cases if occupational therapy is in the physician's order.

Response: We recognize commenters' requests for consideration of additional flexibilities in care redesign efforts as part of a new voluntary bundled payment model.

Final Decision: As we did not propose changes to the BPCI initiative in the proposed rule, we do not have any changes to finalize in this final rule.

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 sought 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 the proposed rule (81 FR 50794). 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 requested 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); other considerations specific to identifying future models as Advanced APMs; and any other issues of importance for the design of such an EPM.

The following is a summary of the comments received and our responses.

Comment: A few commenters requested that in future condition-specific EPMs, CMS should consider episodes beginning before a hospitalization, as one commenter believed that this earlier future EPM episode trigger would engage more meaningful shared care planning. Other commenters stated that future condition-specific EPMs should be based on episodes that are not necessarily tied to a hospital stay. One commenter noted that there is a great degree of variation in cardiac care beyond the two proposed EPM episodes. For example, the commenter noted regional differences in ambulatory and hospital care for heart failure, which the commenter did not believe are explained by disease severity and therefore the commenter suggested such additional cardiac care may become a favorable population-based payment model. Several commenters provided recommendations and perspectives on future condition-specific episode payment models based on MS–DRGs, including examples such as sepsis. However, other commenters suggested the alternative to use the Episode Grouper for Medicare (EGM) for future condition-specific EPMs. The framework for the EGM involves organizing administrative claims data into episodes-of-care, or simply episodes, which are sets of services provided to care for an illness or injury during a defined period of time. One commenter stated that the EGM organizes Medicare beneficiary total cost around two constructs—episodes for specific conditions and episodes for specific treatments. For condition-specific episodes, each episode would be defined by one or more diagnosis codes, however, treatment episodes would be defined by a combination of procedure and diagnosis codes. A few commenters provided specific diagnoses that could be attributable to organized future EPMs, including but not limited to gastroesophageal reflux disease and

obesity. Another commenter disagreed, stating it is inappropriate to expand the current EPM approach to future treatment of chronic conditions because, the commenter suggested, a bigger opportunity for improving quality and achieving savings is avoiding unnecessary episodes and events. In turn, the costs of treatment episodes could be packaged into the costs of managing underlying condition episodes. Commenters stated further that the EGM should also examine utilization patterns, perform comparative analyses for similar conditions, and identify care-improvement opportunities. As such, commenters suggested that the EGM would be better suited to pricing and resource allocation while identifying chronic conditions.

Response: We thank the commenters for their suggestion.

Comment: Another commenter, referencing the Program of All-Inclusive Care for the Elderly (PACE), recommended that CMS consider a comprehensive episode payment model for services for medical care that could be tied with private payment, enrollment in available community services, or an arrangement with Medicaid. Beneficiaries requiring daily help or supervision would serve as a qualifying condition, which could extend for varying durations.

Response: We appreciate the commenter's support for PACE and will work internally to incorporate lessons learned from existing programs in the proposal of future condition-specific EPMs.

Comment: Highlighting the efforts of national medical specialty societies, several commenters provided several condition-specific EPMs which may be successful in reducing emergency department visits, hospital admissions, and excessive testing. Specifically, several commenters gave such examples as coronary artery disease, headache, epilepsy, asthma, opioid use disorder, diabetes, and specialty medical home. Of note, commenters stated that CMS should give additional consideration to defined episode triggers. For example, some commenters suggested that each new episode should be accompanied by time criteria and have a unique but expected time course. These efforts, commenters suggested, might further result in disease prevention, reduced exacerbations, and improved care.

Response: We appreciate commenters' eagerness to participate in this dialogue and to be a part of transforming care.

Comment: Commenters believed that CMS should view organized provider models as qualifying for condition-specific EPMs. Other commenters suggested that CMS simply include more types of participants, including examples such as ACOs and PCMHs. Still, others commented that participation in future condition-specific EPMs be limited to those organizations that are fully committed to coordinated care planning, shared decision-making, comparative quality information, chronic disease management, transparent payments and care transition support. As an alternative approach to considering future condition-specific EPMs, MedPAC suggested that CMS consider allowing hospitals to share savings with physicians as a way to focus doctors on reducing the cost of the inpatient stay.

Response: We acknowledge and appreciate the suggestion to incorporate more participant types in future condition-specific EPMs.

Comment: Additionally, MedPAC recommended that for conditions that are not promising for bundled payments, CMS could focus on an array of other strategies to support providers in lowering costs while improving patient outcomes. For example, the Medicare spending per beneficiary (MSPB) measure in the hospital value-based purchasing (VBP) program encourages lower spending and improved care coordination. Alteration of the ''weight'' of the MSPB could be increased to further incentivize hospitals to reduce spending. Furthermore, MedPAC noted that the hospital readmission policy already encourages hospitals to avoid readmissions for AMIs and CABGs. To increase the pressure to reduce readmissions, it was suggested that CMS move forward with readmission policies in all sectors to increase the penalties for providers with high risk- adjusted potentially avoidable readmission rates.

Response: We appreciate any recommendations MedPAC can provide and will continue to collaborate with stakeholders to develop additional means to improve patient outcome measures. Furthermore, we will work internally to find additional alignment between Innovation Center programs and Medicare payment policies.

Comment: One commenter recommended consideration of an episode that should address behavioral health integration with primary care. The commenter suggested that guidelines which embed behavioral health measurements into any care setting would equip providers with quantification necessary to impact both physical and mental health of patients.

Response: We appreciate the commenter's proposal. We appreciate the many comments received regarding the request for comment and while we did not propose any changes to this section of the final rule, we intend to continually seek to connect those interested to further information on consideration of future condition-specific EPMs that would result in improvement in care for Medicare beneficiaries.

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 final 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 sought 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 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' 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 sought 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 sought 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 include beneficiaries who solely receive medical treatment in the proposed AMI model, 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.[36] 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 sought comment on design features needed to address these considerations, including defining the beginning and end of episodes; setting episode prices, 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.

[36] Medical Severity Diagnosis Related Groups (MS–DRGs): Definitions Manual. Version 33.0A. 3M Health Information Systems. (October 1, 2015).

The following is a summary of the comments received and our responses.

Comment: Many commenters expressed support for the continued commitment of the Agency to testing episode-based payment models under a range of settings. One commenter suggested that CMS generally consider both clinical and economic expertise as well as include large databases as part of the development of future event-based EPM. While recommendations included both specific surgical procedures, such as PCI or spine surgery, chronic conditions, such as diabetes, and discrete events including colonoscopy and an arm arthroplasty, several commenters submitted more general suggestions that CMS take an expansive approach in general for the consideration of future models and not limit alternative payment models to episode payment approaches. When considering future models to qualify as Advanced APMs, one commenter suggested that CMS count capitated MA relationships in MACRA's APM threshold calculation.

Some commenters preferred an emphasis on future EPMs that consider the role of preventative efforts. For example, one commenter suggested that conditions such as osteoporosis could include efforts to improve bone health and functional level to achieve meaningful reduction in falls and subsequent fracture. The commenter followed that concerns such as fracture prevention be included in future models. To this end, one commenter stated that CMS should take a ''bottom-up approach'' that encourages providers to develop alternative payment models.

Response: We thank the commenters for their remarks, and will continue to apply the bottom-up approach to improving the coordination among providers in future EPMs.

Comment: Some commenters expressed concern about the continuation of hospital-based models and recommended that future expansions should include more types of participants, including physicians, and participation should be voluntary. Physicians, one commenter suggested, are best suited to ensure efficient utilization of resources while preserving patient quality by virtue of their direct relationship with the patient during an acute episode. One commenter suggested expansion of physician-focused payment models beyond the Focused Payment Model Technical Advisory Committee (PTAC). In a parallel thought process, many other commenters expressed a desire for CMS to consider post-acute care bundles, ACO based models, and shared

accountability payment models for Inpatient Rehabilitation Facilities (IRFs). One commenter strongly recommended CMS to allow manufacturers to enter into voluntary agreements with CMS to link payment to outcomes. One such outcome proposed by the commenter was the long-term revision rates for total joint arthroplasty (TJA). Any shared savings relative to the average rate of revision among Medicare patients, the commenter suggested, could be shared between implanting surgeons, hospitals and medical device manufacturers. Commenters stated that these additional types of participants could provide a means to ensure efficient utilization within a particular market. In addition, another commenter noted that procedures performed in ambulatory surgical centers may be better situated to serve as the financially accountable entity in order to optimize care coordination to better achieve the goals envisioned by episode-based payment models.

Response: We thank the commenters for their commitment to working with CMS in developing future episode payment models.

Comment: Commenters commonly recommended that future bundles be sensitive to considering risk adjustment, appropriate use criteria, patient expectations, stage of disease progression, treatment options, and appropriate quality measures regardless of setting. Commenters also recommended that future measures in future condition-specific payment models should be more directly related to the condition of the beneficiaries within the EPM. To this end, one commenter recommended that CMS include measures of patient engagement and shared care planning. Another commenter suggested that those who participate in geriatric fracture programs and/or obtain CORE Certification, be incentivized to continue such progress. Even as CMS proposed to exclude IPPS new technology add-on payments and OPPS transitional pass-through payments for medical technologies from EPM episodes, one commenter requested that future EPM episodes include additional innovative technologies to qualify for a payment adjustment similar to the Medicare New-Technology add-on payment.

Many commenters stressed the importance of shared decision-making in the development of future models. One commenter, for example noted the Clinical Practice Improvement Activities Category of the MIPS could be an important first step to greater shared decision-making across healthcare delivery and recommended CMS look to research conducted by PCORI and others for future direction. Specifically, one commenter also noted that shared decision-making and patient engagement tools could be especially informative in situations not triggered by an acute care hospitalization. Several other commenters further strongly encouraged the participation of hospitals, physicians, patients, and other stakeholders in the development, implementation, and testing of future models. Additionally, in future EPM models, a few comments directed CMS to consider directly extending the risk to the other providers, including clinicians as physicians shape the spending during the hospital stay and the selection of the initial post-acute care provider but are not required to be at risk for the 90-day episode spending. Similarly, some commenters noted that post-acute care providers can influence how much spending for post-acute care services is used and the rate of hospital readmissions but are not directly at risk for the 90-day episode spending. Therefore, these commenters suggested such changes to future EPMs would ensure that the financial incentives of the key actors shaping care are aligned.

In addition to model design, one commenter recommended that QIOs serve in a technical assistance role for model participants to include data analyses, convening providers in the area, structuring implementation of improvement activities, and monitoring tests of improvement.

Response: We thank the commenters for these suggestions and will consider the recommendations as we consider future event-based procedures and medical conditions to include in future rulemaking.

Comment: One commenter pointed to the Continuing Care Hospital model, and suggested CMS pilot future event-based episode payment models for procedures and medical conditions. The commenter stated that the CCH would allow predictable and reduced costs to the Medicare program.

Response: We thank the commenter for the reference.

Comment: One commenter suggested the implementation of an evaluation EPM, whereby the episode initiates when a beneficiary enters an inpatient setting with a set of symptoms that may be difficult to attribute to one or more MS–DRGs. Such an evaluation EPM, stated the commenter, would need to be limited to a specific set of symptoms, such as the example CMS provided regarding respiratory symptoms.

Response: We thank the commenter for this specific suggestion.

Comment: One commenter recommended CMS to exclude other potentially high cost drivers, such as psychiatric readmissions and high cost IV therapy, from future EPM bundles.

Response: We acknowledge this suggestion and will consider if it is applicable to specific future EPMs.

Comment: One commenter noted other considerations specific to identifying future models, specifically that CMS update the claims adjudication system and develop contracting tools. The commenter suggested that such changes would encourage participant providers to improve their care pathways and care coordination.

Response: We acknowledge these additional considerations and re-affirm our commitment to continuously engage stakeholders as we establish and operationalize future policies.

Comment: A few commenters requested a meeting with CMS to discuss the specifics of a future innovation model.

Response: We appreciate the interest in meeting with CMS to discuss future models. Commenters should note that ideas can also be submitted through *https://innovation.cms.gov/Share-Your-Ideas/Submit/index.html.*

Final Decision: After seeking comments on future directions for episode payment models, we thank the public for these comments and will evaluate the suggestions for future consideration.

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.[37] 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 in this rule.

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.[38]

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 sought 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?

The following is a summary of the comments received and our responses.

Comment: Commenters recognized the importance that health IT plays in the modern health care landscape, and overall supported the implementation of a more robust health IT system, as such a system may improve the ability to convey quick, accurate information from acute care hospitals related to the discharge MS–DRG and identification of patients who are under a bundled payment program. Many commenters expressed a need for future episode payment models to align with EHR incentive payments, and several commenters expressed concern that post-acute care providers were largely disadvantaged for health IT readiness relative to their inpatient counterparts. For example, commenters stated that post-acute care providers and nonphysician clinicians were marginalized by the Medicare and Medicaid EHR Incentive Programs. Some commenters believe this population represents a significant portion of the health care provider community without the technical and financial support necessary to adopt and implement EHRs in a meaningful way. As many of the measures used under meaningful use, such as e-prescribing, are not applicable to nonphysician practitioners, commenters suggested these and other clinicians have not had the benefit of experience with EHRs at the same rate as their peers who work

[37] 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.

[38] *https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16003.pdf.*

in hospitals. As a result, one commenter noted that small practices who may face financial responsibility, such as physical therapists, would face considerable challenges implementing health IT systems in their practices.

Several commenters recommended that CMS to consider all possible approaches to address this specific concern. One commenter, for example, recommended an approach similar to the ACO Investment Model program whereby participants could receive supplemental payments to offset their upfront investment. Other commenters preferred not to provide specific approaches as the sufficiency of financial incentives or bonus payments may differ for example among Skilled Nursing Facilities (SNFs), Home Health Agencies (HHAs), and institutional or hospital-based post-acute care providers, but highlighted the need for CMS to otherwise incentivize health IT adopters within future models. To effectively implement any such expansion, one commenter further stressed the need for health IT interoperability to be considered, while another commenter stressed instead that CMS should specifically cite the availability of the safe harbors of the Stark and Physician Self-Referral rules, through which health care organizations could choose to assist post-acute, or other providers, in making available EHRs meeting certain requirements in any potential approach. One commenter recommended that CMS continue to engage the long-term and post-acute care community to explore in more detail potential strategies to help overcome challenges providers face, such as the high costs of participating in health information exchange or the operational investment of an EHR system. Other comments on ways to incentivize health IT investment by post-acute care providers included: quicker or premium reimbursement for health IT adoption or upgrade, returning savings to post-acute care providers to offset health IT costs and incentive grants for training staff in health IT.

Response: We will consider these and other possible approaches to address the concerns and challenges associated with implementing health IT systems.

Final Decision: After consideration of the public comments received, we believe we have a better understanding of the issues related to readiness of providers and suppliers that are not hospitals to take achieve interoperability through CEHRT in potential future episode payment models.

B. Definition of the Episode Initiator and Selected Geographic Areas

1. Background

The 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 and in the EPMs proposed rule, 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 proposed 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 (80 FR 73274). 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 sought comment on those areas where alternative options were proposed or should be considered that would not add additional operational burden or complexity. A summary of comments received and CMS' response to those comments are included in the following sections.

2. Definition of Episode Initiator

Under the proposed EPMs, consistent with our episode initiator definition under the CJR model, we proposed 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 the proposed rule (81 FR 50834). As with the CJR model, we proposed 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 the proposed rule (81 FR 50847). This is the same policy that is being followed with the CJR model. In addition, we also proposed to exclude other all-payer state models which may be implemented in the future. We welcomed comments on this proposal and sought comment on 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 proposed 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 the proposed rule (81 FR 50834) 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 the proposed rule. We believe that utilizing the hospital admission 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, as stated in the proposed rule, we will be able to expand our testing of a more generalized bundled payment model. Finally, as described in section III.B.4. of the proposed rule (81 FR 50815) our proposed geographic area selection approach relied upon our definition of hospitals as the entities that initiate episodes.

The following is a summary of the comments received on our proposed episode definition and our responses.

Comment: We received many comments supporting our proposal to initiate these EPM episodes of care with the inpatient hospital admission. However, we also received multiple comments noting the important role that physicians play in managing patient care throughout the episode period including after discharge from the hospital. These same commenters expressed support for more physician based payment models so that physicians can have a more substantial role in managing episodes.

Response: We appreciate the support commenters expressed for initiating the EPM episodes with the inpatient hospital admission. While we acknowledge and understand that inpatient initiated episodes represent only one of many potential models for improving the quality of care while restraining the growth in costs, we continue to believe that the appropriate initiating point for the episodes in these EPMs is the inpatient admission. Hospitals play a central role in coordinating episode-related care and ensuring smooth transitions for beneficiaries undergoing services related to these episodes and a large portion of a beneficiary's recovery trajectory from an AMI or CABG or SHFFT begins during the hospital stay which is why we are finalizing the inpatient admission as the initiating event in the episode definition. We also note that CMS has supported and is supporting other voluntary demonstrations and models that focus on providing financial support for care coordination services as recommended by these commenters. In addition, in recent years, the range of services eligible for payment under the Medicare physician fee schedule has expanded to include care transition and chronic care management codes. For further discussion of future models, we refer the reader to section III.A.3. of this final rule, ''Future Directions for Episode Payment Models.''

We did not receive any comments related to our exclusion of Maryland nor on the potential inclusion or exclusion of future all-payer state models. Therefore we are finalizing our proposal to exclude Maryland providers from this model.

Subsequent to the publication of this final rule CMS announced on October 26, 2016 the implementation of the Vermont All Payer ACO Model which will begin on January 1, 2017. Since this new Vermont model is an all payer model and since we proposed to exclude all of the all payer state models from the EPM we are also finalizing the exclusion of Vermont providers from selection for participation in the EPMs. We note that currently none of the MSAs in Vermont are participating in the CJR model and would, therefore, not have been selected to participate in the SHFFT EPM.

Final Decision: After consideration of the public comments received, we are finalizing the proposed episode definition, without modification, such that these EPM episodes will be initiated 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 final rule. We are also finalizing the exclusion of hospitals in Maryland and Vermont from participation in the EPMs.

3. Financial Responsibility for the Episode of Care

As with the CJR model, and as discussed in the proposed rule, 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. Therefore, we proposed 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 IT, 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 proposed that the financial responsibility be given to the hospital to which the episode is attributed, as described in section III.C.4 of the proposed rule. 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 encouraging this coordination across providers and sought 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 proposed 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, as we stated in the proposed rule, 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 sought 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 proposed. We proposed that IPPS hospitals located in an area selected for any one of the episode payment models proposed in the proposed rule (81 FR 50834) 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 proposed 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 proposed under the proposed rule (81 FR 50834). 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, we proposed that 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. As stated in the proposed rule, 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. of the proposed rule we discussed in more detail how we proposed 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 welcomed 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 proposed that the EPM participant be financially responsible for the episode of care under these EPMs, we also stated that we 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 continue to believe it is 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 noted 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 the 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 acknowledged the important role of conveners in the BPCI model, and that 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 proposed that the ultimate financial responsibility of the episode would remain 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. of this final rule. As with the CJR model, we did 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 referred readers to section III.I. of the final rule for further discussion of model design elements that may outline financial arrangements between EPM participants and other providers and suppliers.

The following is a summary of the comments received and our responses.

Comment: We received numerous comments related to our proposal to have the hospital be the single accountable entity for the EPM episodes. Many commenters were supportive of this policy and, while not ignoring the importance of other providers, agreed that hospitals were best positioned to assume risk for these episodes. Other commenters were less supportive of this proposal, noting that hospitals could be disadvantaged if physicians and post-acute care providers were not also at risk or if conflicting interests hindered their willingness to collaborate. A few commenters expressed concern that while hospitals would bear the risk, hospitals might be limited in their ability to control that same risk. For example, one commenter referenced the penalty that hospitals already face for readmissions which may not be correlated to inpatient care. One commenter stated that post-acute care providers would be more motivated if they were required to share in even a small percentage of the incentives or risk directly. Another commenter noted that the current per-diem payment system for SNFs put SNF providers at particular risk. Although SNFs will invest resources to reduce/shorten SNF stays, which can create significant savings for the EPM participant, the

commenter stated SNF providers will be disadvantaged/harmed as the proposed regulations do not require proportional sharing of reconciliation payments by the EPM participant with post-acute care providers and requested that we amend the language to more clearly outline how reconciliation payments should be shared proportionally among all EPM collaborators, noting that this change would also likely require these same providers to share in downside risk as well.

Other commenters objected to the hospital holding sole financial accountability for the models as they believe that physicians, including hospitalists, surgeons, and internal medicine subspecialists are best positioned to impact the process of care. These commenters stated that CMS should be giving priority to physician-centered alternative payment models. One commenter believes that having the hospital in charge of the bundle could give the hospital inappropriate leverage over other participants and or lead to the exclusion of providers if they failed to agree to the hospital's terms. Other commenters wanted the flexibility for conveners to assume risk and organize groups of providers, as is allowed under BPCI.

One commenter specifically stated that determination of the accountable entity should be based not only on the ability to accept risk but also the ability to change care delivery patterns. While one commenter explicitly stated that ''only physicians can make the determination as to what types of care could effectively address patients' needs,'' that commenter also wanted payment to physicians to be predictable and physician financial accountability limited to ''costs that are within their control.'' The perspective that physicians were best positioned to manage the episode of care and desire for them to have the opportunity to bear risk, particularly as it might pertain to eligibility for advanced alternative payment model status, was expressed by a number of commenters although the focus in such comments was on voluntary models.

Response: We appreciate the support expressed by certain commenters for our proposed policy to hold the initiating hospital as the financially accountable entity for the EPM episodes. While we acknowledge the critical importance of physicians and other providers, in particular those providing post-acute care, in managing episodes which extend 90 days beyond discharge from the anchor hospitalization, we continue to believe the hospital should be the financially accountable entity for these models. For hospitals to be successful in managing EPMs, we firmly believe that they will need to actively solicit the support of physicians, post-acute care providers, and other clinical care providers in order to provide the best quality of care in a cost effective manner. In many, if not most situations, this may involve establishing collaborative agreements with a risk sharing arrangement. We support other types of providers assuming risk where they are financially able to do so and agree that providers that have a share in the risk, both positive and negative, may be more motivated to establish collaborative agreements. However, we do not believe that in a model with required participation, any other provider group is consistently as financially positioned to assume risk as is the hospital to which the episode is attributed. We also do not want to mandate a specific division of risk between providers or to direct the specific terms of any collaborator agreements that may be established. We disagree that the current proposal to make hospitals the financially accountable entity undermines the role of the physician, and in providing for a range of collaborator agreements, we hope that EPM participants will actively engage in gainsharing with others. We refer readers to section III.I of this final rule for a fuller discussion of allowable collaborator relationships. We believe that in order to be most successful, hospitals will reach out to other providers to establish agreements with collaborators, although we acknowledge that it may take time to negotiate and establish such arrangements. While some physician groups and post-acute care providers are in a position to take on risk, we continue to believe that many, particularly those in smaller groups and those in more rural areas, are not and, in fact, no commenter suggested that this was the case. Even where the focus of a comment was on providing more opportunities for physicians to assume risk, it was in the context of voluntary models such as BPCI. We appreciate those comments and, in fact, will give precedence to BPCI participants where there is such overlap. Readers are referred to section III.D.6. of this final rule, ''Adjustments for Overlaps with Other Innovation Center Models and CMS Programs,'' which addresses in more detail how situations where there is an overlap between EPMs and other episode based models will be handled. We address in section III.D.6.b.(2). of this final rule, how patients attributed to other physician-centric episode models will be attributed. We also note in section III.A.3 of this final rule opportunities for future alternative payment models which may be more physician-centric. We are committed to testing a number of alternative payment models, many of which may be voluntary and more appropriate for physicians or other providers to assume risk.

Comment: We received a few comments that not only advocated for more flexibility in which entity would be allowed to assume risk for the episode but also suggested that CMS more actively encourage collaboration by providing more specific operational guidance regarding how risk should be shared among different providers. A few commenters noted that financial agreements may not always be feasible. One commenter noted that in markets where physicians, hospitals and post-acute care providers already work well together, the foundation for effective gainsharing arrangements are more likely to be in place. Others noted that some organizations may be willing to share in any savings but not be willing to accept downside risk.

One commenter recommended that CMS require that EPM participants execute gainsharing arrangements with providers to establish a third party entity to receive and distribute reconciliation payments in accordance with the terms of such sharing agreements.

Response: We acknowledge the challenges that some EPM participants may have in establishing effective collaborative agreements. Similarly, we acknowledge the potential challenges that non-hospital providers such as physicians and post-acute care providers may have in getting EPM participants to share risk in a manner that is believed to be equitable to all. However, we do not believe it is appropriate for CMS to either require or establish specific criteria for the terms of such agreements nor to specify how they should be operationalized. We continue to believe, however, that the most successful EPMs will be motivated to engage other providers so that interests and incentives are aligned. We refer readers to section III.I. of this final rule, ''Financial Arrangements under EPM,'' for a full discussion of EPM financial arrangements.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to make hospitals the episode initiators and financially responsible for the episode of care.

4. 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 proposed 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, if we were to limit participation based on volume, 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 the 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 and SHFFT models.

Therefore, given the authority in section 1115A(a)(5) of the Act, which allows the Secretary to elect to limit testing of a model to certain geographic areas, we proposed that the SHFFT model be implemented in those MSAs where the CJR model is being implemented.

We also proposed that the AMI and CABG models be implemented in MSAs selected independently based on the criteria discussed in the proposed rule (81 FR 50815). This would 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 sought 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.

The following is a summary of the comments received and our responses.

Comment: While several commenters explicitly noted concurrence with our proposed method for selecting the MSAs where these models will be implemented, we did receive a few comments related to the selection of areas based on MSAs vs. other geographic units such as CBSAs as well as other recommended criteria upon which to base our selection. We address some of the specific factors in the comments located in this section. Independent of the selection methodology, several commenters requested that CMS publish a list of the hospitals CMS believed were in the selected MSAs and allow hospitals 60 days to comment. Other commenters requested that CMS publish the list of MSAs selected as soon as possible to allow those hospitals impacted additional preparatory time prior to the initial effective date of EPMs. Other commenters emphasized the importance of maintaining beneficiary freedom of choice in selecting where and how to receive care regardless of the beneficiary's geographic residence or the MSAs selected for EPMs.

Response: With regard to MSAs as the geographic unit of selection, we continue to believe, consistent with CJR, that MSAs allow us to observe the impact of the model in a variety of circumstances and provide the best balance between choosing smaller geographic units while still capturing the impact of market patterns reflecting the mobility of patients and providers. We also believe that MSAs limit the potential risk for patient shifting and steerage. As such, we see no reason to change the unit of selection or to be inconsistent with what has already been implemented with CJR. For an in depth discussion of this, we refer the reader to the final CJR rule (42 CFR part 510, 80 FR 73288). We concur that it is important that all participants clearly understand which hospitals will be impacted. Prior to implementation and in conjunction with the publication of this final rule, CMS will publish a list of hospitals that, based on the geographic location associated with the hospital's CMS Certification Number (CCN), we believe are located in the selected MSAs and will be subject to participation in these EPMs. Hospitals identified using this method will have the opportunity to correct any information CMS has on file that may impact whether they are or are not in a selected MSA by contacting *epm@cms.hhs.gov* within 45 days after the publication of the Final Rule. Finally, we concur that beneficiaries continue to have the freedom to choose where they will receive services, regardless of the payment model in place in a particular geographic area. We refer readers to

section III.G. of this final rule, ''Monitoring and Beneficiary Protection,'' for a discussion of these issues.

Comment: A number of commenters expressed concern about implementing the SHFFT EPMs in those MSAs where the CJR model is being implemented. Some commenters expressed concern that we were adding the SHFFT model to the existing CJR model. Other commenters expressed concern that sufficient time had not elapsed to allow hospitals or CMS to learn from their experience. Many believe they needed more time to be able to analyze the results from at least the first year of CJR as well as incorporating findings from the BPCI experience before adding the additional burden of implementing a new model with required participation. While both CJR and SHFFT involve some of the same providers and specialties, some commenters noted that the SHFFT patient population was distinctly different requiring different care pathways and resources. Because of the concern about additional burden on those MSAs where the CJR model has been implemented, some commenters believe that those same MSAs should, therefore, be exempt from implementing the additional cardiac EPMs.

Response: To clarify for commenters, the SHFFT model is separate and distinct from the CJR model although it is designed to run in the same MSAs in which the CJR model is currently operational. We acknowledge the challenges that hospitals implementing CJR may have in order to implement the SHFFT EPM. While recognizing that the patients covered under the SHFFT EPM may be frailer and potentially require different and/or a more intensive level of care, we also continue to believe that SHFFT is similar to CJR in that it involves many of the same specialties and provider types. While there may be different care pathways, we hope that much of the infrastructure and collaborator agreements put in place will provide a solid base upon which to build for SHFFT. As CMS seeks to move away from fee for service payment systems to more value based purchasing, we believe that SHFFT represents a reasonable next step in this transition.

We also acknowledge that in those MSAs where the cardiac EPMs will be alongside CJR and now SHFFT, EPM participants will face additional burdens and challenges. However, we do not believe that it is appropriate to exclude those MSAs where CJR and SHFFT will be implemented from eligibility for selection for the cardiac EPMs. Exclusion of these MSAs would result in a comparative over representation in the cardiac EPMs of lower cost and lower population MSAs due to the manner in which the CJR MSAs were selected. For a full discussion of the criteria for selecting cardiac EPMs, we refer readers to section III.B.5. of this final rule, ''Overview and Options for Geographic Area Selection for AMI and CABG Episodes''. As we move towards more inpatient care being covered under these types of models, we will monitor and evaluate the impact on different types of hospitals implementing multiple EPMs so as to minimize operational burden and improve outcomes.

Comment: Several commenters did not disagree with the use of MSAs specifically, but did note the potential for negative impact on certain hospitals in a model where all hospitals in the MSA providing the covered services are required to participate. This included concern for both high performing regional and national referral centers which may already be providing high quality care at a lower cost as well as hospitals with more limited numbers of eligible discharges and/or those serving at risk populations which often have lower operating margins and thus may be at greater financial risk. These commenters suggested that demographic factors such as age, race, and poverty levels could be used to limit which MSAs were selected.

Response: We acknowledge that some hospitals may face particular challenges in implementing EPMs whether it be due to demographic factors related to their patient base, a lower number of potential EPMs each year, or other factors. A key reason for doing a model with required participation is, in fact, to examine and better understand the impact of a model on a broader range of facility types and communities than are usually included in a voluntary model. Although we do not believe that using specific demographic factors in MSA selection is appropriate, in response to comments on other sections of this rule around risk-adjustment, we are finalizing a timeframe for the implementation of downside risk that allows us time to look carefully at different approaches for recognizing and adjusting for risk in these models which we will discuss via notice and comment rulemaking for FY 2019 and we believe that these actions will help to resolve concerns expressed regarding greater financial risk for high performing regional and national referral centers.

A key rationale for conducting a model with required participation is the ability to examine variations in the impact of the model on a broad range of hospitals in a variety of different market conditions in order to better understand how the model operates in a variety of circumstances. Although demographic factors are not proposed to be part of the selection process for MSAs, we do consider, as noted in the proposed and this final rule, these factors to be important to the proper understanding of the impact of the models and where is more or less successful. The evaluation will consider the suggested demographic domains and other measures in determining which MSAs are appropriate comparison markets as well as for possible subgroup analyses.

Comment: A few commenters suggested eliminating those MSAs that had a higher penetration of Medicare Advantage plans or suggested that we select MSAs that will minimize overlap with BPCI and ACO participating hospitals.

Response: We note in this rule the reasons for aligning the MSAs where the SHFFT EPM will be implemented with those MSAs where the CJR model has already been implemented. In doing so, we accept the exclusion of those MSAs that were excluded from the CJR model due to the limited volume of LEJR procedures performed there.

In the proposed rule we similarly proposed elimination of some MSAs from selection for the cardiac EPMs due to having lower numbers of episodes and having a higher number of episodes covered under the BPCI models. We refer readers to section III.B.5. of this final rule for a full discussion of the selection criteria for MSAs where the cardiac episodes will be implemented.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to implement the SHFFT EPM in those MSAs where the CJR model is being implemented. Further, we are finalizing the proposal to implement the cardiac EPMs in randomly selected MSAs from among all those in the country meeting the criteria specified in section III.B.5. of this final rule.

5. Overview and Options for Geographic Area Selection for AMI and CABG Episodes

We proposed that the AMI and CABG EPMs be implemented together in the same MSAs. These AMI/CABG-participating MSAs may or may not also be CJR/SHFFT–EPM participating MSAs. The selection of MSAs for AMI/CABG EPMs would occur through a random selection of eligible MSAs.

We proposed to require participation in the AMI and CABG models of all hospitals, with limited exceptions as

previously discussed in section III.B.4. of the 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. of the proposed rule (81 FR 50815), to test and evaluate the effects of an episode-based payment approach for the proposed EPMs. We proposed to determine that a hospital is located in an area selected if the hospital is physically located within the boundary of any of the counties in that MSA as of the date the selection is made.

Although MSAs are revised periodically, with counties added or removed from certain MSAs, we proposed 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 proposed 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 final 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 sought 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.

The following is a summary of the comments received and our responses.

Comment: One commenter expressed that implementing the two cardiac EPMs, CABG and AMI, in the same geographic areas would overburden participant hospitals. They stated that the two cardiac conditions are characterized by clinically different populations and require distinct care teams and the opportunities for common care redesign approaches are limited.

Response: We understand the amount of effort required to redesign care processes and that often these are specific to a condition and not always immediately transferrable between conditions. In regards to implementing two cardiac episodes there is an expectation that some economies of scale will present themselves with the cardiac episode-based approaches even though the care teams and patient populations are distinct.

As discussed in section III.C. of this final rule, the 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. Beneficiaries experiencing an AMI can be treated by different clinical modalities including medical management and surgical intervention such as PCI and CABG. The decision as to which treatment is medically appropriate for a given beneficiary is both complex and subject to evolving medical knowledge and practice norms. Furthermore, approximately 30 percent of CABGs are performed during the care of AMIs. Because of the close connection between these two models, CMS believes that testing the AMI and the CABG EPMs in the same markets decreases the probability that clinical decision making regarding the course of treatments would be unduly influenced by inclusion or exclusion in one of the two cardiac EPMs. If the two cardiac EPMs were in different areas, the AMI EPM would be structured in such a way as to include AMIs treated with CABG. Thus, the separation of the two cardiac EPMs into different MSAs would not reduce the burdens associated with hospitals who are simultaneously needing to manage patients treated under a variety of modalities. It would, on the other hand, conceivably increase the complexity of management for participants who would be faced with the situation of having only the 30 percent of CABGs done in conjunction with an AMI included in a model.

Comment: One commenter requested that if a health system had member hospitals within MSAs selected for inclusion in a cardiac EPM that they be allowed to have their member hospitals in non-selected areas also be included in the model. They stated that the ability to have all of their member hospitals in one model would allow for care to be provided under a unified system and would result in increased coordination.

Response: The cardiac EPMs are structured as required models. As such, they will require hospitals within selected geographic areas to participate (unless otherwise excluded as set forth in this final rule). Hospitals who are not in a selected MSA but are part of a health system that includes selected included hospitals will not subject to the EPM rules and incentives structures. However, if a health system wishes to implement certain care coordination activities across their entire spectrum of hospitals they would not be precluded from doing so as long as they comply with current regulations and law. The inclusion of additional hospitals outside of these selected areas would constitute a major change to the model that was not considered in the proposed rule. CMS previously offered solicited participation in the BPCI initiative, a bundled payment model. Please refer to section III.A.3. of this final rule for a discussion of the possibility of future bundled payment models.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to implement the CABG and the AMI EPMs in the same areas, and to 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.

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 some 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 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 models 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 proposed 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 proposed an exclusion rule that MSAs with fewer than 75 AMI episodes (determined as discussed in section III.C. of this final 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 proposed 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 proposed 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 their respective initiatives. 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 threshold of 75 AMI episodes. Consequently, we did not propose 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.

TABLE 1—MSA EXCLUSION RULE STATUS AND ELIGIBILITY FOR SELECTION STATUS FOR INCLUSION IN AMI AND CABG EPMS IN THE PROPOSED RULE

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.

TABLE 1—MSA EXCLUSION RULE STATUS AND ELIGIBILITY FOR SELECTION STATUS FOR INCLUSION IN AMI AND CABG EPMS IN THE PROPOSED RULE—Continued

CBSA_OMB	MSA name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA eligible for selection
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.
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.
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.

TABLE 1—MSA EXCLUSION RULE STATUS AND ELIGIBILITY FOR SELECTION STATUS FOR INCLUSION IN AMI AND CABG EPMS IN THE PROPOSED RULE—Continued

CBSA_OMB	MSA name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA eligible for selection
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.
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.

TABLE 1—MSA EXCLUSION RULE STATUS AND ELIGIBILITY FOR SELECTION STATUS FOR INCLUSION IN AMI AND CABG EPMS IN THE PROPOSED RULE—Continued

CBSA_OMB	MSA name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA eligible for selection
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.
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.
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.

TABLE 1—MSA EXCLUSION RULE STATUS AND ELIGIBILITY FOR SELECTION STATUS FOR INCLUSION IN AMI AND CABG EPMS IN THE PROPOSED RULE—Continued

CBSA_OMB	MSA name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA eligible for selection
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.
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.
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.

TABLE 1—MSA EXCLUSION RULE STATUS AND ELIGIBILITY FOR SELECTION STATUS FOR INCLUSION IN AMI AND CABG EPMS IN THE PROPOSED RULE—Continued

CBSA_OMB	MSA name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA eligible for selection
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.
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.
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.

TABLE 1—MSA EXCLUSION RULE STATUS AND ELIGIBILITY FOR SELECTION STATUS FOR INCLUSION IN AMI AND CABG EPMS IN THE PROPOSED RULE—Continued

CBSA_OMB	MSA name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA eligible for selection
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.
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.

The following is a summary of the comments received and our responses.

Comment: The issue of MSA exclusions was a subject raised by a variety of commenters. Commenters expressed concerns with the possibility of the same MSAs being selected for inclusion in both the cardiac EPMs and in the CJR model. Commenters stated that the introduction of 3 new required models simultaneously in MSAs where CJR is still in the early stages of implementation would divert participants' focus from being able to successfully implement CJR and would pose resource allocation challenges. Commenters stated that hospitals have a limited capacity to successfully take on new models and that hospitals could best achieve success when they are allowed to focus on specific projects. Commenters stated that adding too many required models will result in diluted resources given to each model and increased administrative costs to the hospital. One commenter expressed concern that implementing too many models can compromise both the success of the models and patient care. Commenters requested that CMS add an exclusion rule that removes the CJR MSAs from the possibility of selection as a cardiac EPM area.

Response: We acknowledges the concern of CJR participant hospitals with respect to having the capacity and ability to take on the new cardiac and SHFFT episodes in addition to their current model participation. While recognizing the logistical and resource challenges of implementing multiple models simultaneously, CMS believes that there are commonalities between the models that would result in some efficiencies. For example, experiences in CJR with creating gainsharing approaches, analyzing claims feeds, and understanding reconciliation methodologies will be directly transferable to managing the cardiac episodes.

CMS considered the exclusion of CJR MSAs from the possibility of selection as a cardiac EPM. The effect of removing the CJR MSAs was considered relative to a variety of other considerations including the impact of this removal on the remaining MSAs and whether it would create a biased pool due to the disproportionate removal of areas with high episode payments as well as areas with a larger population.

In determining which areas were eligible for selection for CJR, MSAs were required to have at least 400 LEJRs in the reference year. In contrast, the equivalent exclusion rule for the cardiac EPMs requires at least 75 AMI episodes. These two different rules means that the pool of MSAs eligible for selection as a cardiac EPM contains many smaller MSAs who were not eligible for selection in CJR. Removing the CJR MSA would disproportionately remove larger cities from the selection pool and the pool would be artificially weighted towards MSAs with lower numbers of

cases. The resulting random selection in this pool would similarly be over-weighted to select smaller areas with lower numbers of episodes.

MSAs were selected for inclusion in CJR by dividing MSAs into quartiles based on the MSA average LEJR episode spending. The likelihood of being selected as a CJR area differed between the quartiles such that MSAs in the least expensive quartile had a 30% chance of selection and MSAs in the most expensive quartile had a 45% chance of selection. Thus, the removal of the CJR MSAs from the cardiac EPM selection pool would disproportionately leave relatively more efficient MSAs eligible for selection and remove relatively inefficient areas. In order to quantify the extent of this potential bias, the impact of removing the CJR areas was examined relative to the average MSA spending for AMI episodes. CJR MSAs represented just 12% of MSAs in the least expensive quartile (9 of 74) but represented 26% of the MSAs in the most expensive quartile (19 of 74).

In summary, because the CJR MSAs were proportionately underweighted for more efficient MSAs, and over weighted for more expensive MSAs with higher LEJR episode payments, their removal resulted in introducing bias which would result in the selection of more small cities as well as more efficient cities. This bias to disproportionally select relatively more efficient MSAs is counter to the overall orientation that these models are most likely to result in cost savings in inefficient areas. Furthermore, CMS anticipates that an increase in the probability of selection in smaller cities may also be problematic to commenters, many of whom expressed concern with the ability of hospitals with few cases to succeed under the model.

CMS further notes that a variety of models and efforts are currently underway with the goal of controlling health care costs. While this presents an operationally challenging situation, CMS hopes to be able to assess the extent to which these different models interact and complement (or compete with) one another. The evaluation of CJR and the EPMs will include a systematic look at hospital experiences in regard to model uptake given their range of prior experience, capabilities, and circumstances.

Comment: One commenter recommended the exclusion of MSAs with less than 20 CABG episodes per quarter rather than basing the exclusionary criteria only on AMI volume episode volume.

Response: We continue to 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, and consequently, does not find it appropriate to exclude MSAs on the basis of CABG volume.

Comment: One commenter suggested that MSAs with significant penetration of Medicare Advantage Plans and considerable ACO activity be excluded from the possibility of selection. They stated that the models should be implemented in markets with more limited alternative payment and/or managed care activity. They suggested that the selection of MSAs believed to be fully invested in care design efforts would make it challenging to evaluate whether improvements in efficiency were related to the EPMs or associated with these other efforts. The commenter stated that restricting to MSAs with minimal involvement with other APM would ease both administrative burden and allow for better results and more accurate reconciliation.

Response: While including MSAs with experience in APMs may pose challenges to the evaluation in its effort to assess causation, CMS believes that the exclusion of MSAs who may be relatively more experienced in care redesign and thus more likely to be able to achieve success in the models would be undesirable. It would be considered a positive if participant hospitals are able to leverage the knowledge and experience of experts in their areas in order to successfully reduce episode spending in eligible patients. Experience with care management under managed care or within APMs might be one source of expertise from which participant hospitals may wish to draw. The evaluation of EPMs will include an examination of market characteristics and model activity, so as to explore how the overlapping nature of these two factors impacts performance.

Comment: One commenter expressed the concern that some hospitals act as regional referral centers or may otherwise have a large proportion of the beneficiaries they treat who reside outside of the MSA where the hospital is located. They expressed concern that it would be difficult to manage care for these beneficiaries in the post hospital episode period due to this distance. They requested that MSAs with a significant percent of cases coming from out of the state be excluded from the possibility of selection.

Response: We recognize that many hospitals treat patients from a wide catchment area and that this catchment area may possibly extend beyond the MSA. This situation is particularly relevant to the CABG EPM. The management of the beneficiary's recovery in the post hospital period may be a challenge for some providers. Multiple patient characteristics, including the physical distance between the beneficiary and the hospital, will influence both what type of care redesign approach will be most appropriate and the likelihood that the approach taken will result in improved efficiency and quality. While distance may pose a challenge to improving patient coordination, it is one that many providers have successfully undertaken. Many providers, including regional referral centers, have been able to form and maintain relationships with providers outside their communities.

CMS holds that regional referral centers are a critical component of how CAGB episodes are treated and, as such, are an important part of the cardiac EPM and to gaining an understanding of the ability of such participants to manage patient episodes.

Comment: Commenters expressed concern that low-volume hospitals are included in the models and requested that thresholds be added to remove low-volume providers from the model. Commenters stated that lower volume providers are subject to issues of random variation and that the cost and quality experiences observed in these hospitals may not be due to efficiencies and care coordination. They stated that smaller hospitals will be at a disadvantage due to the inability to achieve stability or predictability due to this variation.

Finally, a commenter noted that they believed that minimum number of applicable cases is necessary for a hospitals to perform internal analyses to determine the appropriate strategies to use to successfully re-engineer care. They stated that having a minimum number of cases is a key factor in whether or not a facility can be ready for undertaking bundled payments. Minimal numbers are necessary for generating adequate levels of involvement in potential partners such as physicians and post-acute care providers. The commenter proposed that the definitions of minimal volume used in the payment methodology be used instead as minimal requirements for hospitals to be required to participate in the cardiac EPMs.

Response: We acknowledge the fact that hospitals, particularly low-volume hospitals, may have limited resources to fully engage in care re-design efforts and, due to the low volume, they are

much more susceptible to wider episode cost fluctuations. We refer readers to the following sections of this final rule III.D.4.b.(9). of this final rule for a discussion of how target prices for hospitals with low volume are determined and to III.D.7.c.(1). of this final rule for a discussion of low volume hospital protections under the cardiac EPMs.

The inclusion of low-volume hospitals in the EPMs is consistent with the goal of evaluating the impact of bundled payment and care redesign across a broad spectrum of hospitals with varying levels of infrastructure, care redesign experience, market position, and other considerations, and circumstances. We are interested in evaluating the experience of these hospitals in the models as part of our overall desire to see the impact of an episode payment model in providers who would not otherwise choose to participate in a model. We would be concerned that setting a threshold for low volume could result in hospital gaming in order to be below that threshold and thus be excluded from the models.

Similar to the CJR model, the design of the EPMs and the inclusion of low-volume providers within the models reflects our interest in testing and evaluating the impact of a bundled payment approach for these procedures in a variety of circumstances, especially among those hospitals that may not otherwise participate in such a test. The inclusion of these providers allows CMS to better appreciate and understand how the models operate as a general payment approach and its impact across a wide range of hospitals. The impact of EPMs on low-volume hospitals is of great interest to the evaluation of these models.

We acknowledge that providers with low volumes of AMI, CABG, or CJR cases may not find it advantageous to engage in an active way with the EPMs. We expect that low volume providers may decide that their resources are better targeted to other efforts because they do not find the financial incentive present in the EPMs sufficiently strong to cause them to shift their practice patterns. We believe this choice is similar in nature to that made as hospitals decide their overall business strategies and where to focus their attentions.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to exclude MSAs that fail one or more of the following rules:

Exclusion Rule 1: Exclude MSAs with fewer than 75 AMI episodes (determined as discussed in section III.C. of this final rule).

Exclusion Rule 2: Exclude MSAs with fewer than 75 non-BPCI AMI episodes in the MSA in the reference year.

Exclusion Rule 3: Exclude MSAs if 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.

As discussed in section III.B.2. of this final rule, the Burlington Vermont MSA was found to no longer be eligible for possible selection because of the Vermont All-Payer ACO Model. Thus, 293 MSAs out of 384 total MSAs are eligible for the possibility of selection as a cardiac EPM area.

b. Selection Approach

We proposed the selection of 98 MSAs for the cardiac EPMs through the use of simple random selection from the 294 (now 293) 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 were 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 the proposed EPMs.

The following is a summary of the comments received and our responses.

Comment: A few commenters expressed general support for the selection approach. Several commenters identified considerations that they believed would increase the likelihood of success in these models and believed that those factors should influence the likelihood of selection.

One commenter believed that the selection methodology used should instead select MSAs where there is unwanted clinical or fiscal variation in care. They stated that the implementation of the cardiac EPMs in these MSAs would be most likely to target patients who would benefit from novel care delivery initiatives. In contrast, another commenter noted that the implementation of the cardiac EPMs in a variety of markets, including those who are relatively more efficient, could help with improving care management/coordination overall.

One commenter mentioned that CMS did not incorporate any MSA-level demographic measures in its selection process, such as distributions of population by age, gender, or race; percent of population dually eligible for Medicare and Medicaid; percent of population with specific health conditions; and other demographic composition measures. They believed these factors vary not only between MSAs, but also by hospitals within an MSA, and could affect a hospital's chances of success in the proposed EPMs.

Response: We appreciate the suggestions of alternative MSA selection criteria and note that we considered whether to disproportionately select higher cost areas. As discussed above, the range of average episode costs between MSAs was relatively narrow and even relatively efficient MSAs would have opportunity for care redesign and increased efficiency under these models. The examination of the distribution of expenses did not seem to indicate that there are substantial pattern of care differences between MSAs that needed to be recognized in the selection methodology.

We acknowledge that demographic factors may indeed influence the ability of hospitals to succeed under the models. However, in creating the EPMs, we are seeking to understand how the models impact costs and quality under a variety of circumstances. We seek to understand if the models work in both more and less challenging circumstances in order to be able to gain an understanding of successes and failures of the episodic payment approach in all types of initiating participants. We did not choose to incorporate MSA level demographics in our selection methodology but instead we are relying on random selection to include MSAs with a variety of circumstances. We did not believe it was necessary to preemptively over-sample areas with a larger percent of vulnerable patients.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to select MSAs for inclusion in the cardiac EPMs by simple random selection.

(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, to participate in both the AMI and CABG EPMs. At the time of the proposed rule 294 MSAs were eligible for selection out of a total of 384 MSAs. 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 proposed 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 a 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 EPMs 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 previously mentioned 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.

The following is a summary of the comments received and our responses.

Comment: One commenter expressed the opinion that the models should be tested in 5 to 10 MSAs rather than be done as a large scale test.

Response: As stated in the proposed rule, we believe that the evidence base related to episode payments is sufficient enough to justify a large scale test and we believe that it is appropriate to size the models so as to be able to generate statistically reliable estimates of the impact as well as to be able to understand how well the models operate in a variety of circumstances.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to select 98 MSAs to participate in the cardiac EPMs.

(3) Method of Selecting MSAs

As previously discussed, we are sought to choose 98 MSAs from our pool of eligible MSAs through simple random selection. We proposed to make the selection in the proposed 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.[39]

We sought 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.

The following is a summary of the comments received and our responses.

Comment: Comments were received from multiple sources that expressed that the list of selected MSAs be published as soon as possible to allow for better preparation for the start of the models. One commenter requested that the list of hospitals in the selected areas also be published and that hospitals be given 60 days to comment on its accuracy. Commenters expressed a preference that, in future rule making of a similar nature, the list of selected MSAs be displayed in the proposed rule rather than the final rule to allow for comment by the impacted MSAs and additional preparation time.

Response: We appreciate the suggestion that MSAs and affected providers be published at the time of rulemaking, and will take it under advisement in any future rule. One of the reasons for not selecting MSAs at the time of the proposed rule was to encourage all potentially impacted providers to comment. In addition, we wished to be able to maintain flexibility that would allow for the creation of new exclusion rules to be suggested in the comment period without necessitating the need to re-select MSAs between the proposed and final rules. In order to accommodate the later announcement of impacted MSAs, we proposed a July 1, 2017 model start. This represents a similar amount of time between the CJR MSA announcement and the start of that model as for the announcement of the cardiac EPM MSAs and the finalization of the SHFFT MSAs and the start of those models.

The list of MSAs selected for the cardiac EPM is included in TABLE 2. The list of hospitals identified as in the MSAs selected for the cardiac EPMs can be found at *https://innovation.cms.gov/initiatives/epm/*. Hospitals believing that they have erroneously been identified as being in a selected area should send an email to *epm@cms.hhs.gov* within 45 days of the publication of the final rule. Hospitals should include identifying information including the hospital CCN. CMS will periodically review and revise the list of hospitals that meet the requirements for participation in the cardiac EPMs and

[39] 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/*.

will update this information on *https://innovation.cms.gov/initiatives/epm/.*

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification. We selected the participating MSAs for the CABG and AMI EPMs through simple random selection. SAS for Windows Version 9.4 software was used to run a computer algorithm designed to randomly select MSAs. SAS for Windows Version 9.4 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. The random number seed utilized was 19730609.

The MSAs selected for inclusion are shown in TABLE 2.

TABLE 2—MSAS SELECTED TO PARTICIPATE IN THE CARDIAC EPMS

CBSA_OMB	MSA name	CJR selected MSA?
10180	Abilene, TX.	
10420	Akron, OH	yes.
10780	Alexandria, LA.	
10900	Allentown-Bethlehem-Easton, PA-NJ.	
11260	Anchorage, AK.	
12100	Atlantic City-Hammonton, NJ.	
12220	Auburn-Opelika, AL.	
12420	Austin-Round Rock, TX	yes.
13380	Bellingham, WA.	
13460	Bend-Redmond, OR.	
14020	Bloomington, IN.	
14260	Boise City, ID.	
14460	Boston-Cambridge-Newton, MA-NH.	
15940	Canton-Massillon, OH.	
15980	Cape Coral-Fort Myers, FL.	
16020	Cape Girardeau, MO-IL	yes.
16300	Cedar Rapids, IA.	
16700	Charleston-North Charleston, SC.	
16860	Chattanooga, TN-GA.	
16980	Chicago-Naperville-Elgin, IL-IN-WI.	
17020	Chico, CA.	
17660	Coeur d'Alene, ID.	
17860	Columbia, MO	yes.
17900	Columbia, SC.	
17980	Columbus, GA-AL.	
18880	Crestview-Fort Walton Beach-Destin, FL.	
19100	Dallas-Fort Worth-Arlington, TX.	
19300	Daphne-Fairhope-Foley, AL.	
19740	Denver-Aurora-Lakewood, CO	yes.
19780	Des Moines-West Des Moines, IA.	
20100	Dover, DE.	
20500	Durham-Chapel Hill, NC	yes.
21060	Elizabethtown-Fort Knox, KY.	
21500	Erie, PA.	
21660	Eugene, OR.	
22520	Florence-Muscle Shoals, AL.	
22660	Fort Collins, CO.	
23060	Fort Wayne, IN.	
23580	Gainesville, GA	yes.
24300	Grand Junction, CO.	
24860	Greenville-Anderson-Mauldin, SC.	
25940	Hilton Head Island-Bluffton-Beaufort, SC.	
26580	Huntington-Ashland, WV-KY-OH.	
26820	Idaho Falls, ID.	
26900	Indianapolis-Carmel-Anderson, IN	yes.
26980	Iowa City, IA.	
27620	Jefferson City, MO.	
27860	Jonesboro, AR.	
27900	Joplin, MO.	
28020	Kalamazoo-Portage, MI.	
28140	Kansas City, MO-KS	yes.
28420	Kennewick-Richland, WA.	
29100	La Crosse-Onalaska, WI-MN.	
29420	Lake Havasu City-Kingman, AZ.	
29460	Lakeland-Winter Haven, FL.	
29620	Lansing-East Lansing, MI.	
30460	Lexington-Fayette, KY.	
30620	Lima, OH.	
30780	Little Rock-North Little Rock-Conway, AR.	

TABLE 2—MSAS SELECTED TO PARTICIPATE IN THE CARDIAC EPMS—Continued

CBSA_OMB	MSA name	CJR selected MSA?
31540	Madison, WI	yes.
31700	Manchester-Nashua, NH.	
32780	Medford, OR.	
32820	Memphis, TN-MS-AR	yes.
33340	Milwaukee-Waukesha-West Allis, WI	yes.
33540	Missoula, MT.	
34820	Myrtle Beach-Conway-North Myrtle Beach, SC-NC.	
34980	Nashville-Davidson-Murfreesboro-Franklin, TN	yes.
35100	New Bern, NC.	
35660	Niles-Benton Harbor, MI.	
36420	Oklahoma City, OK	yes.
36540	Omaha-Council Bluffs, NE-IA.	
39140	Prescott, AZ.	
39380	Pueblo, CO.	
39580	Raleigh, NC.	
39660	Rapid City, SD.	
39740	Reading, PA	yes.
39900	Reno, NV.	
40060	Richmond, VA.	
40220	Roanoke, VA.	
41100	St. George, UT.	
41140	St. Joseph, MO-KS.	
41420	Salem, OR.	
41500	Salinas, CA.	
42340	Savannah, GA.	
43300	Sherman-Denison, TX.	
44060	Spokane-Spokane Valley, WA.	
44100	Springfield, IL.	
46060	Tucson, AZ.	
46140	Tulsa, OK.	
46220	Tuscaloosa, AL	yes.
46540	Utica-Rome, NY.	
47940	Waterloo-Cedar Falls, IA.	
48300	Wenatchee, WA.	
48620	Wichita, KS	yes.
48900	Wilmington, NC.	
49180	Winston-Salem, NC.	
49660	Youngstown-Warren-Boardman, OH-PA.	
49740	Yuma, AZ.	

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 episode; and (2) a time dimension that describes the beginning, middle, and end of the episode.

2. Overview of Three Episode Payment Models

We proposed three new EPMs—AMI, CABG, and SHFFT—that each begin with a hospitalization and extend 90 days after hospital discharge. The proposed AMI model 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 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 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.[40] Although PCIs can be performed and

[40] Amsterdam et al. 2014 AHA/ACC Guideline for the Management of Patients with Non-ST-Elevation Acute Coronary Syndromes. Circulation. 2014; 130:e344–e426.

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.[41] 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 2017 OPPS final rule with comment period that is posted on the CMS Web site.[42] 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 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.[43] In the case of procedural episodes such as CABG, SHFFT, and AMI 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.[44] Therefore, we proposed 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 Episodes

As we stated in the CJR 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 proposed 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).

The following is a summary of the comments received and our responses:

Comment: Many commenters expressed support for CMS' proposal to use many of the BPCI Model 2 and CJR episode parameters to define EPM episodes because of the provider experience to date with these design features and their applicability to the clinical conditions that are the basis of the EPMs. Several commenters specifically recommended that CMS begin EPM episodes with emergency department care because including beneficiaries with emergency department care and observation status would include all beneficiaries with the clinical conditions that were included in the proposed EPMs. While the commenters acknowledged that many beneficiaries with the clinical conditions in the EPMs would be admitted to the hospital, they believe there is a subset of beneficiaries for whom care could solely be furnished through emergency department and observation care. Other commenters requested clarification on how a beneficiary treated in observation status and then transferred to another hospital would be handled under the EPMs because the beneficiary would never be assigned to an MS–DRG at the initial treating hospital. The commenters believe that a hospital could use this strategy to avoid including high-cost beneficiaries in the EPMs. The commenters stated that patient stabilization is critical and the resources needed to care for the beneficiary should not dictate observation status versus inpatient status due to a hospital participation in an EPM. Several commenters encouraged CMS to provide additional guidance on instances when the beneficiary is never admitted at the initial hospital, but rather transferred from the emergency department or observation status to another hospital for AMI or CABG.

One commenter recommended that CMS modify the Episode Grouper for Medicare (EGM) which, to date, has only been considered for resource-use measurement, to implement advanced APMs designed around EPMs to correct problems the commenter believes would be present in the proposed EPMs that would rely on MS–DRGs, including limited severity adjustment, the limits on who can bear risk, and the inadequate incentives against complications. The commenter claimed that an acute care bundle in the hospital setting is important, but so is managing chronic conditions in an outpatient setting (which often lead to acute inpatient episodes). While contracting for condition episodes and procedure episodes separately is feasible and creates a different level of accountability, the commenter stated that it is even more desirable to consider contracting for the whole patient; that is, procedure episodes should be considered downstream events deeply tied to the effective management of condition episodes. The commenter stated that the nested construction logic of the EGM was designed with this in mind.

A commenter contended that the proposed structure for the new EPM episodes would continue to reward providers for complications. Payments would be based on the beneficiary's assigned MS–DRG, so a complication of care could move a low risk patient from a lower paying MS–DRG to a higher paying MS–DRG that could result in a

[41] 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 the proposed rule, that end in CY 2014.

[42] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1656-FC.html.*

[43] 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.*

[44] 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.*

significant increase in revenue. The commenter believes the problem is further compounded because it penalizes providers who invest in quality improvement. Providers that invest time and resources into care redesign that successfully reduces complications that influence MS–DRG assignment do not share in the savings that they generate through their efforts. The commenter stated that the MS–DRG payment categorization creates a substantial financial incentive to avoid quality improvement in favor of focusing on improving the management of adverse events after they occur. The commenters stated that the benefit of using MS–DRG assignment in the EPMs could be preserved without the perverse incentive if the payment group for the episode were assigned based on an MS–DRG assignment that depended only on diagnosis codes that were present on admission.

Another commenter claimed that MS–DRGs do not map well to care delivered in post-acute care settings, especially for chronically ill beneficiaries. MS–DRGs, in identifying diagnoses and procedures delivered in the acute care hospital setting, often do not relate to the skilled nursing needs, functional limitations, or therapy/rehabilitation focused on in post-acute care settings after hospital discharge. Additionally, the commenter pointed out that MS–DRGs do not take into account a patient's functional status, which is an important indicator for determining a patient's post-acute care needs. The commenter recommended CMS to develop a more robust risk adjustment methodology under the EPMs, because MS–DRGs alone are not sufficient for medically complex patients. For those providers caring for the sickest beneficiaries, the commenter recommended that CMS create separate bundled payments for seriously ill beneficiaries, as defined by something other than MS–DRG.

Response: We appreciate the support that many commenters expressed for our proposal to identify Medicare beneficiaries included in the proposed EPMs by their admission to an acute care hospital for a hospitalization paid under EPM-specific MS–DRGs under the IPPS. We and many stakeholders have gained substantial experience with bundled payment models of a similar design under BPCI Model 2 and the CJR model. We agree with the many commenters who stressed the importance of EPM participants being able to identify EPM beneficiaries on a timely basis as early as possible during the episodes in order to maximize the opportunities for care redesign to improve EPM episode quality and reduce costs. As we discussed in the proposed rule (81 FR 50813), we believe that a straightforward approach to EPM model design that would allow 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, and agree with many commenters that our proposed design of the EPMs meets these objectives.

While we acknowledge the perspective of some commenters that a small number of beneficiaries with clinical conditions that are the focus of the EPMs, especially AMI, may be appropriately treated in the emergency department with observation status without hospital admission, we believe it is infeasible to include these beneficiaries in the EPMs due to complex operational challenges for CMS and EPM participants and model design parameters, such as appropriate pricing in the context of varied hospital cardiac care capabilities. We refer to section III.C.4.a.(1) of this final rule for further discussion of comments on outpatient treatment scenarios and our responses. We refer to section III.C.4.a.(5) of this final rule for discussion of outpatient-to-inpatient (o–i) transfer scenarios for beneficiaries with AMI, including when AMI episodes would begin and to which hospital the episode would be attributed. We agree with the commenters that patient stabilization of serious conditions such as AMI in the emergency department of a hospital is critical and the resources needed to care for the beneficiary should not dictate observation status versus inpatient status due to a hospital participation in an EPM. We believe our final EPM policies, including our AMI model transfer policies, reflect our commitment to ensuring that the initial care of beneficiaries with urgent conditions such as those targeted by the EPMs is not influenced by hospital participation in an EPM. We also refer to sections III.G.4. through 6. of this final rule for discussion of our monitoring plans to detect changing patterns of care under the EPMs, including practices that could indicate that medically complex beneficiaries who otherwise would be expected to be in high-cost EPM episodes do not initiate EPM episodes.

While we have an interest in future condition-specific episode payment models and sought public comment on this topic in the proposed rule (81 FR 50810 through 50811), we have not identified long-term management of beneficiaries with chronic disease as the focus of these EPMs, which are proposed to extend 90 days post-hospital discharge from an anchor hospitalization for beneficiaries who have cardiac or orthopedic surgery or a cardiac event.

As one commenter pointed out, MS–DRGs currently provide higher payments for beneficiaries who experience complications during the inpatient hospitalization and we appreciate the interest of the commenter in EPMs that encourage improvement in quality of care during the anchor hospitalization for which hospitals would be rewarded. However, given the operational challenges that EPMs that require participation present for EPM participants and CMS, it would be infeasible in models like the EPMs to regroup beneficiaries to different MS–DRGs for setting EPM episode prices based only on their diagnoses that were present on admission to address underlying payment incentives under the IPPS. Instead, the EPMs focus EPM participants on care redesign to improve the quality of care for EPM beneficiaries that may achieve internal hospital cost savings for the anchor hospitalization and/or savings to Medicare in the post-hospital discharge period. We expect that some of those care redesign strategies that improve care coordination for EPM beneficiaries may have spill-over effects that result in reduced in-hospital complications as well.

Finally, we refer to section III.D.4.b.(2) of this final rule for a discussion of risk adjustment under the EPMs. Because all EPM participants care for some seriously ill beneficiaries, some hospitals may disproportionately care for such beneficiaries due to their service area, referral patterns, and/or specialized hospital capacity. We believe appropriate risk adjustment of EPM episode prices, particularly by performance year 3 when the pricing blend shifts to reflect predominantly regional pricing, addresses the commenter's concern that led them to recommend that CMS create separate bundled payments for seriously ill beneficiaries as defined by something other than MS–DRG for those providers caring for the sickest patients. While we agree with the commenter that MS–DRGs only reflect the resources for the anchor hospitalization and, therefore, do not necessarily reflect the post-acute care resources required by a beneficiary, we note that the IPPS payment for the anchor hospitalization is included in the EPM episode and constitutes, on average, a significant percentage of the EPM episode spending, specifically 33

percent of AMI episode spending for episodes anchored by AMI MS–DRGs; 58 percent of AMI episode spending for episodes anchored by PCI MS–DRGs; 63 percent of CABG episode spending; and 27 percent of SHFFT episode spending.[45] Thus, we do not believe it is necessary or appropriate to create separate bundled payments for seriously ill beneficiaries defined by a grouping other than MS–DRG, because the specific MS–DRG of the anchor hospitalization determines a significant percentage of spending for the episode for EPM beneficiaries, including seriously ill beneficiaries.

Comment: Several commenters expressed concern about EPM participants' ability to identify EPM beneficiaries on a timely basis. The commenters explained that the final MS–DRGs assigned to the beneficiary's hospitalization is not generated until several days post-discharge, thus impacting the EPM participant's ability to predict whether a beneficiary is in or out of an EPM episode at the time the beneficiary is in the hospital. One commenter added that because the MS–DRG is assigned to a patient's case upon discharge, it may not be predictable during a patient's treatment prior to discharge, making it difficult for providers to implement care redesign targeted to a patient population identified by MS–DRGs. This commenter believes that the MS–DRGs assigned to a patient's stay are often inaccurate or otherwise inappropriate for the patient's diagnosis, making the classification an inappropriate basis for episode triggers, budgets, quality measurement and adjusting for underlying patient illnesses. Another commenter reported on their BPCI Model 2 experience where 70 percent of model beneficiaries were elective admissions, and 30 percent presented to the hospital through the emergency department. Given that the proposed EPMs would be more similar to the commenter's experience with emergency department admissions, the commenter expressed concern that the EPMs would limit an EPM participant's ability to intervene with the beneficiary prior to admission and skepticism that the participant could even identify the beneficiary as being eligible for the EPM prior to hospital discharge. The commenter added that with very sick patients, hospitals often must wait for the appropriate coding to confirm which MS–DRG the patient ultimately is assigned to prior to billing.

Several commenters further stated that precedence rules among different models and programs can touch the same beneficiary, and stated that hospital case managers, nurses, and administrators cannot know at admission or even before discharge which model the beneficiary may already be enrolled in or attributed to based on prior utilization.

Response: We appreciate the interest of the commenters in the timely identification of EPM beneficiaries that would allow EPM participants the most significant opportunity to influence the care of these beneficiaries to improve the quality and reduce the cost of EPM episodes. While we appreciate that many EPM beneficiaries would be admitted to the hospital on an emergency basis for treatment of hip fracture, AMI, or CABG surgery under circumstances that would not allow EPM participants to engage these beneficiaries prior to hospital admission, we believe that our proposals for the clinical conditions in the EPMs make identification of most EPM beneficiaries unambiguous while they are still in the hospital, without a need for hospitals to wait for coding following discharge to confirm which MS–DRG the patient ultimately is assigned to for the hospitalization.

As we stated in the proposed rule (81 FR 50829), we agree with the commenters that hospitals' ability to identify EPM beneficiaries during the anchor hospitalization is an important consideration in developing episode payment models that rely upon MS–DRG assignment for IPPS claims following their submission in order to identify beneficiaries for model inclusion. We believe the identification of SHFFT and CABG model beneficiaries should be straightforward for EPM participants because the relevant MS–DRG assignments directly result from the surgical procedure performed during the hospitalization and would, therefore, be accurate. However, identification of beneficiaries for a model focused on medical management of conditions may be more challenging because the predictability of the ultimate MS–DRG for the hospitalization is less certain than for surgical or procedural MS–DRGs. We believe that AMI represents a relative exception among medical conditions as it is associated with specific clinical and laboratory features that should enable hospitals to identify beneficiaries with AMI during the anchor hospitalization who are treated medically or with PCI and who would likely be included in an AMI episode through their ultimate discharge under an AMI MS–DRG. Therefore, we proposed 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 generally 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.

We refer to section III.D.6.c. of this final rule for discussion of issues related to beneficiaries whose care could be included in the EPMs as well as other CMS models and programs.

Comment: One commenter expressed appreciation for CMS' intent to not have overlap between the same care for a beneficiary in episodes under more than one EPM. The commenter sought clarification about how CMS would attribute episodes that originate with one EPM and then cross over into another EPM. The commenter provided an example of a beneficiary with a surgical hip fracture who has an AMI during the hospitalization that is coded in a secondary position, yet the precipitating event for the hip fracture was through syncope and a fall.

Response: When an IPPS claim is submitted to Medicare for payment of a beneficiary's hospitalization, the claim is grouped to an MS–DRG using the MS–DRG grouper, a software that uses ICD–10–CM diagnosis and procedures codes submitted on the hospital claim to assign an acute hospital stay to a particular MS–DRG. Claims are assigned to an MS–DRG using the grouper effective for the discharge date of the claim. Under the EPMs, regardless of the chronology and causality of events that led to the diagnoses and treatment during the hospitalization, we would rely upon the MS–DRG (and the presence of an ICD–10–CM AMI diagnosis code on the claim in the case of a PCI MS–DRG) assigned to the claim following hospital discharge to initiate an EPM episode and define the EPM to which the beneficiary's care would be attributed. In the commenter's example in which a patient is admitted to a hospital for surgical hip fracture fixation and has an AMI during the hospitalization, the MS–DRG grouper would assign a SHFFT MS–DRG to that hospitalization. Therefore, the beneficiary would initiate a SHFFT episode if the hospital is a SHFFT model participant. Regardless of

[45] 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 the proposed rule that began in CYs 2012–2014.

whether or not the hospital is an AMI model participant, no AMI episode would be initiated.

Final Decision: After consideration of the public comments received, we are finalizing the proposal to initiate EPM episodes by an admission to an acute care hospital for an anchor hospitalization paid under EPM-specific MS–DRGs under the IPPS, without modification. We refer to section III.D.4.a.(5) of this final rule for a discussion of outpatient-to-inpatient and inpatient-to-inpatient transfers between hospitals under the AMI model. We refer to section III.D.6.c of this final rule for further discussion of issues related to overlap of beneficiaries in other Innovation Center models and CMS programs.

a. Definition of the Clinical Conditions Included in AMI, CABG, and SHFFT Episodes

(1) AMI (Medical Management and PCI) Model

We proposed 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 proposed 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.'' [46] We proposed 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 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 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.

In the proposed rule (81 FR 50830), we acknowledged that this proposal to identify beneficiaries included in the AMI model through a combination of MS–DRGs and AMI ICD–CM diagnosis codes represented a modification of the CJR 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 episodes would be 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 episodes, we proposed to exclude beneficiaries discharged under PCI MS–DRGs with an AMI ICD–9–CM diagnosis code in the principal or secondary position if there was 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 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 proposed to define historical AMI episodes for beneficiaries discharged under PCI MS–DRGS 246–251 as those that do not include the ICD–9–CM procedure codes in Table 3. These codes were also posted on the CMS Web site at *https://innovation.cms.gov/initiatives/epm.*

[46] *http://www.cdc.gov/nchs/data/icd/icd10cm_guidelines_2014.pdf.*

TABLE 3—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 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.
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 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.[47] 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 further note that CMS' 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 performance years of the model, are displayed in Table 5. The proposed 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.[48] This number was 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 did not result in historical episodes when a beneficiary did not meet the beneficiary care inclusion criteria discussed in section III.C.4.a.(1) of the proposed rule (81 FR 50834); was not discharged alive from PCI MS–DRGs 246–251; was discharged from a transfer hospital during a chained anchor hospitalization; or was discharged from a readmission during an AMI episode that did not initiate new model episodes.

The 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 would be included in the AMI episodes were discussed in section III.C.4.a.(2) of the proposed rule (81 FR 50834 through 50835). 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 proposed implementing the following sub-regulatory process, which mirrors the sub-regulatory process as described in the CJR Final Rule for updating hip fracture ICD–9–CM and ICD–10–CM diagnosis codes (80 FR 73340) and for updating the exclusion list (80 FR 73305 and 73315). We proposed 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 proposed 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 proposed to then post a list of potential AMI ICD–10–CM diagnosis codes to the CMS Web site at *https://innovation.cms.gov/initiatives/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 were included in proposed § 512.100(c)(1) and (d), respectively. We sought comment on our proposals to identify beneficiaries included in the AMI model and the sub-regulatory process for updating the AMI ICD–10–

[47] 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.

[48] 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 the proposed rule that began in CYs 2012–2014.

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 was an ICD–9–CM intracardiac procedure code on the claim was included in proposed § 512.100(d)(4). We sought 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 was an ICD–9–CM intracardiac procedure code on the claim.

We received no comments on the proposed sub-regulatory process for updating the AMI ICD–10–CM diagnosis code list. The following is a summary of the comments received on the other AMI model proposals to define the included clinical conditions and our responses.

Comment: Several commenters expressed concern that the AMI model would be so heavily reliant upon coding that creates an artificial clinical population which is so heterogeneous as to make clinical care redesign efforts nonspecific and likely ineffective. They contended that while EPMs based on surgical MS–DRGs streamline patient identification and inclusion, the AMI model would depend on multiple levels of coding, both ICD–10–CM and MS–DRGs. One commenter explained that an important distinction between medical diagnosis and procedural-based episode-of-care models is that medical diagnosis models tend to involve a patient population of greater complexity, often with life-threating conditions. The commenter believes that, where appropriate, this awareness should be reflected in the design of the EPMs. The commenters were concerned that the proposed AMI model would put a greater emphasis on coding methodologies and increase the chance of disparities between cases identified by each responsible hospital for inclusion in the AMI model versus cases identified by CMS from historical claims data upon which quality-adjusted target prices would be based. The commenters stressed the need for CMS to establish clinical homogeneity in the AMI model, limiting ambiguity as much as possible.

Several commenters recommended CMS to use ICD–10–CM coding strategies to limit inclusion of AMI model beneficiaries to the most clinically similar subset of beneficiaries in order to allow for meaningful comparisons and ultimately provide CMS the opportunity to clearly evaluate the impact of the AMI model on patient care and outcomes. The commenters stated that with the move from ICD–9–CM to ICD–10–CM, the coding stages associated with AMI have changed, warranting additional considerations. Specifically, a number of commenters recommended that CMS limit the AMI model to beneficiaries with ST-elevation myocardial infarction (STEMI) discharged under AMI MS–DRGs and PCI MS–DRGs with an AMI ICD–10–CM code only in the principal diagnosis code position on the inpatient claim. The commenters claimed that while STEMIs occur due to an acute coronary artery occlusion, many non-ST elevation (NSTEMI) beneficiaries with AMI experience open coronary arteries but there is an imbalance between the oxygen demands of the heart and the coronary arteries' ability to meet them. The commenters added that due to these substantial differences in the underlying pathophysiology of STEMI and NSTEMI AMI patients that lead to more variation in clinical presentation in NSTEMI patients, in addition to the different approaches to their evaluation and management, the AMI model should only include STEMI beneficiaries which, when risk adjustment is applied, represent a more homogenous population compared to NSTEMI patients.

These commenters presented the most current consensus driven definition of AMI, the third universal definition, as: ''Evidence of myocardial necrosis consistent with acute myocardial ischemia. Under these conditions, any one of the following criteria meets the diagnosis for MI:

- Detection of a rise and/or fall of cardiac biomarker values, preferably cardiac troponin with at least one value above the 99th percentile upper reference limit; and at least one of the following:
- Symptoms of new ischemia;
- New or presumed new significant ST-segment-T wave (ST–T) changes or new left bundled branch block (LBBB);
- Development of pathological Q waves in the ECG;
- Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality; and
- Identification of an intracoronary thrombus by angiography or autopsy.'' [49]

The commenters recommended CMS to clearly define AMI for the EPM because they claimed that currently what is coded as AMI often only meets this definition in part and may be limited to abnormal biomarkers that can be detected without an acute occlusion of a coronary artery. Aligning coding with clinical reality is necessary for establishing clinical homogeneity in the AMI model. The commenters believe that including in the AMI model beneficiaries not only with a principal but a secondary diagnosis of AMI would make it difficult to establish a clearly defined clinically homogeneous population for the following reasons:

- Critically ill patients often receive a secondary diagnosis of AMI for what is more correctly characterized as supply-demand ischemia due to the routine and inaccurate coding of any troponin leak or elevation as an AMI, despite the absence of a clinical event suggestive of infarction. The commenters provided examples such as a beneficiary with metastatic breast cancer and internal bleeding who exhibits a slight cardiac troponin leak or a beneficiary with multi-organ failure, stating that the root cause of small elevation of troponin in these cases would be the underlying condition, not CAD. They also claimed that elderly patients with heart failure or rapid atrial fibrillation may have a secondary AMI ICD–CM diagnosis, yet the heart failure or atrial fibrillation would drive decisions about care, not the AMI.
- Outcomes and cost-of-care for critically ill patients with a secondary AMI diagnosis are likely driven more by the primary condition than by AMI resulting from possible CAD.
- Patterns of care are very different for patients with a secondary, as compared to a principal, diagnosis of AMI; and
- Including patients with a secondary diagnosis of AMI increases the variability within the AMI model, limiting opportunity to draw clear conclusions when testing the model.

One commenter requested that CMS account for beneficiaries with AMI who do not have a traditional AMI but coding results in discharge under an AMI MS–DRG by specifying a concrete list of ICD–10–CM codes that, if included on a claim for a beneficiary discharged under an AMI MS–DRG from an AMI model participant, would exclude the beneficiary from the AMI model.

Response: We appreciate the suggestions of the commenters that we include a more homogeneous group of beneficiaries in the AMI model by limiting the model to those beneficiaries with a STEMI ICD–CM diagnosis code in the principal position on the claim for the anchor hospitalization. Under our proposal to include all beneficiaries

[49] Thygesen K., Alpert J.S., Jaffe A.S., et al and the Writing Group on behalf of the Joint ESC/ACCF/AHA/WHF Task Force for the Universal Definition of Myocardial Infarction. Circulation. 2012;126:2020–2035.

in the AMI model discharged from AMI MS–DRGs and beneficiaries discharged from PCI MS–DRGs with an AMI ICD–CM diagnosis code listed in Table 3 (the codes we are finalizing are listed in Table 4) in the principal or a secondary position on the inpatient claim for the anchor hospitalization, all of the diagnosis codes except 410.71 (Subendocardial infarction, initial episode of care) in ICD–9–CM and 121.4 (Non-ST elevation (NSTEMI) myocardial infarction) and 122.2 (Subsequent non-ST elevation (NSTEMI) myocardial infarction) are for STEMI diagnoses. We analyzed historical AMI episodes from 2012–2014 and found that about 78 percent of episodes were for NSTEMI, while 22 percent were for STEMI.[50] There are well-established clinical guidelines for the management of beneficiaries with both NSTEMI and STEMI, and the clinical care pathways generally differ for these beneficiaries.[51] [52] However, to limit the AMI model to beneficiaries with STEMI only, the minority of beneficiaries with AMI whose care is less varied, and exclude beneficiaries with NSTEMI, the majority of beneficiaries with AMI whose care is more varied and highly dependent on the beneficiary's risk factors for adverse outcomes, would miss a substantial opportunity to test an EPM for a large proportion of Medicare beneficiaries with AMI. We believe there are substantial opportunities for care redesign under the AMI model to improve the quality and efficiency of episode care for both NSTEMI and STEMI patients so we will not limit the model to one subgroup of beneficiaries hospitalized for treatment of AMI. In response to the commenters who were concerned that including beneficiaries with NSTEMI and STEMI in the AMI model could interfere with CMS' ability to evaluate the impact of the AMI model on patient care and outcomes, we note that as discussed in section IV. of this final rule, we will examine the impact of the AMI model on subgroups of beneficiaries to better understand variations in payments and outcomes within and between hospitals. The identification of subgroups to be examined will include a variety of key clinical and demographic factors.

We also analyzed the distribution of AMI ICD–9–CM diagnosis codes for FY 2014 discharges from AMI and PCI MS–DRGs (ICD–10–CM was not in use in that year) in the principal versus secondary position for beneficiaries who would be included in the AMI model under our proposal because of their assignment to an AMI MS–DRG or to a PCI MS–DRG.[53] We found that 94 percent of historical episodes assigned to PCI MS–DRGs had an AMI ICD–9–CM diagnosis code in the principal position. Of those episodes with an AMI ICD–9–CM diagnosis code in the secondary position, the most common principal diagnoses were 996.72 (Other complications due to other cardiac device, implant, and graft) and 414.01 (Coronary atherosclerosis of native coronary artery), which constituted 53 percent of cases with an AMI ICD–9–CM diagnosis code only in a secondary position, while the remaining episodes had one of over 200 different ICD–9–CM diagnoses codes in the principal position. In addition, we found that 86 percent of episodes assigned to AMI MS–DRGs had an AMI ICD–9–CM diagnosis code in the principal position. Of those cases with an AMI ICD–9–CM diagnosis code in the secondary position, the most common principal diagnoses in descending order of frequency were 428.23 (Acute on chronic systolic heart failure); 427.31 (Atrial fibrillation); 428.33 (Acute on chronic diastolic heart failure); 428.43 (Acute on chronic combined systolic and diastolic heart failure); 428.0 (Congestive heart failure, unspecified); and 428.21 (Acute systolic heart failure). These diagnoses constituted 62 percent of cases with an AMI ICD–9–CM code only in a secondary position, while the remaining episodes had one of over 200 different, but primarily cardiac, ICD–9–CM diagnoses codes in the principal position. We note that the diagnosis code patterns we observed did not confirm the views of some commenters that beneficiaries with underlying non-cardiac disease and a troponin leak, such as a metastatic breast cancer with internal bleeding, would be included in the AMI model based on our proposal. However, the AMI model would include some beneficiaries discharged from AMI MS–DRGs with significant underlying cardiac conditions such as heart failure and atrial fibrillation in the principal diagnosis code position, another example provided by some commenters.

ICD–CM diagnosis coding does not rely on clinical definitions; it is the physician who is responsible for documenting the patient's diagnosis. In other words, coders cannot determine if a patient suffered an AMI based on cardiac biomarkers. If the physician documents an AMI, then the coder is required to report the ICD–10–CM code describing the type of AMI. The coder does not interpret the troponin levels of a beneficiary.

Based on our analysis of historical claims and the established rules for medical coding, we believe that it is appropriate to include the small percentage of beneficiaries with an ICD–CM AMI diagnosis code only in the secondary position upon discharge from AMI and PCI MS–DRGs in the AMI model because the principal diagnoses on these claims generally represent beneficiaries with coronary obstruction. The secondary AMI diagnosis on the claim would have resulted from a physician diagnosis of AMI which, as the commenters stated, should be represented by changes in cardiac biomarker values and at least one other characteristic of a specified list. In addition to representing a reasonably homogeneous population, we believe this approach provides an unambiguous definition for AMI model participants to use to identify beneficiaries discharged from PCI MS–DRGs who would be in the AMI model. Because the model is focused on a condition, AMI, rather than a procedure, and some beneficiaries admitted for PCI will not have an AMI, it is necessary for PCI MS–DRGs to pair ICD–CM diagnosis codes with the MS–DRG to identify AMI model beneficiaries.

While we observed that 14 percent of beneficiaries assigned to AMI MS–DRGs only had an AMI ICD–9–CM diagnosis code in the secondary position and most commonly another cardiac diagnosis in the principal position, this group is a small minority of beneficiaries discharged from AMI MS–DRGs. We do not believe that it is necessary to exclude these beneficiaries from the AMI model for purposes of clinical homogeneity because the beneficiaries should have had an AMI documented by a physician for an AMI diagnosis

[50] 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.

[51] 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.

[52] 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.

[53] 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.

code to be included in a secondary position on the hospital claim. We further observed from our analysis of FY 2014 claims for discharges from AMI MS–DRGs that those beneficiaries with an AMI ICD–9–CM code in the principal position commonly had similar cardiac diagnoses (for example, atrial fibrillation and heart failure) as those beneficiaries where the order of diagnosis coding was reversed.[54] Care coordination and management of other cardiac conditions which would be included in the AMI episode definition as discussed in section III.C.3.b. of this final rule would be common for beneficiaries discharged from AMI MS–DRGs, regardless of whether AMI is the principal or a secondary diagnosis on the hospital claim that led to the beneficiary's discharge from an AMI MS–DRG. Therefore, limiting the AMI model beneficiaries only to those assigned to AMI MS–DRGs based on a principal diagnosis code of AMI would not significantly increase clinical homogeneity of those AMI model beneficiaries discharged after medical treatment for AMI. Moreover, to exclude beneficiaries discharged from AMI MS–DRGs with an AMI ICD–9–CM diagnosis code only in a secondary position on the hospital claim from the model could substantially complicate timely EPM participant identification of the beneficiaries in the model by including only a subset of beneficiaries assigned to AMI MS–DRGs upon discharge. Thus, we do not believe it is necessary for AMI MS–DRGs to pair AMI ICD–CM diagnosis codes with the MS–DRG to identify AMI model beneficiaries.

Comment: In addition to the commenters who recommended that CMS apply specific coding strategies to increase clinical homogeneity of beneficiaries in AMI episodes, other commenters recommended that CMS exclude a variety of beneficiaries who would otherwise meet the proposed AMI model criteria for inclusion. Some commenters further recommended CMS to make a pricing adjustment for AMI episodes for these beneficiaries if CMS does not exclude them from the model altogether. Suggestions included excluding beneficiaries who are in the following clinical scenarios:

- Cardiogenic shock or, at a minimum, the subset of beneficiaries with cardiogenic shock who are transferred from an AMI model participant or who are transferred to an AMI model participant, as the impact of the AMI model on transfer decisions could delay access to life-saving therapies at specialized centers.
- Sepsis who do not have clinically traditional AMI and would not be expected to follow a typical clinical pathway for AMI.
- Experiencing a second or greater AMI, who are more likely to have complex cardiac needs beyond immediate management of the AMI.
- Undergoing organ transplantation or ventricular assist device (VAD) implantation during the episode, because regional pricing could limit access to life-saving therapies only available at those few centers capable of caring for advanced heart failure patients and organ transplant candidates.
- Receiving outpatient inotropes for advanced heart failure during AMI episodes, because these therapies allow beneficiaries to avoid a surgical bridge to transplant with VAD implantation but are used in a group of beneficiaries who might otherwise receive a VAD. The commenters believes this would be consistent with excluding beneficiaries who receive VAD during AMI episodes from the AMI model.
- Undergoing CABG or other cardiac surgery within 90 days following discharge from the hospitalization for AMI because they must be medically optimized prior to surgery to ensure safe outcomes. This percentage of beneficiaries is higher for certain hospitals with complex patient populations, and the proposed payment methodology would not adequately account for these high-cost cases.

Response: We appreciate the recommendations of the commenters regarding the exclusion of certain complex, potentially high-cost beneficiaries from the AMI model. We do not believe it would be appropriate to exclude beneficiaries experiencing cardiogenic shock or a second or subsequent AMI from the AMI model because there are significant opportunities for improving the quality and efficiency of care for these beneficiaries during episodes, despite their greater complexity and medical needs, and we believe it is important to include these beneficiaries in the test of the AMI model. In response to the commenters who recommended that we exclude beneficiaries with sepsis and atypical AMI from the AMI model, based on our proposed definition of the beneficiaries to be included in the AMI model and the ICD–CM diagnosis code analysis discussed in the response to the previous comment, we do not believe that beneficiaries with sepsis and clinically atypical AMI would generally be included in the AMI model because they would not be assigned to AMI or PCI MS–DRGs.

While readmission for cardiac transplantation or VAD implantation would be excluded from AMI episodes based on our proposed AMI model exclusion list, these beneficiaries would otherwise initiate and remain in AMI episodes throughout the 90-day post-discharge period both before and following cardiac transplantation or VAD implantation that occurs during the 90-day period. Other readmissions and Part B services furnished to these beneficiaries would be included in the episodes based on the proposed exclusion list. We believe it is important to include in the AMI model these beneficiaries with complex care needs following hospitalization for AMI, including those receiving outpatient inotropes during AMI episodes, because there are opportunities to improve the quality and efficiency of their care, despite their experiencing severe sequelae following AMI.

Finally, we note that we also do not believe it would be appropriate to exclude from the AMI model those beneficiaries receiving CABG or other cardiac surgery during AMI episodes after a period of medical optimization following discharge from the anchor hospitalization. As discussed in section III.D.4.b.(2)(c) of this final rule, we are providing a pricing adjustment for AMI episodes with a CABG readmission for beneficiaries who follow this medically appropriate clinical pathway. We refer to section III.D.4.b.(2) of this final rule for further discussion of risk adjustment in the context of the AMI model's implementation of downside risk and progression to regional pricing for AMI episodes.

Comment: Several commenters supported excluding intracardiac valvular and ablation procedures from historical AMI episodes for clinical consistency between historical AMI episodes and those during the AMI model performance years. They explained that intracardiac valvular and ablation procedures are typically unrelated to management of an AMI but would historically have substantially impacted the total spending in historical AMI episodes for beneficiaries discharged from MS–DRGs 246 through 251 in centers that performed those procedures.

Response: We appreciate the support from the commenters. We continue to believe it is appropriate to define historical AMI episodes for beneficiaries discharged under PCI MS–DRGS 246–251 as those that do not include the ICD–9–CM procedure codes in Table 4.

[54] 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.

Final Decision: After consideration of the public comments received, we are finalizing the proposals in § 512.100(c)(1) to include the care of beneficiaries in the AMI model who meet the general beneficiary care inclusion criteria as discussed in section III.C.4.a.(1) of this final rule and who are discharged under an AMI MS–DRG (280–282), representing those individuals admitted with AMI who receive medical therapy but no revascularization, or discharged under a PCI MS–DRG (246–251) with an ICD–10–CM diagnosis code of AMI as displayed in Table 6 on the IPPS claim for the anchor hospitalization in the principal or secondary diagnosis code position, without modification.

We are also finalizing the proposals in § 512.100(d)(4) to define historical AMI episodes for beneficiaries discharged under PCI MS–DRGS 246–251 as those that do not include the ICD–9–CM procedure codes in Table 4, without modification.

TABLE 4—FINAL ICD–9–CM PROCEDURE CODES IN ANY POSITION ON THE IPPS CLAIM FOR PCI MS–DRGS (246–251) THAT DO NOT DEFINE HISTORICAL AMI 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.
37.36	Excision, destruction, or exclusion of left atrial appendage.
37.90	Insertion of left atrial appendage device.

Finally, we are finalizing the proposals in § 512.100(d)(1)–(3) for the sub-regulatory process to be used on an annual, or more frequent, basis to update the AMI ICD–10–CM diagnosis code list and to address issues related to AMI diagnosis codes raised by the public, without modification. As part of this process, we will use 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 will post a list of potential AMI ICD–10–CM diagnosis codes to the CMS Web site at *https://innovation.cms.gov/initiatives/epm* to allow for public input on our planned application of the standard, 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 will provide sufficient time for public input based on the complexity of potential revisions under consideration, typically at least 30 days, and, while we will not respond to individual comments as would be required in a regulatory process, we can discuss the reasons for our decisions about changes in response to public input with interested stakeholders.

We note that we reviewed the FY 2017 ICD–10–CM diagnosis code changes that became available after publication of the EPM proposed rule in the **Federal Register** on August 2, 2016. There are no changes or additions to the ICD–10–CM diagnosis codes reporting AMI for FY 2017 so we are not suggesting modifications for FY 2017 to the final list displayed in Table 6 of 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 episodes. Thus, we are not initiating a sub-regulatory update process for FY 2017 AMI ICD–10–CM diagnosis code updates at this time.

(2) CABG Model

We proposed 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 would be similar to the CJR model in that the anchor hospitalization would be defined by admission for a surgical procedure, which would be defined by the MS–DRGs for that procedure alone (80 FR 73280). All CABG procedures are performed in the inpatient hospital setting. Thus, we proposed 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.[55]

The proposal for identifying beneficiaries included in the CABG model was included in proposed § 512.100(c)(2). We sought comment on our proposal to identify beneficiaries included in the CABG model.

The following is a summary of the comments received and our responses.

Comment: Similar to the suggestions of commenters recommending that CMS exclude certain beneficiaries discharged from AMI MS–DRGs or PCI MS–DRGs with an AMI ICD–10–CM diagnosis code from the AMI model, several commenters recommended that CMS exclude a variety of beneficiaries from the CABG model who would otherwise meet the proposed CABG model criteria for inclusion. Recommendations include excluding beneficiaries who are in the following clinical scenarios:

- Cardiogenic shock or, at a minimum, the subset of beneficiaries with cardiogenic shock who are transferred from a model participant or who are transferred to a model participant, as the impact of the CABG model on transfer decisions could delay access to life-saving therapies at specialized centers;
- Undergoing organ transplantation or VAD implantation during the CABG episode, as regional pricing could limit access to life-saving therapies only available at those few centers capable of caring for advanced heart failure patients and organ transplant candidates.
- Receiving outpatient inotropes for advanced heart failure during CABG episodes, because these therapies allow beneficiaries to avoid a surgical bridge to transplant with ventricular assist device (VAD) implantation but are used in a group of beneficiaries who might otherwise receive a VAD. The

[55] 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 the proposed rule, that began in CYs 2012–2014.

commenters state that this would be consistent with excluding beneficiaries who receive VAD during CABG episodes from the CABG model.

• Undergoing a second or greater CABG, given the increase in complexity and comorbidities associated with this population.

• Undergoing a salvage CABG due to a failed or aborted PCI, either during a single admission or a readmission, due to the clinically frail beneficiaries that result in high-cost episodes.

Response: We appreciate the recommendations of the commenters regarding the exclusion of certain complex, potentially high-cost beneficiaries from the CABG model, and note that in some cases recommendations for exclusion were the same as for the AMI model. We do not believe it would be appropriate to exclude beneficiaries experiencing cardiogenic shock, undergoing a second or subsequent CABG, or undergoing salvage CABG from the CABG model because there are significant opportunities for improving the quality and efficiency of care for these beneficiaries during episodes, despite their greater complexity and medical needs, and we believe it is important to include these beneficiaries in the test of the CABG model.

While readmission for cardiac transplantation or VAD implantation would be excluded from CABG episodes based on our proposed CABG model exclusion list, these beneficiaries would otherwise initiate and remain in CABG episodes throughout the 90-day post-discharge period both before and following cardiac transplantation or VAD implantation that occurs during the 90-day period. Other readmissions and Part B services furnished to these beneficiaries would be included in the episodes based on the proposed exclusion list. We believe it is important to include in the CABG model these beneficiaries with complex care needs following CABG surgery, including those receiving outpatient inotropes during CABG episodes, because there are opportunities to improve the quality and efficiency of their care, despite their experiencing severe sequelae following CABG. We refer to section III.D.4.b.(2) of this final rule for further discussion of risk adjustment in the context of the CABG model's implementation of downside risk and progression to regional pricing for CABG episodes.

Final Decision: After consideration of the public comments received, we are finalizing the proposals in § 512.100(c)(2) to include the care of beneficiaries in the CABG model who meet the general beneficiary care inclusion criteria as discussed in section III.C.4.a.(1) of this final rule and are discharged under a CABG MS–DRG (231–236) paid under the IPPS, without modification.

(3) SHFFT (Excludes Lower Extremity Joint Replacement) Model

We proposed 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 would cover all surgical treatment options (that is, hip arthroplasty and fixation) for Medicare beneficiaries with hip fracture.

The SHFFT model would be similar to the CJR model in that the anchor hospitalization would be defined by admission for a surgical procedure, which would be 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 proposed 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 2012–2014, the annual number of potentially eligible beneficiary discharges for the SHFFT model nationally was approximately 109,000.[56]

The proposal for identifying beneficiaries included in the SHFFT model was included in proposed § 512.100(c)(3). We sought comment on our proposal to identify beneficiaries included in the SHFFT model.

The following is a summary of the comments received and our responses.

Comment: A number of commenters expressed support for the proposal to define the clinical conditions included in the SHFFT model as beneficiaries who are admitted and discharged under SHFFT MS–DRGs. Other commenters recommended that CMS apply additional episode-specific criteria to exclude beneficiaries from the SHFFT model who would be discharged from the SHFFT MS–DRGs. Recommendations of beneficiaries from some commenters to be excluded include:

• Beneficiaries with fracture due to falls or trauma in association with acute myocardial infarction; cardiac arrhythmia; syncope; cerebrovascular accident; seizure; head injury; or polytrauma to reduce the large risk of increases in patient transfers from EPM participants seeking to reduce their financial responsibility for high-cost beneficiaries;

• Beneficiaries with dementia or Alzheimer's disease due to ethical issues around withholding surgery that could arise in the case of EPM participants attempting to reduce their financial risk;

• Beneficiaries already residing in a SNF at the time of fracture, who would necessitate an unavoidable SNF stay after discharge from the anchor hospitalization that would increase the episode cost attributable to the EPM participant;

• Beneficiaries with fractures related to cancer, who would be expected to be high-cost cases;

• Beneficiaries with a history of previous hip fracture; previous surgery in the region; retained hardware; open fracture; periprosthetic fractures; and congenital deformities who would be expected to have atypical and potentially costly hip fracture care pathways; and

• Beneficiaries who smoke or have diabetes, which are risk factors for fracture nonunion and infection, respectively, because these behaviorally mediated risk factors for costly care cannot be managed prior to hip surgery, unless the SHFFT model adjusts prices for the higher financial risk attributable to these beneficiaries.

Response: We appreciate the recommendations of the commenters to exclude certain beneficiaries receiving SHFFT from the SHFFT model due their personal circumstances, other clinical conditions, or circumstances that led to the hip fracture. We agree with the commenters that beneficiaries in this group may be more likely to require complex care during the anchor hospitalization and significant, intensive health services during the 90 day post-hospital discharge period, which could result in high-cost SHFFT episodes. However, we do not believe it would be appropriate to exclude beneficiaries with complex social or clinical circumstances from the SHFFT model because there are significant opportunities for improving the quality and efficiency of care for these beneficiaries during episodes, despite their greater complexity and medical needs, and we believe it is important to

[56] 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 the proposed rule, that began in CYs 2012–2014.

include these beneficiaries in the test of the SHFFT model. As discussed in section III.G.4. of this final rule, we will be monitoring for issues related to access to care. We expect that all Medicare beneficiaries with hip fracture are offered clinically appropriate treatments for their fracture and that all transfers of beneficiaries with hip fracture to other hospitals are medically necessary and not determined by the SHFFT model participant's assessment of the beneficiary's risk of a high-cost SHFFT episode. We also refer to section III.D.4.b.(2) of this final rule for further discussion of risk adjustment in the context of the SHFFT model's implementation of downside risk and progression to regional pricing for SHFFT episodes.

Comment: Some commenters stated that there is a sizeable minority of beneficiaries with hip fracture who should not and do not get hospitalized or if hospitalized are not treated with surgery for fracture so would not be included in the SHFFT or CJR models. These commenters observed that these beneficiaries were not discussed in the proposed rule and, therefore, no discussion was included about the decisions related to the appropriate treatment of hip fracture in the case of serious disability, frailty, and concurrent illness. The commenters contended that EPM participants that have historically served a substantial frail population could be seriously disadvantaged under the SHFFT model due to the significant care needs for these beneficiaries following hip fracture surgery and might seek to reduce their traditional commitment to this population in various ways, which were contrary to the interests of this highly vulnerable population. Some commenters further speculated that beneficiaries with hip fracture could be shifted to no surgery or to joint replacement if SHFFT model participants seek to reduce high-cost cases that present the most financial risk under the SHFFT model. The commenters further stated that the SHFFT model may drive SHFFT model participants to provide more expensive hip replacement to beneficiaries due to their desire to avoid SNF admission because of the longer need for protected weight-bearing post-internal fixation after SHFFT in comparison with total joint replacement where immediate weight-bearing may be possible.

Response: While we agree with the commenters that surgical fracture repair may not be appropriate for some beneficiaries with hip fracture, the proposed SHFFT model was designed to include only those beneficiaries with surgical fracture repair other than joint replacement and not those for which surgical fracture repair was not performed. We believe the decision about fracture treatment should remain that of the beneficiary in consultation with any caregivers and his or her treating physicians. We did not propose to define the SHFFT model by hip fracture alone because we believe the primary opportunities for care redesign under an EPM that seeks to improve episode quality and efficiency are in the surgical treatment of hip fracture, rather than in the primary non-surgical management of hip fracture for beneficiaries who may or may not be hospitalized.

We do not believe that EPM participants would direct Medicare beneficiaries to other treatments that would result in their not being included in the SHFFT model simply on the basis of the beneficiary's potential for being a high-cost hip fracture surgical episode. We refer to section III.D.4.b.(2) for discussion of risk adjustment for complex beneficiaries under the SHFFT model. In addition, we note that beneficiaries with hip fracture who are treated with joint replacement, a care pattern that some commenters believe could result from SHFFT model participants' efforts to avoid of high-cost cases under the SHFFT model, would be included in the CJR model for most SHFFT model participants who are also CJR participant hospitals as discussed in section III.B.3. of this final rule. Thus, it is unlikely that a shift from a SHFFT procedure to joint replacement would financially benefit the SHFFT model participant. As discussed in sections III.G.4. through 6. of this final rule, we will be closely monitoring for access to care, quality of care, and delayed care under the SHFFT model.

Final Decision: After consideration of the public comments received, we are finalizing the proposals in § 512.100(c)(3) to include the care of beneficiaries in the SHFFT model who meet the general beneficiary care inclusion criteria as discussed in section III.C.4.a.(1) of this final rule and are discharged under a SHFFT MS–DRG (480–482) under the IPPS, without modification.

b. Definition of the Related Services Included in EPM Episodes

The general principles for the 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 episodes to incentivize comprehensive, coordinated, patient-centered care for the beneficiary throughout the episode (80 FR 73303). Therefore, we proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 episodes also could include certain per-member-per-month model payments as discussed in section III.D.6.d. of the proposed rule (81 FR 50871 through 50872). These items and services for the

EPMs are the same items and services included in CJR episodes (80 FR 73303 and 73315).

Similar to the CJR model and for the reasons explained in the CJR Final Rule, we proposed 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 proposed 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 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 proposed 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 proposed 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 proposed to identify unrelated Part B services and readmissions based on the BPCI Model 2 Part B exclusion 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 final rule. This proposal is consistent with our use of the BPCI Model 2 LEJR ICD–9–CM, ICD–10–CM, and MS–DRG exclusion lists in the CJR model (80 FR 73304 and 73315).

The BPCI episode-specific exclusion lists were initially developed more than 3 years ago for the BPCI initiative 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 the BPCI initiative, 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 exclusion 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 proposed 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 episodes, for both providers and CMS, and based on our rulemaking for the CJR model. We note that the BPCI Model 2 exclusion 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 AMI, CABG, and SHFFT episodes.

Similar to the CJR model, we proposed 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 proposed 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 proposed 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 exclusion list that applies to the EPM episode. For example, AMI episodes may have different exclusion lists applied based on whether the AMI 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 episode that includes a chained anchor hospitalization as described in section III.D.4.b.(2)(a) of this final rule, the exclusion list that applies to the price MS–DRG would apply to the AMI episode. Complete lists of excluded MS–DRGs for readmissions and 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 proposed 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 previously discussed general principles for determining excluded services. That is, we proposed 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 proposed 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 proposed that the potential revised exclusions, which could include additions to or deletions from the exclusion 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 proposed 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 was included in proposed § 512.210(a). The proposal for excluded services from the EPM episode was included in proposed § 512.210(b). The proposal for updating the lists of excluded services for EPMs was included in proposed § 512.210(c). We sought comment on our proposals for included and excluded services for the AMI, CABG, and SHFFT models and updating the lists of excluded services.

The following is a summary of the comments received and our responses.

Comment: Most commenters expressed general support for CMS' proposed episode definition strategy that would include Part A and Part B items and services and exclude certain unrelated readmissions based on a list of MS–DRGs, as well as certain unrelated Part B services based on the principal diagnosis on the claim, consistent with the episode definition approach for LEJR under the CJR model and the approach used in the BPCI initiative for several years for BPCI, SHFFT, AMI, PCI, and CABG episodes. The commenters acknowledged that most items and services would be included in the episode definition under the proposal, thus creating broadly defined SHFFT, AMI, and CABG episodes. In some cases, while commenters agreed with the proposed general strategy for identifying EPM episode exclusions, they made specific recommendations for additional exclusions based on a different exclusions standard, and these commenters are summarized later in this section, where responses are also provided. In other cases, commenters who agreed with the strategy for identifying EPM episode exclusions stated that if CMS finalizes broad EPM episode definitions, risk adjustment would be necessary in order to ensure fair payment to EPM participants.

Several commenters recommended CMS to provide greater clarity about the services included in and excluded from EPM episodes. One commenter stated that it is hard to differentiate included versus excluded services, and further added that people are ''irreducible bundles'' and someone needs to be responsible for all of the issues for people when they are very sick. The commenter recommended that the longer-term value of patient-centered medical homes, comprehensive ACOs, and primary care geriatricians should be considered for beneficiaries completing EPM episodes and recommended that moving people with complex illness into such arrangements should be a feature of all CMS innovations as part of moving fee-for-service payment toward quality and value. A few commenters recommended that CMS provide a clear definition and methodology for the term ''related services'' which would be applied consistently throughout various payment models so providers could verify how their services would be identified and paid. Finally, several commenters requested that CMS utilize an inclusions list rather than an exclusion list to avoid including inappropriate services by default. One commenter presented analysis that showed AMI model readmission for seizures and other for organic disturbance and mental retardation would be included in AMI episodes, and the commenter believes that neurological and mental health conditions are not related to cardiac care for AMI.

Response: We appreciate the support of many commenters for our proposed general approach to identifying excluded items and services for the EPMs. As we stated in the proposed rule (81 FR 50832), we are interested in testing inclusive AMI, CABG, and SHFFT episodes to incentivize comprehensive, coordinated, patient-centered care for the beneficiary throughout the episode. We agree with the commenter that it can be hard to distinguish included versus excluded services because sick people have many complex and interrelated clinical conditions and corresponding health care needs. The proposed EPM episode definitions are broad in part for this reason. Additionally, while we also agree with the commenter that the ongoing and acute health care needs of medically complex beneficiaries may be addressed through a patient-centered medical home or ACO, many of these vulnerable beneficiaries currently are not included in such models or programs. In the case of other beneficiaries who are included in medical home or ACO models or programs, they may have specific, new care management needs arising from an acute cardiac event, CABG, or hip fracture surgery that may be best managed by the EPM participant that has substantial expertise in coordinating and managing care throughout AMI, CABG, or SHFFT episodes because of its participation in the EPM, while the ACO or patient-centered medical home may have less specific expertise in managing beneficiaries recovering from major orthopedic or cardiac surgery or an AMI. We expect that EPM participants, accountable for EPM episode quality and cost performance

under the EPMs, will work closely with all providers and other organizations with which a model beneficiary has established relationships, toward the mutual goal of high quality, well-coordinated care that maximizes the rate of a beneficiary's return of function and improvements in health following surgery or AMI. We further expect that the medical management and care coordination during EPM episodes will continue to be provided as beneficiaries' transition out of EPM episodes, potentially into a primary care medical home or other model or program with accountability for population health, such as an ACO.

Because our proposed inclusive approach to EPM episode definitions results in many more items and services that are included in EPM episodes than excluded, we believe it is most efficient to identify excluded items and services as we proposed. With regard to the commenters who were concerned that an exclusion list could include inappropriate services by default, we note that we posted to the CMS Web site the proposed exclusion lists for the AMI, CABG, and SHFFT models for comment in association with the proposed rule and are finalizing the initial exclusion lists through this rulemaking where we have considered and responded to all the comments we received on our proposed exclusions. Thus, no items and services would be included in EPM episodes by default because the exclusion lists have been established through notice and comment rulemaking. In addition, as discussed later in this section, we proposed a sub-regulatory process for updating the exclusion lists to reflect 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 periods. The standards for the process reflect the proposed general principles for excluded services and the process itself allows opportunity for public input. Thus, we believe that all items and services included in EPM episodes are intentionally included, after consideration of public input, rather than included by default.

We note that in the example raised by the commenter of ''default inclusion,'' we disagree with the commenter that readmissions for neurological and mental health conditions are unrelated to cardiac care for AMI. For example, an AHRQ Evidence Report on post-myocardial infarction found that the evidence is consistent that in patients with AMI, depression is common at the time of the hospitalization and persists for at least several months after hospital discharge without treatment.[57] Further, the report found that depression is associated with a significantly increased risk of subsequent death, and of cardiac readmission and poor quality of life during the first year. Thus, we would not exclude readmission for treatment of depression from AMI episodes because we believe that depression would generally be a chronic condition that was likely to have been affected care during the AMI model episode. Under our proposal, readmissions for neurological and mental health conditions would not be excluded from AMI episodes because they are not MS–DRGs that we proposed to exclude from the AMI episodes, specifically oncology; trauma medical; chronic disease surgical unrelated to a condition likely to have been affected by care during the EPM episode; or acute disease surgical unrelated to a condition resulting from or likely to have been affected by care during the AMI episode. Thus, we consider those readmissions related to AMI episodes as they are medical MS–DRGs for conditions that are likely to have resulted from or been affected by care during the AMI anchor hospitalization or during the 90 days post-hospital discharge.

By posting to the CMS Web site the lists of excluded services for the EPMS, we believe we are providing the clarity and detail needed for any provider to understand whether his or her services furnished to a beneficiary in an EPM episode are included in the EPM episode definition because they are related to the episode or excluded from the EPM episode because they are unrelated. To date, we have applied the same general approach to identifying exclusions in the BPCI initiative, the CJR model, and the proposed EPMs, which should facilitate provider understanding about exclusions under these different episode payment models. We note, however, that the exclusion list differs based on the clinical condition that is the focus of the episode so a provider that is paid under Part B or a hospital would not be able to have a uniform determination of whether services furnished were included or excluded from an episode without knowledge of the beneficiary's specific episode in an episode payment model as well as the clinical condition for which the provider furnished services. All of the Innovation Center episode payment models except Model 4 of BPCI use retrospective payment, so all providers would be paid according to the usual fee-for-service systems that apply, regardless of whether the items or services furnished by the provider are included in or excluded from a beneficiary's episode.

Comment: While some commenters expressed full support for CMS' proposed definition of related services, other commenters recommended CMS to exclude specific additional groups of services from EPM episodes. The commenters requested that CMS further exclude:

- Readmissions that were already planned for the beneficiary prior to the anchor hospitalization because their occurrence would be unrelated to episode care;
- Readmissions that were part of the planned post-discharge care for the beneficiary after the anchor hospitalization, because these provide no opportunity for efficiency yet could lead to high-cost episodes:
- Medical readmissions for unrelated acute and chronic conditions;
- Part B services that are not directly related to the episode;
- Cardiac rehabilitation, intensive cardiac rehabilitation, and chronic care management services where appropriate utilization under the EPMs in the context of historical low utilization would lead to increased episode costs during the EPM performance period;
- Behavioral and substance abuse services because these are not always integral or of strong relevance to the clinical definitions of the EPMs, and CMS does not provide claims data to model participants for these services so no participants can predict, model, or calculate episode spending; and
- Outpatient chemotherapy, psychiatric readmissions, and high cost intravenous therapy administered through DME that are unrelated to the episode and could lead to increased episode costs.

Response: We believe that it is not necessary to exclude from EPM episodes planned readmissions and outpatient services, regardless of whether those plans were made prior to the anchor hospitalization or during the anchor hospitalization but prior to discharge, solely because the readmissions or outpatient services are planned in advance. While we understand that certain other CMS programs account differently for planned readmissions by excluding them from readmission calculations, such as the HRRP which reduces payments to hospitals with excess readmissions, we do not believe that planned readmissions should be

[57] Bush DE, Ziegelstein RC, Patel UV, et al. Post-Myocardial Infarction Depression. Rockville (MD): Agency for Healthcare Research and Quality (US); 2005 May. (Evidence Reports/Technology Assessments, No. 123.) Available from: *https://www.ncbi.nlm.nih.gov/books/NBK37817/.*

excluded from EPM episodes, where the goals of the EPMs are to improve the quality and efficiency of episode care and where we do not make a specific assessment about excess readmissions. Just like unplanned readmissions, we believe that planned readmissions should be excluded from EPM episodes only if they are unrelated to the EPM episodes based on the proposed standards for exclusion of inpatient readmissions that group to the following categories of diagnoses: Oncology; trauma medical; chronic disease surgical unrelated to a condition likely to have been affected by care during the EPM episode; and acute disease surgical unrelated to a condition resulting from or likely to have been affected by care during the EPM episode. We continue to believe these standards are appropriate to identify excluded readmissions from EPM episodes given our design of the EPMs to test comprehensive, coordinated patient-centered care for the beneficiary throughout broadly defined EPM episodes. Unless a readmission is excluded from the EPM episode based on these standards, any readmission, whether planned or unplanned, would be related to the EPM episode and be affected by the clinical condition that is the basis for that episode. We appreciate the concerns of the commenters about ensuring appropriate EPM episode prices in the case of planned readmissions. While we are not adopting any specific methodologies for identifying and making episode payment adjustments for such planned, related readmissions now except in the case of a CABG readmission during an AMI episode as discussed in section III.D.4.b.(2)(c), we will study this issue in more detail especially as it relates to the cardiac models. Should we determine a change to our policies regarding planned, related readmission could be appropriate, we will make proposals through future rulemaking.

To the extent that planned readmissions reflect certain clinically appropriate care patterns for beneficiaries in EPM episodes based on plans made during the anchor hospitalization, we expect that such readmissions would be included in the historical EPM episodes used to establish EPM-episode payments and thus hospitals would be appropriately paid, on average, for EPM episode care. To the extent that efficiencies in EPM episode care are possible and medically appropriate, reducing planned readmissions may provide an opportunity for increased EPM episode efficiencies. However, we would not expect EPM participants to reduce EPM-episode spending by shifting the utilization of medically necessary services, such as planned readmissions, until after the EPM episode ends. We refer to section III.D.4.b.(2)(c) of this final rule for discussion of the pricing adjustment for CABG readmissions during AMI episodes due to this costly, clinically-appropriate care pattern of delayed CABG for some beneficiaries with AMI.

Furthermore, while we expect that certain elective admissions considered related under the EPMs may be planned prior to the anchor hospitalization for the EPM episode and could, therefore, occur during the 90-day post-discharge period, we believe that such actual readmissions after CABG, SHFFT or AMI treatment are uncommon during the post-surgical recovery or post-AMI recovery period for EPM beneficiaries that extends 90 days following discharge from the anchor hospitalization. If such readmissions were planned, they would often be canceled due to the intervening surgery or AMI until the beneficiary has fully recovered. We will not exclude them all as unrelated because any readmission not on the EPM exclusion list may be related care furnished during the post-surgical or post-AMI recovery period. Our exclusion methodology does not allow us to identify those readmissions that are truly elective; that is, the condition was present and the readmission was planned prior to the hospitalization that anchored the EPM episode and scheduled during the 90-day post-hospital discharge period.

For readmissions to medical MS–DRGs, the selection of the principal diagnosis code is not clear-cut so we believe they should all be included in the EPM episode definition so providers focus on comprehensive care to beneficiaries in episodes. We believe that readmissions to medical MS–DRGs are generally linked to the hospitalization or event as a complication of the illness that led to the procedure or event, a complication of treatment or interactions with the health care system, or a chronic illness that may have been affected by the course of care. Therefore, we believe it is infeasible under the EPMs to identify medical readmissions for unrelated acute and chronic medical conditions, other than our proposal to exclude readmissions for oncology and trauma medical diagnoses.

Similarly, our proposal identified those Part B services unrelated to the episode as 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 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. We do not believe that requiring a direct relationship between the diagnosis for the Part B services and the clinical condition that is the basis for the EPM episode is appropriate under the broadly defined episodes of the EPMs. Most medical conditions are likely to be affected by care during the EPM episode, yet they may not have a direct relationship to the clinical condition that is the reason for the anchor hospitalization.

We also do not believe that it would be appropriate to exclude other specific Part B services that are related to the clinical conditions that are the basis for EPM episodes, such as cardiac rehabilitation, intensive cardiac rehabilitation, and chronic care management services, just because they are underrepresented in the baseline period upon which benchmark episode prices are set. As discussed in section III.D.4.b.(3) of this final rule, to the extent that care redesign under the EPMs increases utilization of these services to improve episode quality and efficiency, periodic updates to the 3 years of historical data used to establish EPM-episode benchmark prices would result in greater representation of these services that reflect more recent care patterns.

Additionally, we do not believe that it would be appropriate to exclude behavioral health and substance abuse services, including psychiatric readmissions, from EPM episodes because these services are for conditions that are likely to affect EPM episode care. We note that these services are not common in episodes and, while we acknowledge that the episode claims data provided to EPM participants will not include these data, our proposal to exclude this information but include the costs of the services in EPM episodes is consistent with our usual treatment of these services in other similar CMS programs and models where providers must take on risk in managing the care of their beneficiaries, such as the Shared Savings Program and BPCI initiative. Based on our experience to date with bundled payment models and the Shared Savings Program, this policy has not been a significant impediment to the operations of these efforts. For example, in the most recent episodes in BPCI Models 2 and 3, the claims for behavioral health and substance abuse services included in episodes that we

did not share with BPCI participants accounted for less than 0.1 percent of total episode spending. We refer to section III.K. of this final rule for further discussion of issues related to sharing beneficiary-identifiable data for behavioral health and substance abuse services with EPM participants.

With regard to the commenters requesting that we exclude outpatient chemotherapy services from the EPM episode definitions, we agree that these should be excluded from EPM episodes in accordance with our proposal that excludes services based on ICD–9–CM and ICD–10–CM cancer diagnosis codes on the proposed EPM exclusion lists from historical and actual EPM episodes. In the case of high-cost intravenous therapy administered through DME, we would only exclude such treatments if the claims reported ICD–10–CM diagnosis codes that would identify these services as unrelated to the EPM episodes. Otherwise, despite the cost of this therapy, these services would be included in EPM episodes because they are related.

Comment: Several commenters recommended CMS to exclude readmissions for PCI from AMI episodes, stating that current STEMI clinical guidelines for the culprit artery lesion in addition to other multi-vessel stenosis states, ''Approximately 50% of patients with STEMI have multivessel disease. PCI options for patients with STEMI and multivessel disease include: (1) Culprit artery-only primary PCI, with PCI of non-culprit arteries only for spontaneous ischemia or intermediate or high-risk findings on pre-discharge noninvasive testing; (2) multi-vessel PCI at the time of primary PCI; or (3) culprit artery-only primary PCI followed by staged PCI of non-culprit arteries.'' [58] Another commenter quoted on the topic from the most recent update to the guidelines published in 2016, ''Although several observational studies and a network meta-analysis have suggested that multivessel staged PCI may be associated with better outcome than multivessel primary PCI, there are insufficient observational data and no randomized data at this time to inform a recommendation with regard to the optimal timing of nonculprit vessel PCI.''

The commenters recommended CMS to exclude planned readmissions for PCI from the AMI episode definition because the AMI model as proposed would discourage the recommended course of care of a secondary PCI procedure for AMI patients with multivessel disease. The commenters believe that the AMI episode definition could encourage the treatment of secondary lesions during the initial angioplasty and in other cases could provide an incentive to delay treatment of the secondary lesions until after the 90-day post-hospital discharge duration of the AMI episode has concluded. The commenters added that another strategy of EPM participants to deal with limited AMI episode payments might be to inappropriately refer multivessel disease patients into the separate CABG model.

Alternatively if CMS does not excluded planned PCI readmissions, the commenters recommended CMS to exclude STEMI beneficiaries with multivessel disease from the AMI model and/or make accommodations in the pricing methodology for the extra cost of treating such beneficiaries appropriately. As another alternative, the commenters requested that CMS shorten the AMI episode duration to 30 days post-discharge so that secondary PCI could be performed for multivessel disease without the financial constraints of an ongoing AMI episode. Finally, the commenters recommended that if the AMI episodes cannot be revised to avoid these potentially harmful incentives, CMS should monitor and evaluate whether these shifts in pattern of care are occurring and whether they have affected patient outcomes.

Response: While we appreciate the concerns of the commenters, as we stated in the proposed rule (81 FR 50852), 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 an anchor or chained anchor hospitalization. Since a PCI for an AMI typically is provided during the anchor hospitalization and most PCIs later in an episode occur in the context of a beneficiary presenting through the emergency department, we believe that in most cases of PCI following discharge from the anchor hospitalization, the beneficiary likely has experienced a complication of care resulting in a PCI that may potentially be avoided through care management during the AMI episode. This PCI would clearly be related to the AMI episode and should not be excluded from the AMI episode.

It would also be inappropriate to exclude beneficiaries with STEMI and multivessel disease from the AMI model simply because their plan of care could include a secondary PCI procedure as these beneficiaries would represent nearly 50 percent of STEMI patients, who themselves make up a significant percent of beneficiaries in the AMI model. While we expect that few beneficiaries would follow this care pattern based on our analysis of historical AMI episodes, in this scenario the PCI would clearly be related to the AMI and, therefore, be appropriately included in the AMI episode definition. 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 a pricing adjustment for a PCI readmission or outpatient PCI would not be appropriate.

We note that the recently updated treatment guidelines cited by the commenters state there is insufficient observation data and no randomized data to inform a recommendation regarding the optimal timing of non-culprit vessel PCI. The guidelines contain no specific recommendation for the timing of delayed treatment of secondary lesions, while specifically stating that the ''recommendation with regard to multivessel primary PCI in hemodynamically stable patients with STEMI has been upgraded and modified . . . to include consideration of multivessel PCI, either at the time of primary PCI or as a planned, staged procedure.'' Given that there is no specific recommendation regarding the routine performance of multivessel PCI for patients with STEMI and multivessel disease, nor a recommendation on the timing for multivessel PCI if it is performed, we do not believe the AMI model definition discourages patterns of care that are recommended for AMI patients with multivessel disease. We also do not see any reason why the care patterns related to performing PCI for multivessel disease following STEMI should lead us to shorten the AMI episode duration from 90 days post-discharge to 30 days or to make a pricing adjustment for AMI episodes that include this pattern of care. We refer to section III.C.4.c.(2) of this final rule for further discussion of the AMI episode duration.

As recommended by the commenters, we will evaluate care patterns under the AMI model for secondary PCI following an initial PCI for treatment of AMI to determine whether shifts in care are

[58] Levine GN, Bates ER, Blankenship JC, et al. 2015 ACC/AHA/SCAI Focused Update on Primary Percutaneous Coronary Intervention for Patients With ST-Elevation Myocardial Infarction: An Update of the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention and the 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction. J Am Coll Cardiol. 2016;67(10):1235–1250. doi:10.1016/j.jacc.2015.10.005.

occurring and whether changes in beneficiary outcomes are observed. We refer to section IV. of this final rule for further discussion of our plans for evaluation of the AMI model.

Comment: One commenter requested confirmation of their understanding of CMS' proposal to exclude MS–DRGs for inpatient hospital readmissions that group to the ''Trauma medical'' category of diagnoses. The commenter interpreted this provision as trauma diagnoses unrelated to the initial MS–DRG triggering an episode.

Response: By trauma medical diagnoses, we mean that those MS–DRGs that represent a readmission for medical treatment of trauma during an EPM episode are excluded. For example, we would exclude MS–DRGs 082–087 in the Traumatic Stupor & Coma series and MS–DRGs 088–090 in the Concussion series.

Comment: Several commenters recommended CMS to exclude hospice services from the EPM episode definition as they generally would be unrelated to the EPM episodes. The commenters stated that including hospice services in EPM episodes could result in incentives for underutilization of the hospice benefit. They encouraged CMS to exclude all hospice services in order to ensure timely access to hospice for EPM beneficiaries. One commenter pointed out that exclusion of hospice services from the EPM episode definitions would be consistent with their exclusion from BPCI episodes.

Response: We appreciate the interest of the commenters in ensuring continued beneficiary access to hospice services under the EPMs. We note that although we exclude hospice services from BPCI episodes, we include them in LEJR episodes in the CJR model (80 FR 73307). We understand that EPM beneficiaries could receive hospice services during an episode under several different types of clinical circumstances. For example, the beneficiary could be enrolled in hospice prior to a SHFFT episode, experience a pathologic hip fracture, and require a SHFFT procedure to stabilize his or her hip. Alternatively, the beneficiary could have a CABG and enter into hospice at some point during the episode in the 90 days following discharge from the anchor hospitalization, either after experiencing a surgical complication leading to a terminal prognosis, progressive severe heart failure despite the CABG, or based on a new diagnosis of a terminal stage of an illness.

As we explained in the CJR Final Rule (80 FR 73307), Medicare hospice care is palliative care for individuals with a prognosis of living 6 months or less if the terminal illness runs its normal course. As referenced in § 418.22(b)(1), to be eligible for Medicare hospice services, the patient's attending physician (if any) and the hospice medical director must certify that the individual is ''terminally ill,'' as defined in section 1861(dd)(3)(A) of the Act and our regulations at § 418.3; that is, the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course. When an individual is terminally ill, many health problems are brought on by underlying condition(s), as bodily systems are interdependent. Section 1861(dd)(1) of the Act establishes the services that are to be rendered by a Medicare certified hospice program and those services include: Nursing care; physical therapy; occupational therapy; speech-language pathology therapy; medical social services; home health aide services (now called hospice aide services); physician services; homemaker services; medical supplies (including drugs and biologics); medical appliances; counseling services (including dietary counseling); short-term inpatient care (including both respite care and care necessary for pain control and acute or chronic symptom management) in a hospital, nursing facility, or hospice inpatient facility; continuous home care during periods of crisis and only as necessary to maintain the terminally ill individual at home; and any other item or service which is specified in the plan of care and for which payment may otherwise be made under Medicare, in accordance with Title XVIII of the Act. The services offered under the Medicare hospice benefit must be available, as needed, to beneficiaries 24 hours a day, 7 days a week (section 1861(dd)(2)(A)(i)of the Act).

The regulations at § 418.54(c) stipulate that the comprehensive hospice assessment must identify the patient's physical, psychosocial, emotional, and spiritual needs related to the terminal illness and related conditions, and address those needs in order to promote the hospice patient's well-being, comfort, and dignity. The comprehensive assessment must take into consideration the following factors: The nature and condition causing admission (including the presence or lack of objective data and subjective complaints); complications and risk factors that affect care planning; functional status; imminence of death; and severity of symptoms (§ 418.54(c)). Additionally, the hospice Conditions of Participation (CoPs) at § 418.56(c) require that the hospice must provide all reasonable and necessary services for the palliation and management of the terminal illness, related conditions and interventions to manage pain and symptoms. Therapy and interventions must be assessed and managed in terms of providing palliation and comfort without undue symptom burden for the hospice patient or family. In the December 16, 1983, Hospice final rule (48 FR 56010 through 56011), regarding what is related versus unrelated to the terminal illness, we stated: ''We believe that the unique physical condition of each terminally ill individual makes it necessary for these decisions to be made on a case–by-case basis. It is our general view that hospices are required to provide virtually all the care that is needed by terminally ill patients.''

Thus, we believe that hospice services furnished to EPM beneficiaries should be included in the episode definition for the EPMs, regardless of the specific diagnosis of the beneficiary, because hospices are to provide virtually all care that is needed by terminally ill patients. This is consistent with our conclusion when we considered hospice services in the LEJR episode definition under the CJR model (80 FR 73307). If an EPM beneficiary was receiving hospice services during an episode, either because the beneficiary was enrolled in hospice prior to surgery or a cardiac event and continued in hospice following surgery or the cardiac event or the beneficiary enrolled in hospice following the surgery or cardiac event that initiated the EPM episode, we believe that hospice services would encompass care related to the EPM episode and should, therefore, be included in the episode definition. As previously noted, given the comprehensive nature of the hospice benefit and the fact that body systems are interdependent at end of life, virtually all care needed by the terminally-ill individual would be related to the terminal prognosis and thus the responsibility of the hospice.

As previously noted, hospices are required, per the Hospice CoPs at § 418.56(c), to provide all reasonable and necessary services for the palliation and management of the terminal illness, related conditions, and interventions to manage pain and symptoms. For patients that underwent surgery or cardiac care under the EPMs that have also elected the Medicare hospice benefit, hospice services would need to respond to the care needs of the EPM beneficiary following surgery or hospitalization for cardiac care. As in the case of other medically necessary services that would improve a beneficiary's quality of care and quality

of life, we expect that EPM beneficiaries will receive clinically appropriate referrals to hospice in a timely manner. Furthermore, we also believe hospice services could contribute to episode efficiency through improved comprehensive care coordination and management for EPM beneficiaries that have a terminal prognosis. As previously stated, hospices are required to provide comprehensive care coordination and management per the hospice CoPs at 418.56. As discussed in sections III.G.4. through 6. of this final rule, we will be monitoring for access to care, quality of care, and delayed care and will take actions as described if problems are found.

Comment: One commenter recommended that CMS exclude Inpatient Psychiatric Facility (IPF) services from the EPM episode definition as not being related to or resulting from the EPM clinical condition, consistent with their treatment in BPCI episodes.

Response: We are clarifying that under the BPCI models, IPF services furnished following discharge from the episode anchor hospitalizations but during the episode are included in the episode definition, unless they fall into one of the excluded MS–DRGs for the episode. Thus, we include inpatient psychiatric services whether paid under the IPPS or the IPF PPS in all episodes under the BPCI initiative according to the same policy that would exclude readmissions paid under either payment system based on the same exclusion list. As we concluded for the CJR model (80 FR 73306), we see no reason for the EPMs not to apply the standards we proposed to define related and unrelated Part A and Part B services with respect to IPF services furnished during EPM episodes. Therefore, we believe the list of excluded MS–DRGs applicable to the EPM episode identifies those IPF admissions during the episode that would be clinically unrelated to the episode so we exclude them from the EPM episode definition, whereas IPF services any time during an EPM episode that result in discharge from an MS–DRG that is not excluded would be related and included in the EPM episode definition. We disagree with the commenter that all IPF services furnished following discharge from the anchor hospitalization that initiates the EPM episode after surgery are unlikely to be related to or resulting from the EPM clinical condition or its treatment. Thus, we believe the MS–DRG exclusions for the EPM episodes identify those circumstances when IPF services are unrelated to the episode.

Comment: Several commenters recommended that CMS exclude post-acute care services from EPM episodes if the beneficiary chooses a facility not recommended by the EPM participant or treating physician. Other commenters recommended that CMS exclude post-acute care services following excluded readmissions due to how little is known about the causal relationship between an unrelated hospital readmission and subsequent post-acute care services.

Response: As discussed in section III.G.2. of this final rule, the proposed EPMs would not limit an EPM 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. Therefore, it would not be appropriate to exclude post-acute care services from the EPM episode definition if the beneficiary chooses a post-acute care facility that is not recommended by the EPM participant or the beneficiary's treating physician.

With regard to requests that we exclude post-acute services from EPM episodes following excluded readmissions, as Part A services are generally intended to be comprehensive in nature and because the beneficiary in an EPM episode would still be in the recovery period for the 90 days following surgery or an AMI, we believe any post-acute care services provided during the EPM episode would be related to the SHFFT, CABG, or AMI. Regardless of the reason for the hospitalization immediately preceding the initiation of post-acute care services during an EPM episode, the post-acute care provider would need to address the beneficiary's post-surgical or post-AMI recovery, even if the post-acute care services followed an unrelated admission to the hospital.

Comment: Several commenters identified additional MS–DRGs or conditions resulting in hospitalization that they recommended be excluded from the cardiac episodes. The commenters requested that clinical conditions that group to the following MS–DRGs be excluded from the AMI and CABG model episode definitions, generally on the basis that these readmissions are not integral to the management of beneficiaries in the 90 days following discharge from the AMI or CABG anchor hospitalization:

- 222 (Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock with MCC).
- 223 (Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock without MCC).
- 224 (Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock with MCC).
- 225 (Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock without MCC).
- 226 (Cardiac Defibrillator Implant without Cardiac Catheterization with MCC).
- 227 (Cardiac Defibrillator Implant without Cardiac Catheterization without MCC).
- 266 (Endovascular Cardiac Replacement with MCC).
- 267 (Endovascular Cardiac Replacement without MCC).
- 273 (Percutaneous Intracardiac Procedures with MCC).
- 274 (Percutaneous Intracardiac Procedures without MCC).

Another commenter claimed that CMS' proposal to include nearly all surgical MS–DRGs within Major Diagnostic Category (MDC) 5 (Diseases and Disorders of the Circulatory System) in the AMI and CABG episode definition, rather than also requiring an acute care ICD–CM diagnosis code on the claim for the MS–DRG in MDC 5 to be included in the episode, especially within the 31 to 90 days following discharge from the anchor hospitalization, could penalize hospitals for providing necessary care within the timeframe for AMI and CABG episodes. Examples provided by the commenter included abdominal aortic aneurysm; peripheral bypass surgical and endovascular procedures; surgical valve repair or replacement; planned inpatient or outpatient electrophysiology admissions to replace cardiac defibrillators or pacemakers; and staged outpatient revascularization procedures several months after an initial intervention for AMI.

One commenter recommended that readmissions for extracorporeal membrane circulation (ECMO) that would group to MS–DRG 003 (ECMO or Tracheostomy with MV > 96 hours or PDX Except Face, Mouth and Neck with Major O.R. Procedure) be excluded from the CABG episode definition. Another commenter recommended the addition of 241 MS–DRGs to CMS' the readmissions exclusion list for CABG episodes, in addition to the 370 MS–DRGs proposed by CMS on the list, on the basis that these MS–DRGs did not have any clinical relevance to CABG. These additional MS–DRGs would result in the exclusion of 611 MS–DRGs out of a total of approximately 760 MS–DRGs from CABG episodes.

Finally, the commenter who favored CMS' adopting a more robust methodology for differentiating planned from unplanned use of inpatient and outpatient services within the 90-day post-discharge period, similar to the methodology used in the HRRP for AMI and CABG, requested that should CMS continue with the MS–DRG exclusion list that CMS revisit the proposed exclusion lists for AMI and CABG episodes. The commenter claimed there were some inconsistencies in the treatment of AMI MS–DRG-anchored AMI episodes and CABG episodes compared with PCI MS–DRG-anchored AMI episodes. The commenter identified MS–DRGs 326 (Stomach, Esophageal, and Duodenal Procedures with MCC); 327 (Stomach, Esophageal, and Duodenal Procedures with CC); 328 (Stomach, Esophageal, and Duodenal Procedures without CC/MCC); 266 (Endovascular Cardiac Valve Replacement with MCC); and 267 (Endovascular Cardiac Valve Replacement without MCC) as on the PCI MS–DRG-anchored AMI exclusion list but not on the AMI MS–DRG-anchored AMI and CABG MS–DRG exclusion list, and was unclear about the rationale for these differences.

Response: We appreciate the requests by the commenters to add certain MS–DRGs to the exclusion list for one or both of the cardiac care models. CMS clinicians and coding staff reviewed the three different proposed exclusion lists for AMI MS–DRG-anchored AMI episodes, PCI MS–DRG-anchored AMI episodes, and CABG episodes for the inconsistencies identified by one of the commenters against the proposed standards for excluding readmissions during EPM episodes. We proposed to exclude MS–DRGs 326–328 from PCI-anchored AMI episodes and CABG episodes but not from AMI MS–DRG-anchored episodes. Based on clinical review, we determined that admissions to these MS–DRGs would be for acute disease surgical diagnoses unrelated to a condition resulting from or likely to have been affected by care during the AMI or CABG episode so these MS–DRGs meet the proposed standards for exclusion from AMI MS–DRG-anchored AMI episodes. Therefore, we are adding MS–DRGs 326–328 to the AMI MS–DRG-anchored AMI exclusion list. MS–DRGs 266–267 are on the exclusion list for PCI MS–DRG-anchored AMI episodes, but not on the exclusion list for AMI MS–DRG-anchored AMI episodes or CABG episodes. Based on clinical review, we determined that admissions to these MS–DRGs would be for chronic disease surgical diagnoses unrelated to a condition likely to have been affected by care during the AMI or CABG episode so these MS–DRGs meet the proposed standards for exclusion from both AMI MS–DRG-anchored AMI episodes and CABG episodes. Therefore, we are adding MS–DRGs 266–267 to the AMI MS–DRG-anchored AMI exclusion list and the CABG exclusion list.

We note that MS–DRGs 222–227 and 273–274 requested for exclusion from AMI and CABG episodes by several commenters are surgical MS–DRGs in MDC 5. As another commenter pointed out, some of these may represent planned readmissions following discharge from the anchor hospitalization during the 90-day post-discharge period. However, based on our proposed readmission exclusion methodology that identifies excluded MS–DRGs without examining the diagnosis coding on hospital claims to determine the reason for the readmission, as discussed in our response to comments earlier in this section, we will not exclude planned readmissions from the AMI and CABG episode definitions. Thus, we proposed that MS–DRGs 222 through 227 and 273 through 274 not be excluded from AMI (regardless of PCI or AMI MS–DRG-anchor) and CABG episodes, and we are continuing to include these MS–DRGs in those episodes, as well as the other surgical MS–DRGs in MDC 5 that we did not propose to exclude from all AMI and CABG episodes. Based on clinical review, we determined that these readmissions for circulatory system procedures are related services in AMI and CABG episodes, based on our proposed standards for excluding surgical MS–DRGs from the EPMs: Chronic disease surgical diagnoses unrelated to a condition likely to have been affected by care during the EPM episode; and acute disease surgical diagnoses unrelated to a condition resulting from or likely to have been affected by care during the EPM episode. While some commenters stated that these readmissions were not integral to AMI and CABG episodes, that is not the standard we used for determining related readmissions because we are adopting broad episode definitions for the EPMs. While we are not adopting any specific methodologies for identifying and making episode payment adjustments for such planned, related readmissions now except in the case of a CABG readmission during an AMI episode as discussed in section III.D.4.b.(2).(c). of this final rule, we will study this issue in more detail especially as it relates to the cardiac models. Should we determine a change to our policies regarding planned, related readmission could be appropriate, we will make proposals through future rulemaking.

Finally, we carried out a clinical review of the 241 MS–DRGs recommended by a commenter for addition to the CABG exclusion list, as well as MS–DRG 003 that was recommended for exclusion by another commenter. About three-quarters of the MS–DRGs recommended for exclusion were medical MS–DRGs that did not meet our proposed standards for excluding readmissions based on medical diagnoses, specifically oncology or trauma medical diagnoses. As we first discussed in the CJR Final Rule (80 FR 73304) and in the EPM proposed rule (81 FR 50833), we believe all other readmissions for medical MS–DRGs should be included in EPM episodes because these are generally linked to the condition that was the focus of the anchor hospitalization as a complication of that illness, a complication of treatment or interactions with the health care system, or a chronic illness that may have been affected by the course of episode care. The inclusion of most MS–DRGs in EPM episodes should encourage providers to focus on comprehensive care for beneficiaries during episodes. More than half of the surgical MS–DRGs recommended for CABG episode exclusion were in MDC 5 and, with the exception of MS–DRGs 266–267 discussed previously, we will not exclude them from CABG episodes based on the reasons discussed earlier in this response. Of the remaining surgical MS–DRGs spread across 7 MDCs representing different body systems, we will also not exclude any of these MS–DRGs because they do not meet our standards for excluding MS–DRGs from CABG episodes, namely that the readmissions are for chronic disease surgical diagnoses unrelated to a condition likely to have been affected by care during the CABG episode or acute disease surgical diagnoses unrelated to a condition resulting from or likely to have been affected by care during the CABG episode. We believe that our determinations may be different than the commenters' recommendations because our standard for exclusion in broadly defined CABG episodes is much more stringent than the commenters' review of MS–DRGs based on their clinical relevance to CABG.

Comment: Several commenters requested that CMS add MS–DRGs 469 and 470 for major joint replacement of the lower extremity to the exclusion list for SHFFT episodes, unless the joint replacement was for the joint that

underwent a SHFFT procedure that initiated the SHFFT episode. The application of the exclusion in this way would exclude elective LEJR readmissions from SHFFT episodes. The commenters claimed this approach would avoid outliers and penalizing the orthopedic surgeon for identification and treatment of unmet medical needs while treating a beneficiary following a hip fracture. One commenter stated that these circumstances would be highly variable, particularly in hospitals with small patient volume. They recommended excluding MS–DRGs 469 and 470 from SHFFT episodes so as not to penalize low-volume hospitals who performed costly elective LEJR during SHFFT episodes on an occasional basis.

Response: Based on our proposed methodology to identify excluded readmissions by a list of MS–DRGs, we would have to substantially increase the complexity of our exclusions methodology to identify only a subset of MS–DRG 469 and 470 readmissions for exclusion because they were not related to the joint surgery that initiated the SHFFT episode. We do not believe this additional complexity is necessary because we expect that LEJR replacement of another joint, whether elective or for fracture, would be rare during SHFFT episodes. Most LEJR is elective, rather than for fracture, and given the prolonged partial weight-bearing commonly required for recovery from SHFFT procedures and the general complexity and frailty of many beneficiaries who would be included in SHFFT episodes, we believe that elective LEJR of a joint other than that involved in the initial SHFFT surgery during the 90 days post-discharge from the SHFFT model anchor hospitalization would be exceedingly rare. We would expect that most LEJR procedures during SHFFT episodes would be related because they would involve the joint that had an initial SHFFT procedure.

Comment: One commenter recommended that CMS exclude Part B services from CABG episodes based on individual ICD–9–CM and ICD–10–CM diagnosis codes, rather than categories as CMS proposed. The commenter claimed that CMS' proposed process would result in over 22,000 ICD–10–CM diagnosis codes that would be classified as included in the CABG episode, thereby resulting in those services being considered as related items and services. The commenter believes that this methodology would result in many of the included services having no clinical relevance to a CABG. The commenter recommended CMS to specify Part B episode exclusions at the ICD–CM code level to ensure that only services that are clinically related to a CABG are included in the episode. The commenter recommended 4,960 specific ICD–9–CM and 18,859 specific ICD–10–CM diagnosis codes be added to the CABG exclusion list.

Another commenter recommended that CMS exclude the following ICD–10–CM diagnosis code categories from AMI episodes as they are not integral to AMI treatment: I47 (Paroxysmal tachycardia); I48 (Atrial fibrillation and flutter); and I49 (Other cardiac arrhythmias). The same commenter recommended that CMS exclude ICD–9–CM diagnosis code category 427 (Cardiac dysrhythmias) from AMI episodes.

Response: We appreciate the recommendations from the commenter about additional ICD–9–CM and ICD–10–CM diagnosis code categories to be excluded from AMI episodes. However, with respect to their requested additions to the AMI Part B exclusion list, we believe the four categories of ICD–CM codes recommended for exclusion do not meet our proposed Part B exclusions standards, specifically those services that are for acute disease diagnoses unrelated to a condition resulting from or likely to have been affected by care during the EPM episode or for certain chronic disease diagnoses, 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. The ICD–CM diagnosis code categories describe different types of cardiac arrhythmias, which can result from an AMI, where the arrhythmia would be an acute condition related to the AMI episode, or can be a chronic condition where the management of the arrhythmia would be affected by the AMI treatment. Thus, we do not agree with the commenter that these ICD–CM diagnosis code categories should be excluded from AMI episodes.

With respect to CABG episodes, another commenter recommended almost 19,000 ICD–10–CM diagnosis codes be added to the CABG exclusion list. The commenter submitted individual codes in 750 ICD–10–CM categories for exclusion, of which there were 563 categories (75%) in which they requested excluding all codes. We note that there are about 71,000 billable ICD–10–CM codes in 1,910 categories, compared to about 15,000 ICD–9–CM codes in 1,042 categories. Due to the large number of diagnosis codes, we believe it would be operationally infeasible and unnecessarily complex to determine excluded Part B services at the individual diagnosis code level. We further believe that the ICD–CM diagnosis code categories are sufficiently narrow and descriptive that they can be appropriately used to determine Part B exclusions without substantial risk of misidentifying services that are unrelated to CABG episodes according to our proposed Part B exclusions standards. We have several years of experience with 48 different BPCI clinical episodes in Model 2, including CABG, which has a similar design to the proposed CABG model. We have encountered no significant concerns from BPCI Awardees or other stakeholders about our BPCI methodology which excludes Part B services based on ICD–CM diagnosis code categories, just as we use in the CJR model and proposed for the CABG model. Therefore, we are continuing to consider changes to the Part B exclusion list for the EPMs based on ICD–CM categories.

We did not perform another clinical review of the 187 categories where the commenter only requested that we exclude some of the individual ICD–10–CM diagnosis codes in the category, because we will continue to exclude ICD–10–CM codes at the category level. CMS clinicians and coding staff reviewed all of the 563 ICD–10–CM diagnosis code categories where the commenter recommended that we exclude all the diagnosis codes in order to make a determination about additional exclusions at the category level. While the commenters claimed that diagnosis codes in these categories had no clinical relevance to CABG, we do not agree that the additional categories where the commenter recommended 100 percent of the ICD–10–CM diagnosis codes for exclusion meet our proposed standards for exclusion. For example, the commenter requested that we exclude the categories K20 (Esophagitis) and I12 (Hypertensive chronic kidney disease) for Part B services from the CABG model episode definition. However, these two ICD–10–CM diagnosis code categories do not meet our proposed standards for the exclusion of Part B services because they include acute disease diagnoses for a condition arising from or likely to have been affected by care during the CABG episode in the case of Esophagitis and chronic disease diagnoses likely to have been affected by care during the CABG episode in the case of Hypertensive chronic kidney disease. The commenter's recommendations were prepared based on a standard of ''clinical relevance'' to CABG which we believe is too narrow to define related

Part B services for the proposed CABG model which was designed to test comprehensive, coordinated patient-centered care for the beneficiary throughout broadly defined EPM episodes. In our clinical review based on the proposed standards for Part B exclusions, we determined that the 563 ICD–10–CM diagnosis code categories where the commenter recommended that we exclude 100 percent of the diagnosis codes do not meet the standards for exclusion from CABG episodes. Therefore, we are making no changes to the CABG episode ICD–10–CM Part B exclusion list.

The same commenter who made recommendations about additional ICD–10–CM diagnosis code exclusions also recommended ICD–9–CM diagnosis codes in 436 ICD–9–CM categories for exclusion, and of those, the commenter recommended that all codes be excluded in 336 (77 percent) of the categories. We did not perform an additional clinical review of the categories where the commenter only requested that we exclude some of the individual ICD–9–CM diagnosis codes in the category, as we will continue to exclude ICD–9–CM codes at the category level. CMS clinicians and coding staff reviewed all of the 100 ICD–9–CM diagnosis categories where the commenter recommended that we exclude all the diagnosis codes in order to make a determination about additional exclusions at the category level. Similar to our findings from our review of the ICD–10–CM diagnosis code categories where all codes were recommended for exclusion, the ICD–9–CM categories with all codes recommended by the commenter for CABG episode exclusion do not meet our proposed exclusion standards for Part B services. For example, the commenter recommended that we exclude all codes in ICD–9–CM diagnosis code category 584 (Acute kidney failure) and 250 (Diabetes mellitus) from CABG episodes. However, these two ICD–9–CM diagnosis code categories do not meet our proposed standards for the exclusion of Part B services because they include acute disease diagnoses for a condition arising from or likely to have been affected by care during the CABG episode in the case of Acute kidney failure and chronic disease diagnoses likely to have been affected by care during the CABG episode in the case of Diabetes mellitus. In our clinical review, we found that none of the 100 ICD–9–CM categories where the commenter recommended that we exclude 100 percent of the diagnosis codes meet our proposed standards for excluding Part B services from CABG episodes, so we are making no changes to the CABG episode ICD–9–CM Part B exclusion list.

Comment: One commenter stated that their understanding was that emergency transportation of beneficiaries with AMI would be included in AMI episodes. The commenter pointed out that this cost could vary substantially based on the transport mileage and the mode of transport, with air transport being substantially more costly than ground transport. The commenter claimed that the EPM participant where the episode would be initiated has little or no input on the transport method used but would be held accountable for the transportation cost in the AMI episode. The commenter requested that transport of the beneficiary to the AMI model participant where the AMI episode is initiated be excluded because the AMI model participant would have little or no control of that cost.

Response: We proposed to include all Part A and Part B items and services in AMI episodes beginning with the admission of the beneficiary for the anchor hospitalization and extending through anchor hospitalization discharge, whereupon the AMI model exclusion list would be applied to Part A and Part B items and services during the 90 days post-discharge to make a determination about their inclusion in the AMI episode definition. With respect to the inclusion of Part B ambulance claims for air or ground transport in the AMI episode definition, we would exclude those services that occurred prior to the hospital admission. If the ambulance transport occurs on the day of initial admission for the anchor hospitalization and has place-of-service code for ambulance on the claim, the claim would not be included in the AMI episode definition, an approach which would be consistent with the specific request of the commenter.

However, if ambulance transport occurs any other time during the anchor hospitalization, the transportation would be included in the AMI episode definition as we include all Part B services without regard to the Part B exclusion list, except DME to which we apply the Part B exclusion list during the anchor hospitalization as well. Following discharge from the anchor hospitalization, the inclusion or exclusion of ambulance transport in the AMI episode during the 90 day post-discharge would be determined by our proposed methodology for determining exclusion of any Part B items and services based on the principal diagnosis code on the claim and whether that diagnosis code is on the AMI model exclusion list.

We note that medically appropriate air ambulance transportation is a Medicare-covered service regardless of the state or region in which it is rendered. However, contractors approve claims only if the beneficiary's medical condition is such that transportation by either basic or advanced life support ground ambulance is not appropriate. Medical reasonableness is only established when the beneficiary's condition is such that the time needed to transport a beneficiary by ground, or the instability of transportation by ground, poses a threat to the beneficiary's survival or seriously endangers the beneficiary's health.[59] Thus, the circumstances of covered air transport are limited and, once the AMI episode is initiated, the AMI model participant would have an ongoing role in beneficiary care that would result in the participant's input into the mode of transport should transport be required.

Comment: One commenter recommended that CMS include the costs of pre-operative home visits in EPM episodes, including services to discuss goals of care and advance care planning services. Another commenter requested that CMS account for preventive services in the EPMs, although they acknowledged the associated challenges in benchmarking target prices based on historical claims data. One commenter suggested that CMS include the proposed HCPCS G-codes for the Collaborative Care model such that screening and follow-up would be included in the payment structure for each EPM, while another commenter recommended CMS to make resources for care coordination strategies available to support advancing care coordination through appropriate pre-discharge planning and post-discharge follow up. The commenter observed that the majority of opportunities to advance care coordination and improve patient outcomes are in decreasing hospital length of stay to only what is necessary for appropriate treatment, preventing unnecessary readmissions, and controlling post-acute care costs. The commenter stated that opportunities to improve care coordination include strong pre-discharge planning activities; prevention of unnecessary patient visits to the emergency department through early recognition of decompensation; increasing appropriate referral to cardiac rehabilitation services; and

[59] Medicare Benefit Policy Manual, Chapter 10—Ambulance Services, 10.4 and 10.4.2.

effective patient and family education. The commenter claimed that ensuring the social and environmental components are in place prior to discharge is critical and that communication of the most appropriate post-acute care facilities to not only the patients, but to their families and caregivers, can be essential to a patient's recovery.

Response: The only items and services that are included in EPM episode definitions are those that are separately paid by Medicare under Part A or Part B. We established EPM episode definitions in order to add Medicare payments for items and services included in the EPM episode definitions into EPM-episode benchmark prices based on historical EPM episodes and into the calculation of actual EPM-episode spending. In addition, we proposed that EPM episodes begin with the anchor hospitalization. Therefore, for the same reasons as discussed in the CJR Final Rule (81 FR 73316 through 73317) regarding LEJR episodes, we would not include any pre-operative home visits that could be separately paid by Medicare in the EPM episode definitions because they would precede the initiation of the episode which begins with admission to the hospital and discharge from an MS–DRG that is included in the EPM.

In terms of including preventive services and potential new HCPCS G-codes for Part B services in the Collaborative Care model in the EPM episode definitions, we note that according to our standard methodology for identifying excluded Part B services under the EPMs, specific Part B services would be included in both historical EPM episodes and actual EPM episodes to the extent that the ICD–9–CM or ICD–10–CM diagnosis code on the claim for the preventive service or HCPCS G-code for Part B services in the Collaborative Care model is related to the EPM episode and, therefore, not on the EPM episode exclusion list. With regard to CMS making specific financial resources available to EPM participants for pre-discharge planning, post-discharge follow-up, or other care coordination activities, EPM participants would need to develop their own strategies and use their own resources for these activities, as well as engage with EPM collaborators, to redesign care to achieve good quality and cost performance under the EPMs. CMS will not provide additional payments under the EPMs specifically for these types of planning and follow-up activities. However, EPM participants who achieve acceptable episode quality or better and reduce actual EPM-episode spending below the quality-adjusted price are eligible for payment of the difference through a reconciliation payment, which can support the resources used by EPM participants and collaborators in redesigning care to achieve model success.

Comment: Several commenters commended CMS for proposing to exclude IPPS new technology add-on payments for drugs, technologies, and services from EPM episodes, as well as OPPS transitional pass-through payments for medical devices. They believe that these proposals would ensure EPM beneficiaries/access to valuable new drugs, technologies, services, and devices. The commenters recommended CMS to go further and exclude additional innovative technologies from EPM episodes by establishing a review process to determine whether their costs should be excluded from EPM-episode benchmark prices and actual EPM-episode spending. The commenters reasoned that this new review process would allow manufacturers to identify high-cost breakthrough technologies and treatments that offer clinical improvements for all or certain types of patients or offer significant therapeutic advances for new populations or conditions. The commenters recommended that CMS utilize the same processes as those used to determine eligibility for IPPS new technology add-on payments but without regard to the statutory or regulatory policies that apply only to new technology approvals. They further suggested that CMS also allow individual EPM participants to request an EPM payment adjustment if they adopt breakthrough treatment in advance of other hospitals, as well as manufacturers and developers to request the adjustment.

One commenter recommended CMS to consider other innovative capital investments for an EPM episode payment adjustment and to provide payment for new technologies at 100 percent of their cost, not 50 percent as under current CMS programs for payment of new technologies. Finally, another commenter suggested that CMS should provide a financial incentive to EPM participants to use technologies that are shown to improve patient outcomes and reduce cost within 12 to 24 months.

Response: We appreciate the support of the commenters for our proposals regarding the exclusion of new technology payments from EPM episodes and agree that EPM beneficiaries should have access to beneficial new technologies while they are in EPM episodes. We do not believe it would be appropriate for the EPMs to potentially hamper beneficiaries' access to new technologies that are receiving IPPS new technology add-on payments or OPPS transitional pass-through payments or to burden EPM participants who choose to use these new drugs, technologies, services, or devices with concerns about these payments counting toward actual EPM-episode spending.

However, for the same reasons that were discussed previously in the CJR Final Rule (80 FR 73308) regarding LEJR episodes, we will not establish a new process to review innovative technologies or different technologies that would be ineligible for a payment adjustment under the Medicare program and make individual determinations regarding their exclusion from the EPM episode definitions, as recommended by some commenters. Because the EPMs are retrospective reconciliation models that pay all providers and suppliers under the regular Medicare program throughout the episode of care, we believe it is more appropriate to rely on the existing processes under the Medicare program to make determinations about separate payment for new technology items and services. If those existing processes identify new technologies that would qualify for add-on payments under the IPPS or transitional pass-through payments under the OPPS, we will exclude them from the EPM episode definitions as we proposed, to ensure that beneficiaries' access to new technology items and services is not influenced by their care being included in the EPMs. Similarly, under these retrospective EPMs, we will not provide additional payments for new technologies beyond those that are paid under the Medicare program.

Finally, we do not believe it would be appropriate under the EPMs to provide financial incentives to EPM participants to use specific technologies that improve beneficiary outcomes and reduce cost over any specific period of time. We understand that because the EPMs would extend 90 days post-discharge from the anchor hospitalization, the EPMs specifically incentivize the use of technologies and provision of services that improve quality and reduce cost within the limited episode timeframe for which the EPM participant is responsible for episode quality and cost performance. However, we believe that EPM participants, treating physicians, and other EPM collaborators are best positioned to select technologies and furnish services that improve the quality of care and reduce cost for EPM beneficiaries and expect that their

decisions factor in the long-term interests of beneficiaries as well.

Comment: One commenter stated that there was significant evidence demonstrating that the use of more expensive drug-eluting stents (DES) results in better long-term outcomes in many patients and fewer repeat procedures for in-stent restenosis. The commenter added that long-term benefit for patients (avoiding the risk, inconvenience and cost of secondary procedures) and to Medicare (via fewer repeat procedures in the long term) would not be fully captured in an episode extending 90 days post hospital discharge, but the full additional costs of DESs would be. The commenter recommended CMS take steps to ensure that the financial models used for the EPMs do not discourage the appropriate use of DES. The commenter claimed that if the AMI model results in fewer beneficiaries receiving DES, long-term outcomes may deteriorate and overall costs may grow.

Response: As discussed in section III.C.4.a.(2) of this final rule, we would initiate AMI episodes from PCI MS–DRGs (246–251) with an AMI ICD–CM diagnosis code in the principal or a secondary position on the claim for the anchor hospitalization. Medicare payment for coronary stents, whether bare metal or DES, used during a PCI performed during a hospitalization are included in the IPPS payment for the inpatient hospitalization. While they are not paid separately by Medicare, payment for the required resources would be included in AMI episodes because the IPPS services for the anchor hospitalization are included in the episodes. We proposed to risk-stratify EPM-episode prices based on MS–DRG as discussed in section III.D.4.b.(1) of this final rule and there are separate MS–DRGs for PCIs that use DES (246 and 247) and non-DES (248 and 249) for which there would be separate AMI episode prices. Therefore, we do not believe that the financial incentives under the AMI model encourage the use of any specific coronary stent because the episode prices take into consideration the IPPS payment for the specific MS–DRG that applies to the AMI model beneficiary. We do not expect the AMI model to discourage the appropriate use of DES.

Comment: Several commenters pointed out that Arkansas and Tennessee have bundled payment programs that include CABG episodes, and their efforts to implement bundled payments include state Medicaid and commercial health plans. The commenters stated that in Arkansas, the episode definition is consistent, specifically naming the duration, responsible entity, and the included services and conditions, across all participating payers. If MSAs from Arkansas or Tennessee are selected for the AMI and CABG models, the commenters recommended that CMS should align the CABG episode definition with that of the state Medicaid plan. The commenters stated that this approach to episode definition would decrease the complexity and cost to providers in those states and reduce overlapping, independent efforts at care redesign that both hospitals and cardiac surgery groups would be simultaneously undertaking, potentially independently. The commenters added that this would also allow CMS to experiment with different episode definitions than those under the BPCI initiative and CJR model and proposed for the EPMs.

Response: We appreciate the commenters drawing our attention to the states that are currently engaged in testing bundled payment models. We are encouraged that several states have identified clinical conditions that overlap with those proposed in the EPMs for testing bundled payment models, specifically CABG and PCI in the context of acute AMI (acute PCI). The choice of these states to test bundled payment models for some of the same clinical conditions that are included the EPMs provides additional support for the opportunities under our proposal of these models for Medicare beneficiaries. Specifically, Arkansas and Tennessee are testing CABG bundled payment models which are similar to the CMS CABG model, while Ohio and Tennessee are testing acute PCI bundled payment models that are similar to the subset of beneficiaries in the CMS AMI model discharged from PCI MS–DRGs with an AMI ICD–CM diagnosis code on the hospital claim. As displayed in section III.B.5 of this final rule, MSAs in Arkansas, Tennessee, and Ohio have been selected for participation in the CMS AMI and CABG models.

The state and CMS models for acute PCI and CABG episodes have similar design features. First, the responsible entity for CABG episodes is the hospital in Tennessee (the physician in Arkansas) like the CMS model and for acute PCI episodes in both states it is the facility where the PCI is performed, which would most commonly be the hospital for an acute procedure as in the CMS model where the hospital is responsible. Second, both the state and CMS models begin with the inpatient hospitalization (or with performance of the procedure), although the state model episodes extend 30 days following discharge, whereas the CMS model episodes extend 90 days. We note that for CMS CABG episodes, 92 percent of episode spending occurs during the anchor hospitalization and the 30 days post-discharge, while 84 percent of acute PCI episode spending occurs during that same period of time.[60] Thus, despite the differences in episode duration between the state and CMS models, the large majority of episode spending occurs in the first 30 days post-discharge so the state and CMS models contain most of the same episode spending. Third, the state and CMS models include most services furnished in the episode post-discharge from the anchor hospitalization, although the state models are not quite as inclusive. Fourth, episode payments are tied to quality measures in both the state and CMS models. Finally, both the state and CMS models included two-sided risk and risk adjustment (or risk stratification) based on payer-specific factors.

Both the state and CMS CABG and acute PCI models support the implementation and testing of bundled payment models for these costly episodes that significantly impact the health of individuals with cardiac disease. While it is operationally infeasible for CMS to apply the different definitions used by state Medicaid agencies in different states testing episode payment in an EPM of the scope of the CMS CABG and AMI models, the state and CMS models that included CABG and acute PCI are sufficiently similar and clinical pathways around CABG and acute PCI care reasonably well-established such that we believe coordination among the various providers, including hospitals and physicians, caring for all beneficiaries in CABG and acute PCI episodes, regardless of payer, should not pose a significant burden on the providers involved. Although the CMS CABG model places the responsibility for the episode upon the hospital, like the Tennessee CABG model, the financial arrangements that are permissible for individuals and entities that collaborate with the hospital toward the goal of improved quality and efficiency of CABG episode care as discussed in section III.I. of this final rule provide participant hospitals with substantial opportunity to share upside and downside risk with their collaborators, including physicians that might be leading CABG bundled payment efforts

[60] Episodes 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 the proposed rule, that began in CY 2012–2014.

in Arkansas. The financial arrangement policies under the CMS CABG model should help to minimize the occurrence of independent, potentially overlapping efforts of hospitals and physician groups to redesign care for CABG patients covered by different insurers. We believe that the state and CMS bundled payment models for overlapping clinical conditions are complementary efforts that will provide substantial new information about the effects of bundled payments on the quality and cost of care for CABG and acute PCI. While we understand that implementation of the EPMs will result in testing CABG and acute PCI episodes with minor differences in design for beneficiaries of Medicare versus Medicaid and other commercial payers in MSAs selected for the AMI and CABG models in Arkansas, Tennessee, and Ohio, these differences are unlikely to affect the episode care redesign strategies of the responsible hospitals under the CMS and state models.

Comment: While a number of commenters supported the proposal to update the EPM excluded services through the proposed sub-regulatory process to provide for flexibility and timeliness in adding exclusions to EPM episodes, several commenters opposed CMS' proposal to make changes to EPM episode exclusions through an annual, at a minimum, update outside of rulemaking. The commenters encouraged CMS to use notice and comment rulemaking to evaluate and exclude additional services from EPM episodes. The commenters stated that because participation in the EPMs is required in selected geographic areas and, therefore, the EPMs affect a large number of hospitals and providers, it is important that CMS implement the process to update services to be excluded from these episodes through notice and comment rulemaking, so that provider feedback throughout the course of EPM implementation is reflected in CMS' decisions. They added that hospitals of different sizes, geographic locations, organizational capabilities, and socio-economic factors all have unique preferences, and their ideas and opinions should be accounted for when CMS makes changes to the list of conditions and services to be included and/or excluded from the episodes.

Many commenters recommended CMS to continue to evaluate the list of services to be excluded from EPM episodes. They encouraged CMS to consider excluding a variety of additional services, including hospital readmissions planned for the beneficiary prior to the anchor hospitalization for consistency with other CMS policies such as the treatment of planned readmissions under the HRRP; ongoing care for beneficiaries' chronic conditions for which management is outside the scope of the EPMs and their exclusion could confound the EPM test of optimizing quality and costs for certain episodes; and post-acute care following excluded readmissions where little is known about the causal relationship between the hospital readmission and subsequent post-acute care services.

Response: We appreciate the interest of the commenters in ensuring that future changes to the EPM episode definitions involve a transparent process with opportunity for broad stakeholder input. We have some experience with a similar sub-regulatory update process for the CJR model for both the list of excluded services and the fracture ICD–10–CM diagnosis codes that are used to identify episodes for fracture risk-stratification. We used this process after publication of the CJR Final Rule and again more recently to update the CJR model exclusion list for changes to the FY 2017 IPPS MS–DRGs and ICD–10–CM diagnosis codes. We have received significant public input through those processes, which has allowed us to consider and incorporate, as appropriate based on the regulatory review standards for the processes, stakeholder input and in turn communicate timely final updates to the exclusions and fracture lists to CJR participant hospitals. We have not heard any concerns about the sub-regulatory update processes as we have applied them during CJR model implementation.

As we concluded for the CJR model, we continue to believe that updating the exclusions annually, at a minimum, is most appropriate for the 5-year EPMs, and allowing more frequent updates than through rulemaking as necessary to accommodate timely ICD–10–CM annual coding changes and annual IPPS MS–DRG changes, as well as to address significant issues raised by EPM participants and other stakeholders or by CMS as we continue to evaluate the list of excluded services for the EPM episodes. We will explore the additional areas recommended by the commenters and others that may arise during EPM implementation, and we will utilize the exclusion list update process to suggest any future changes based on our additional analyses.

The commenters who supported an exclusion list update process outside of rulemaking did not suggest specific revisions to the proposed standards for updating the EPM episode exclusions, namely:

- We would not exclude the following items or services that are:
  - ++ Directly related to the EPM episode or the quality or safety of the EPM episode care.
  - ++ For chronic conditions that may be affected by the EPM episode care.
- We would exclude the following items and services that are:
  - ++ For chronic conditions not generally affected by the EPM episode care.
  - ++ For acute clinical conditions, not arising from existing EPM episode-related chronic clinical conditions or complications of EPM episode care.

Thus, we continue to believe these standards provide the appropriate clinical review framework for updates to the EPM exclusion list. Finally, we believe that our proposed process to post the potential revised exclusions, which could include additions to or deletions from the exclusion list, to the CMS Web site to allow for public input on our planned application of these standards, and then adopt changes to the exclusion list with posting to the CMS Web site of the final revised exclusion list after our consideration of the public input is consistent with the recommendation of commenters that we use a transparent process reflective of broad opportunity for public input, including implementation experience with the EPMs. Conducting this update process outside of rulemaking based on the standards set forth in this final rule allows us the greatest flexibility to update the exclusions as changes to the MS–DRGs and ICD–10–CM diagnosis codes, upon which our exclusions rely, are released. This process also allows us to respond quickly to any episode definition issues that arise during implementation of the EPMs across the broad array of EPM participants in the selected MSAs, as well as consider any new analysis conducted by CMS or stakeholders about the relationship among items and services to the EPM episodes that might result in a different assessment of the inclusion or exclusion of existing MS–DRGs or ICD–10–CM diagnosis codes in the definition of EPM episodes. We would widely publicize the opportunity for review and public input through the CMS Web site and listservs. We also note that any changes to our overall approach to identifying excluded items and services or to our standards for evaluating items and services for exclusion would be address through future rulemaking. Therefore, we are finalizing our proposal to update the exclusion list annually, at a minimum, using the standards and process as described.

Final Decision: After consideration of the public comments received, we are finalizing the proposals in § 512.210(a), without modification, to identify related items and services for EPM episodes as 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.
- IPF services.
- LTCH services.
- IRF services.
- SNF services.
- HHA services.
- Hospital outpatient services.
- Independent outpatient therapy services.
- Clinical laboratory services.
- Durable medical equipment.
- Part B drugs.
- Hospice.

We are also finalizing the proposals, without modification, to use the following standards to exclude items and services from EPM episodes:

- 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.
- Part B items and services for 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.
- Drugs that are paid outside of the MS–DRGs included in the EPM episode definitions, specifically hemophilia clotting factors.
- IPPS new technology add-on payments for drugs, technologies, and services.
- OPPS transitional pass-through payments for medical devices.

We are finalizing the proposals in § 512.210(b) to exclude from EPM episodes specific readmissions, Part B-covered items and services with specific ICD–9–CM or ICD–10–CM diagnosis codes in the principal position on claims for items and services during the 90 days post-discharge from the anchor hospitalization, and additionally Part-B covered DME with specific ICD–9–CM or ICD–10–CM diagnosis codes in the principal position on claims during the anchor hospitalization, with modification to place MS–DRGs 326–328 on the AMI MS–DRG-anchored AMI exclusion list and MS–DRGs 266–267 on the AMI MS–DRG-anchored AMI exclusion list and the CABG exclusion list. As discussed in section III.C.4.a.(5) of this final rule, we are not finalizing our proposed AMI model inpatient-to-inpatient transfer episode initiation and attribution policy so we will not use the terms chained anchor hospitalization and price MS–DRG in the final AMI episode definition and pricing policies. Therefore, the applicable EPM exclusion list is applied to the EPM episode on the basis of the MS–DRG that anchors the EPM episode. The final EPM exclusion lists based on ICD–9–CM and ICD–10–CM diagnosis codes and MS–DRGs as of FY 2016 are posted on the CMS Web site at *https://innovation.cms.gov/initiatives/epm*.

Lastly, we are finalizing our proposals in § 512.210(c) to update the exclusion lists 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, without modification. The standards for this updating process are:

- Include 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);
- Include items or services for chronic conditions that may be affected by the EPM diagnosis or procedure and the post-discharge care (for example, diabetes);
- 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
- Exclude items and services for acute clinical conditions not arising from existing EPM episode-related chronic clinical conditions or complications from the EPM episode (for example, appendectomy).

The potential revised exclusions, which could include additions to or deletions from the exclusion lists, will be posted to the CMS Web site to allow for public input. After receiving and reviewing public input on potential revised exclusions, we will post the final revised exclusion lists, including providing information to the public about when the revisions would take effect and to which episodes they would apply.

With the publication of this final rule, we are initiating the sub-regulatory update process to incorporate changes to the MS–DRGs and ICD–10–CM diagnosis codes for 2017 into the EPMs by posting potential changes to the exclusion lists for the EPMs. We did not consider the 2017 changes in the EPM proposed rule, because the final MS–DRGs and ICD–10–CM codes were not yet available when the proposed rule was published in the **Federal Register** on August 2, 2016. There are no MS–DRG changes for FY 2017 that resulted in our suggesting potential changes to the exclusion lists for the EPMs. We are suggesting potential modifications to the principal ICD–10–CM diagnosis code categories for excluded Part B services in the AMI, CABG, and SHFFT models as of July 1, 2017, based on new ICD–10–CM diagnosis code categories for FY 2017 and clinical review of existing ICD–10–CM diagnosis code categories to which new ICD–10–CM diagnosis codes have been added for FY 2017. The potential modifications to the exclusion list for each EPM are posted on the CMS Web site at *https://innovation.cms.gov/initiatives/epm*. We request that public input on the potential modifications be sent to *epm@cms.hhs.gov* by 11:59 p.m. on Friday, January 27, 2017. After receiving and reviewing public input on potential revised exclusions, we will post the final revised exclusions by February 24, 2017, including providing information to the public about when the revisions will take effect and to which episodes they would apply.

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 proposed to follow the CJR model precedent and not begin an EPM episode prior to the anchor hospitalization (80 FR 73315 and 73318). We proposed that all services that were 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-assigned beneficiaries from EPM episodes, we refer to section III.D.6.c.(3) of the proposed rule (81 FR 50869 through 50870). 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 the proposed rule (81 FR 50868 through 50869).

The proposal for beneficiary care inclusion policies was included in proposed § 512.230. We sought comment on our proposal of beneficiary care inclusion policies.

The following is a summary of the comments received and our responses. We refer to sections III.D.6.c.(1) through (3) of this final rule for a summary of the comments received and our responses on the proposed three general beneficiary care inclusion criteria that relate to beneficiaries in other CMS models and programs.

Comment: Many commenters expressed support for the proposed general beneficiary care inclusion criteria as reasonable and consistent with other models and programs. On the other hand, a number of commenters requested that CMS exclude beneficiaries with certain clinical characteristics from all three proposed EPMs, including beneficiaries receiving hospice care before or during the episode; experiencing an inpatient psychiatric hospitalization preceding or during an episode; having preexisting functional disabilities in activities of daily living; bearing a diagnosis of dementia; residing in a SNF; and experiencing illnesses for which it is expected that the beneficiary would be likely to die within the upcoming year. The commenters generally stated that these beneficiaries should be excluded due to high and variable needs for care that would not be typical for beneficiaries in EPM episodes. One commenter recommended CMS to adopt an ''out clause'' for the most complex patients to be exempt from the EPMs, such as beneficiaries with multi-organ system involvement or comorbidities or poly-chronic illnesses. The commenters were concerned that without accurate risk adjustment under the EPMs, hospitals disproportionately caring for these beneficiaries would experience undue financial risk for necessary episode care. The commenters recommended that if CMS did not exclude high-risk beneficiaries, CMS must adopt more robust risk adjustment to account for socioeconomic, clinical, or other risk factors that are out of the hospital's control and impact patients' health and recovery. Several commenters recommended that at least the initial implementation of the EPMs should exclude vulnerable populations with complicated or intensive care needs from the EPMs until the EPMs demonstrate sufficient quality outcomes and have developed accurate risk adjustments and patient safeguards to ensure high-quality care for populations that the commenters believe could face serious care disadvantages in the EPMs and put hospitals at an unacceptable level of financial risk.

Response: Most beneficiaries with anchor hospitalizations that would initiate EPM episodes would have underlying conditions that may affect care throughout the episode or that may be influenced by the surgery or AMI that initiates the episode. Similar to our rationale in the CJR Final Rule regarding LEJR episodes (80 FR 73371), we believe it is important to include these beneficiaries in the EPMs so that they can benefit from the increased opportunities for care coordination and management throughout the episodes, and including the broadest feasible array of Medicare beneficiaries in the EPMs provides EPM participants with the greatest volume of episodes and incentive to redesign episode care. We do not believe it would be appropriate to exclude beneficiaries from the EPMs just because they are potentially expected to have high-cost, variable health care needs under the EPMs. We refer to section III.D.4.b.(2) of this final rule for a discussion of risk adjustment for the EPMs. Therefore, we will not exclude additional beneficiaries with certain clinical characteristics from the EPMs beyond those general beneficiary care inclusion criteria that we proposed.

Comment: Several commenters requested that CMS exclude beneficiaries with a home address not in the service area of the treating hospital. The commenters believe that including beneficiaries in this scenario would result in an unfair financial and administrative burden for EPM participants relative to other EPM beneficiaries residing in the service area of the hospital in meeting the challenges of remote post-discharge care coordination and ensuring ultimate quality outcomes for medically complex out-of state-patients.

Response: We acknowledge that in occasional circumstances, EPM participants may have limited ability to coordinate care. For similar reasons as our discussion in the CJR Final Rule (80 FR 73317 through 73318) regarding LEJR episodes, following the care coordination that takes place in the EPM participant during the anchor hospitalization, we expect that much of the subsequent coordination of post-acute care services and other related services for EPM beneficiaries during the 90 days post-discharge can be accomplished through telecommunications that do not require the patient to remain within the geographic proximity of the hospital responsible for the EPM episode. In addition, the design of the EPMs does not preclude hospitals from coordinating care with other providers outside of their immediate service area, which may be necessary especially in the case of beneficiaries who are admitted to a o-i or inpatient-to-inpatient (i-i) transfer hospital after an outpatient-to-inpatient or inpatient-to-inpatient transfer, respectively, for a different or higher level of cardiac care that is not available at the local hospital to which they originally presented with symptoms of an AMI. As discussed in section III.C.4.a.(5) of this final rule, under our final AMI model policy we are canceling all AMI episodes that begin at an initial treating hospital through an inpatient admission that

initiates the AMI episode when the beneficiary is transferred for admission to an i-i transfer hospital after the AMI episode begins. Thus, hospitals that are AMI and CABG model participants and that receive beneficiaries in transfer either from outpatient or inpatient status at an initial treating hospital will commonly initiate and be responsible for AMI or CABG episodes that begin at the o-i/i-i transfer hospital. This attribution of episodes to the o-i/i-i transfer hospital increases the probability that the home of beneficiaries is not in the service area of the responsible hospital under the AMI or CABG model, yet most commenters requested that we adopt this transfer attribution policy. Therefore, we believe that most EPM participants have the tools to engage in effective remote care coordination that results in high quality episode care.

Finally, we note that we are finalizing several waivers of Medicare program rules, as discussed in section III.J. of this final rule, to facilitate efficient and effective episode care coordination for beneficiaries in remote or distant locations outside of the EPM participant's immediate community. We are also finalizing policies for financial arrangements in section III.I. of this final rule that allow EPM participants to share upside and downside financial risk with a variety of individuals and entities who collaborate with the EPM participant in redesigning care and caring for EPM beneficiaries, regardless of the geographic proximity of these individuals and entities to the EPM participant. Through financial arrangements, EPM participants could align the financial incentives of providers in the EPM beneficiary's home community with the goals of the EPM participant to improve the quality and reduce the cost of EPM episodes. Therefore, we will not exclude beneficiaries from the EPMs who are referred to EPM participants that are not close to the beneficiary's home.

Comment: Several commenters requested clarification about whether patients who buy in to Medicare A or B through the Medicaid program would be excluded from the EPMs.

Response: As long as the beneficiaries are enrolled in both Medicare Part A and Part B, regardless of whether enrollment occurs through Medicaid program buy in, and assuming the beneficiaries meet the other general beneficiary care inclusion criteria, their care would be included in the EPMs.

Comment: A commenter presented a scenario where an EPM participant admitted and successfully treated a beneficiary with a SHFFT procedure, but the patient later falls and has a subsequent hip fracture requiring surgical fracture repair within the post-acute period of the episode. The commenter requested clarification about whether this instance would trigger a new SHFFT episode or the cost of the readmission to repair the second fracture would be included in the prior SHFFT episode's total cost.

Response: During such a readmission, the beneficiary would already be in a SHFFT episode. Therefore, the ongoing SHFFT episode would not be canceled and a new SHFFT episode would not be initiated because the beneficiary would not meet the proposed beneficiary care inclusion criteria to initiate a SHFFT episode since he or she is already in a SHFFT episode. Because SHFFT MS–DRGs 480–482 are not on the exclusion list for SHFFT episodes, the related readmission would be included in the ongoing SHFFT episode and its cost included in the calculation of actual episode spending for the SHFFT episode that began with the initial hospitalization for a SHFFT procedure.

Final Decision: After consideration of the public comments received, we are finalizing the proposals in § 512.230 for the general beneficiary care inclusion criteria, with modification to remove references to chained anchor hospitalization which we are not including in the final EPM policies as discussed in section III.C.4.a.(5) of this final rule. We are additionally excluding from EPM episodes beneficiaries who are assigned to a Shared Savings Program ACO in Track 3, as discussed in section III.D.6.c.(3) of this final rule. We define the population of Medicare beneficiaries whose care is included in the EPM as those who meet all of the following criteria on admission to the 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 prospectively assigned to:

++ An ACO in the Next Generation ACO model;

++ An ACO in a track of the Comprehensive ESRD Care Model incorporating downside risk for financial losses; or

++ A Shared Savings Program ACO in Track 3.

- 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.

(2) Beginning AMI Episodes

We proposed that, as long as the beneficiary met the general beneficiary care inclusion criteria, then an AMI episode would begin with admission of a Medicare beneficiary to an IPPS hospital for the following MS–DRGs, where the specific MS–DRG would be 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 proposed 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 episodes for beneficiaries discharged from PCI MS–DRGs throughout the duration of the AMI model. The sub-regulatory process for updating this AMI ICD–10–CM diagnosis code list was described in

section III.C.3.a.(1) of the proposed rule (81 FR 50831).

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 proposed 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 crosswalk in Table 5 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.[61]

TABLE 5—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 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 episodes was included in proposed § 512.240(a)(1). We sought comment on our proposal to begin AMI episodes.

We address some of the comments related to the proposed AMI ICD–CM diagnosis codes displayed in Table 5 in section III.C.3.a.(1) of this final rule in the context of our discussion of the clinical conditions that define AMI episodes. We received no comments specific to the ICD–9–CM to ICD–10–CM crosswalk of the AMI ICD–CM diagnosis codes included in Table 5.

[61] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/HIQR-ICD9-to-ICD10-Tables.pdf.*

The following is a summary of the comments received on other issues related to our proposal to begin AMI episodes and our responses.

Comment: Several commenters stated that uncomplicated acute AMI can be treated and discharged the next day. They pointed out that under Medicare's Two-Midnight rule, these beneficiaries would be classified as outpatients. They requested clarification about whether CMS believes these beneficiaries with AMI should be classified as inpatient even if the expectation of the treating physician is a less than Two-Midnight hospital stay so the AMI model would include all beneficiaries with AMI.

Response: The AMI model does not change Medicare's current payment policy for classifying Medicare beneficiaries as outpatients or inpatients, including beneficiaries with AMI. Therefore, AMI model participants should continue to follow all existing Medicare rules that apply to classifying beneficiaries as inpatients or outpatients for beneficiaries with AMI who could potentially initiate AMI episodes if they were admitted to the AMI model participant.

To provide greater clarity to hospitals and physician stakeholders, and to address the higher frequency of beneficiaries being treated as hospital outpatients for extended periods of time, CMS adopted the Two-Midnight rule for admissions beginning on or after October 1, 2013. This rule established Medicare payment policy regarding the benchmark criteria to use when determining whether inpatient admission is reasonable and necessary for purposes of payment under Medicare Part A.[62] In general, the original Two-Midnight rule stated that:

- Inpatient admissions would generally be payable under Part A if the admitting practitioner expected the patient to require a hospital stay that crossed two midnights and the medical record supported that reasonable expectation.
- Medicare Part A payment was generally not appropriate for hospital stays expected to last less than two midnights. Cases involving a procedure identified on the inpatient-only list or that were identified as ''rare and unusual exception'' to the Two-Midnight benchmark by CMS were exceptions to this general rule and were deemed to be appropriate for Medicare Part A payment.

The Two-Midnight rule also specified that all treatment decisions for beneficiaries were based on the medical judgment of physicians and other qualified practitioners. The Two-Midnight rule did not prevent the physician from providing any service at any hospital, regardless of the expected duration of the service.

We acknowledge that full provider implementation of hospital care in accordance with the Two-Midnight rule did not occur immediately on October 1, 2013 and that the first CMS' contractor reviews of short stay inpatient admissions did not begin until October 2015. Therefore, we understand that shifts in classifying certain beneficiaries with uncomplicated AMI as outpatients instead of inpatients could have occurred during the period of historical AMI episodes that would span January 1, 2013 and December 31, 2015 and would be used for setting quality-adjusted target prices in performance years 1 and 2 of the AMI model. Under our monitoring and evaluation activities as discussed in sections III.G.4. through 6. and section IV. of this final rule, respectively, we will monitor the site-of-service for treatment of beneficiaries with AMI over the course of the model to detect any issues related to access to care, quality of care, or delayed care. We will also evaluate the AMI model with respect to changes in AMI case mix for AMI model participants, and if we observe them, we would conduct analyses about the potential causes of such changes, including whether AMI model participants shifted to treating some uncomplicated beneficiaries with AMI as outpatients rather than inpatients. We further note that when we first update the data used for historical EPM episode payments in performance year 3 of the EPMs to be calendar years 2015 through 2017, we expect that any changes in care patterns related to the Two-Midnight rule would have been made by the beginning of that 3-year period.

Comment: One commenter agreed with CMS that it is currently rare for a beneficiary with AMI to have an outpatient PCI and, therefore, almost all beneficiaries with AMI who are treated with PCI would be in the AMI model under current hospital treatment practices. However, the commenter added that by excluding beneficiaries who receive outpatient PCI from the AMI model, EPM participants may change their billing to outpatient PCI, especially for more complex and costly beneficiaries for which AMI episode costs would be expected to be high. The commenter recommended that CMS should put all AMI patients on the inpatient only list.

Response: We appreciate the concern expressed by the commenter about the potential for the financial incentives in the AMI model to lead to shifting in the site-of-service for PCI for beneficiaries with AMI from inpatient to outpatient. We note that the OPPS inpatient only list includes procedures that are only paid under the IPPS and does not assign certain diagnoses to inpatient only care. PCI currently is commonly performed in the outpatient hospital department for beneficiaries that do not have AMI, and we do not believe it would be appropriate to place PCI procedures on the inpatient only list due to concerns about the shifting of the site-of-service from inpatient to outpatient for AMI model beneficiaries who require PCI. As we stated in the proposed rule (81 FR 50829) patients experiencing an AMI are almost uniformly admitted to the hospital for further evaluation and management based on clinical guidelines for the treatment of beneficiaries with AMI.[63] We do not believe that EPM participants would change their patterns of treatment of beneficiaries with AMI, especially for those complex patients with significant medical needs, in ways that would risk beneficiaries not receiving the medically necessary inpatient hospital evaluation and management recommended for their AMI treatment. We will be monitoring patterns of care as discussed in sections III.G.4. through 6. of this final rule for evidence of clinically-unexplained changes in care, including the site-of-service for AMI beneficiaries who receive PCI, especially if we believe there is the potential to compromise beneficiary access to care or quality of care or to delay care.

Comment: A commenter requested that CMS further clarify how an EPM participant can determine whether beneficiaries with AMI who have a CABG would be attributed to the AMI or CABG model.

Response: We appreciate the opportunity to provide clarification on the specific episode attribution of beneficiaries with AMI who have a CABG. We refer to section III.D.4.a.(5) of this final rule for further discussion of the final transfer attribution policy for AMI episodes that involve an inpatient-to-inpatient transfer for AMI care. AMI and CABG episodes are initiated based on the MS–DRG that is assigned to the final discharge that occurs during the anchor hospitalization. Thus, if a beneficiary hospitalized for treatment of AMI has a CABG during that anchor hospitalization, we expect that the

[62] Fact Sheet: Two-Midnight Rule; CMS; October 30, 2015.

[63] Amsterdam et al. 2014 AHA/ACC Guideline for the Management of Patients with Non-ST—Elevation Acute Coronary Syndromes. Circulation. 2014; 130:e344–e426.

beneficiary would be discharged from a CABG MS–DRG (231–236) and, therefore, would initiate a CABG episode. We refer to section III.D.4.b.(b) of this final rule for the pricing adjustment that would apply to CABG episodes for beneficiaries who have a CABG during the initial hospitalization for AMI treatment. However, if a beneficiary with an AMI hospitalized for initial treatment is discharged from the anchor hospitalization and then readmitted for CABG during the 90 day post-discharge episode duration, the beneficiary would initiate an AMI episode, which would not be canceled due to the CABG readmission. We refer to section III.D.4.b.(c) of this final rule for the pricing adjustment that would apply to AMI episodes with CABG readmissions.

Final Decision: After consideration of the public comments received, we are finalizing the proposals in § 512.240(a)(1), without modification, to begin AMI episodes 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 6—

++ 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 6—FINAL 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 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.

TABLE 6—FINAL 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 EPISODES—Continued

ICD–9–CM Diagnosis code	ICD–9–CM Description	ICD–10–CM Diagnosis code	ICD–10–CM Description
		122.9	Subsequent ST elevation (STEMI) myocardial infarction of unspecified site.

(3) Beginning CABG Episodes

We proposed that, as long as a beneficiary met the general beneficiary care inclusion criteria, a CABG 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 would be 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 was included in proposed § 512.240(b)(1). We sought comment on our proposal to begin CABG episodes.

The following is a summary of the comments received and our responses.

Comment: One commenter recommended that CMS begin elective CABG prior to admission for the anchor hospitalization, since all of the workup prior to an elective CABG happens in the weeks or months before the hospitalization. The commenter claimed that the patient workup can vary considerably among providers, which may result in unnecessary costs. As an example, the commenter stated that a patient could have every cardiac diagnostic test prior to CABG when only several may be necessary. To help address unnecessary utilization prior to elective CABG, the commenter recommended that CMS begin the episode for elective CABG prior to the hospitalization for surgery.

The commenter further disagreed with CMS' proposal that elective and urgent CABG would be included in one EPM, because the beneficiaries behave differently during the episode and with respect to their risk profiles. The commenter recommended that CMS separate CABG under these two circumstances into separate EPMs and test both models.

Response: We appreciate the interest expressed by the commenter in starting CABG episodes prior to the hospital admission, and we recognize that the beneficiary's care that ultimately leads to the CABG, including the physician-patient relationship and diagnostic workup, can begin long before the surgical procedure. However, for similar reasons to our consideration of analogous comments in the CJR Final Rule (81 FR 73316 through 73317) regarding LEJR episodes, beginning the episode too far in advance of the CABG would make it difficult to avoid bundling unrelated items and services, and starting the episode prior to the hospital admission is more likely to encompass costs that vary widely among beneficiaries with CAD that are potential candidates for CABG, which would make the episode more difficult to price appropriately. We continue to believe that beginning the CABG episode with the anchor hospitalization is most appropriate due to the clinical variability leading up to the CABG and the challenge of distinguishing between related and unrelated services. We also believe that beginning the episode with the anchor hospitalization, and not prior to admission, would be easier to administer and provide more consistent episodes for testing the CABG model.

Furthermore, we agree with the commenter that beneficiaries experiencing elective versus urgent CABG behave differently during the episode due to their different health care needs. However, rather than creating two EPMs for these beneficiaries for whom we believe the same CABG episode definition would apply, we are providing a pricing adjustment as discussed in section III.D.4.b.(2)(b) of this final rule for CABG model beneficiaries with an AMI diagnosis code on the claim for the anchor hospitalization who have substantially higher historical episode spending than CABG model beneficiaries without AMI. The two groups correspond to the urgent versus elective groups recommended by the commenter. We believe this pricing adjustment policy accomplishes the major objective of the commenter who recommended two CABG EPMs so that we price CABG episodes for the two groups of CABG model beneficiaries differently based on their different patterns of health care utilization.

Final Decision: After consideration of the public comments received, we are finalizing the proposals in § 512.240(b)(1), without modification, to begin CABG episodes 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).

(4) Beginning SHFFT Episodes

We proposed that as long as a beneficiary met the general inclusion criteria, a SHFFT 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 would be 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 episodes was included in proposed § 512.240(c)(1). We sought comment on our proposal to begin SHFFT episodes.

We received no comments specific to our proposal to begin SHFFT episodes.

Final Decision: We are finalizing the proposals in § 512.240(c)(1), without modification, to begin SHFFT episodes 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).

(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.[64]

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 episodes for initial AMI care, our overarching policy was that every AMI or CABG episode would begin at the first AMI or CABG model participant to which the beneficiary was 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 began would then be financially responsible for the AMI or CABG episode unless the episode was canceled.

Based on our analysis of Medicare claims data, in the proposed rule (81 FR 50836) we presented the finding that about 75 percent of historical AMI episodes and CABG episodes for beneficiaries with AMI began through the emergency department of the hospital where the anchor hospitalization for the AMI or CABG episode would occur. In another 18 percent of historical AMI episodes and CABG episodes for beneficiaries with AMI, the anchor hospitalization occurred 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 episode.[65]

In each of these scenarios, policies to determine which episode type would apply, 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 the proposed rule, we discussed each of the scenarios in detail and provide a summary of the scenarios in Table 7.

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 the proposed rule (81 FR 50847 through 50848), and the AMI or CABG episode that applied 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 the proposed rule (81 FR 50861 through 50862).

The inpatient-to-inpatient transfer scenario had several potential outcomes. If the beneficiary initially presented for AMI care to a hospital that was not an AMI model participant and was admitted and then transferred to an i-i transfer hospital that was 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 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 the proposed rule (81 FR 50861 through 50862).

If a beneficiary initially presented for AMI care to an AMI model participant and was admitted and then transferred to an i-i transfer hospital (hereinafter a chained anchor hospitalization) and the i-i transfer hospital was 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 under MS–DRGs that were not anchor MS–DRGs for AMI or CABG episodes as discussed in section III.C.4.b. of the proposed rule (81 FR 50841 through 50842). 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 the proposed rule (81 FR 50861 through 50862). We also refer to section III.D.4.b.(2)(a) of the proposed rule (81 FR 50849 through 50851) for

[64] 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.

[65] 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 the proposed rule, that end in CY 2014.

further discussion of our proposal for price MS–DRGs that could differ from the anchor MS–DRG in AMI episodes that included a chained anchor hospitalization, in order to provide pricing adjustments for episodes where the initial treating hospital was responsible for the AMI episode.

Inpatient-to-inpatient transfers between AMI and CABG model participant hospitals were further considered in this section and specifically included beneficiaries experiencing an AMI who were transferred for revascularization (that is, PCI or CABG) or a higher level of medical AMI care. We noted 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.[66] 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.[67]

However, given the asymmetric distribution of cardiac care capacity, we noted in the proposed rule (81 FR 50837) that there would be beneficiaries who initiated an AMI episode by admission to an initial treating hospital but then required transfer to an i-i transfer hospital for additional treatment during the AMI 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 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 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.[68] This small number of hospitals that transferred the majority of their patients included a range of urban and rural hospitals with 50 to 250 beds.

The need to transfer a beneficiary in an AMI episode during the anchor hospitalization for appropriate care that resulted in a chained anchor hospitalization where the hospitals were both AMI or CABG model participants raised considerations about whether attribution of the AMI 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 initiated an AMI episode by admitting a beneficiary and then transferred the beneficiary to another hospital where the beneficiary was treated and ultimately discharged from acute care, ending the chained anchor hospitalization under a CABG MS–DRG, then we needed to determine whether the beneficiary would be included in the AMI or CABG model, which hospital would assume financial responsibility for the beneficiary's episode, and under what circumstances, if any, would the AMI episode be canceled if a transfer occurred.

In considering the model episode that would include the beneficiary's care and accountability for the beneficiary in inpatient-to-inpatient transfer scenarios between AMI and CABG model participant hospitals that resulted in a chained anchor hospitalization for AMI, several factors were 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 was most responsible for managing the beneficiary's care after discharge; and consistency with other CMS transfer policies. We noted in the proposed rule (81 FR 50837) 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.[69] Of further relevance for beneficiaries with an AMI diagnosis was that significant follow up care was usually performed by cardiologists who managed the patient's underlying cardiovascular disease, rather than the interventional cardiologist or cardiothoracic surgeon that performed 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 noted 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 expected that beneficiaries hospitalized for treatment of AMI, even if they were 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 believed 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 experienced an inpatient-to-inpatient transfer was relevant to developing policies for the AMI and CABG models. Specifically, we noted 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 admitted the patient for the initial AMI hospitalization.[70]

Based on these considerations, we proposed that once an AMI episode was initiated at an AMI model participant hospital through an inpatient hospitalization, the AMI episode would continue under the financial responsibility of that participant hospital, regardless of whether the

[66] 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 the proposed rule, that end in CY 2014.

[67] 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 the proposed rule, that end in CY 2014.

[68] 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 the proposed rule, that end in CY 2014.

[69] 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 the proposed rule, that end in CY 2014.

[70] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

beneficiary was 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 the proposed rule (50861 through 50862) rule. Our proposal to cancel AMI episodes for beneficiaries discharged from the i-i transfer hospital under MS–DRGs that were not anchor MS–DRGs for AMI or CABG episodes was discussed in section III.C.4.b. of the proposed rule (81 FR 50841 through 50842). We also referred to section III.D.4.b.(2)(a) of the proposed rule (81 FR 50849 through 50851) for further discussion of the proposal for price MS–DRGs that could differ from the anchor MS–DRG in AMI episodes that included a chained anchor hospitalization, in order to provide pricing adjustments for episodes where the initial treating hospital was responsible for the AMI episode.

In the proposed rule (81 FR 50838), we noted that we did not propose to cancel the AMI episode even if the transfer and admission to the i-i transfer hospital would otherwise initiate a CABG episode at the i-i transfer hospital. We believed that once the AMI episode had 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 episode in the manner described in this section for the episode and that the first hospital that initiated the AMI episode should be financially responsible for the AMI episode. Therefore, we did not propose to cancel the AMI episode if a CABG was performed during a chained anchor hospitalization, nor did we propose that a beneficiary could simultaneously be in an AMI and CABG episode for overlapping periods of time due to the different MS–DRGs that applied during the chained anchor hospitalization. Instead, we would make an AMI episode pricing adjustment for these circumstances by paying the AMI model participant based on a price MS–DRG that was different from the anchor MS–DRG to reflect Medicare payment for the CABG as discussed in section III.D.4.b.(2)(a) of the proposed rule (81 FR 50849 through 50851).

We considered several alternatives to our proposal for AMI episode attribution for inpatient-to-inpatient transfer scenario where both hospitals are AMI or CABG model participants. First, we considered canceling the AMI episode initiated at the initial treating hospital when a transfer occurs, and basing any AMI or CABG 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 was an AMI or CABG model participant. This would place financial responsibility for the episode on the i-i transfer hospital if the beneficiary went 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 episode based on the model episode definitions in sections III.C.4.a.(2) and (3) of the proposed rule (81 FR 50834 through 50835). That is, if the beneficiary was discharged from the final admission in the chained anchor hospitalization under an AMI MS–DRG or a PCI MS–DRG, then the AMI 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 episode. Similarly, if the beneficiary was discharged from the final admission in the chained anchor hospitalization under a CABG MS–DRG, then the AMI episode initiated at the first hospital would be canceled and the i-i transfer hospital accepting the beneficiary on referral would initiate a CABG 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 the proposed rule (81 FR 50861 through 50862). However, we did not propose this alternative because we believed that post-acute care and care management following hospital discharge would be 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 established 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 the proposed rule (81 FR 50861 through 50862), depending on the specific hospital discharging the beneficiary under the most resource-intensive MS–DRG during the chained anchor hospitalization. However, we did not propose this alternative because we believed, 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 have placed responsibility for care during the 90-day post-hospital discharge period in the AMI 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 episode. Given the broad episode definition of AMI episodes, we believed that the post-discharge care required following hospitalization that included CABG, PCI, or medical management was 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 proposed that, as discussed in section III.I.3. of the proposed rule (81 FR 50918 through 50920), hospitals could 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 were financially responsible for EPM episodes. Therefore, we expected that community hospital participants in the AMI model would be able to enter into sharing arrangements 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 played a significant role in care redesign of AMI or CABG care pathways or management of beneficiaries throughout AMI or CABG episodes, including during the 90 days post-hospital discharge. We expected that community hospitals would need to coordinate closely with i-i transfer hospitals accepting AMI model beneficiaries on referral as the beneficiaries in AMI episodes were discharged from those hospitals, in order to improve the quality and efficiency of AMI episodes. This coordination could potentially be enhanced if i-i transfer hospitals were AMI model collaborators with financial incentives that were aligned with those of the AMI model participants through sharing arrangements.

The proposal for AMI episode attribution in circumstances that involve inpatient-to-inpatient transfers of beneficiaries with AMI was included in proposed § 512.240(a)(2). We sought comment on our proposal for AMI episode attribution in circumstances that involved 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 was 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 proposed that the AMI or CABG 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 was assigned to that anchor hospitalization. That is, if a beneficiary received initial AMI care in a hospital emergency department without admission and was transferred to an AMI or CABG model participant (the o-i transfer hospital) for admission, then the AMI or CABG episode would begin in the first hospital involved in the beneficiary's AMI or CABG care that admitted 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 episode. This attribution was in accordance with the AMI and CABG model rules, as discussed in sections III.C.4.a.(2) and (3) of the proposed rule (81 FR 50834 through 50835), that initiated an AMI 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 episode with a hospitalization that resulted 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 the proposed rule (81 FR 50861 through 50862). Under this proposal, regardless of whether the initial treating hospital was an AMI or CABG model participant, an AMI or CABG episode would only be initiated at the o-i transfer hospital if that hospital was an AMI or CABG model participant.

We considered an overarching alternative policy that would begin every AMI or CABG 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 began would then be financially responsible for the AMI or CABG episode unless the episode was 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 episode would begin at this initial treating hospital when a beneficiary was transferred from the emergency department for his or her first inpatient hospitalization which occurred at an o-i transfer hospital. This would place financial responsibility for the AMI or CABG 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 the proposed rule (81 FR 50861 through 50862).

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 were 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 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 the propose rule (81 FR 50861 through 50862). 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 had the benefit of consistently including all care in each AMI or CABG episode that occurred following presentation of a beneficiary with AMI to the emergency department of an AMI or CABG model participant to the AMI or CABG episode, regardless of whether an AMI or CABG episode involved no transfer, o-i transfer, or i-i transfer. However, because this alternative would have begun the AMI episode prior to the initial hospital admission, we would have needed to establish additional policies for identifying the beneficiaries who initiated these episodes and defined the timeframe and services that would have been included in the AMI or CABG episode prior to admission to the o-i transfer hospital.

We did not propose this alternative because we believed the policies necessary to begin the AMI or CABG episode at the first treating hospital when an inpatient hospitalization did not occur would be complex, challenging to operationalize, and required assumptions about the relationship of care to the AMI based solely on administrative claims data that were insufficient to ensure we could accurately identify related care. We believed it remained problematic to define the services to be included in AMI or CABG episodes if those services preceded an inpatient hospitalization that would otherwise initiate the AMI or CABG episode. For example, we would need to define the timeframe for beginning an AMI or CABG episode with an emergency department visit for AMI that resulted 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 episode that would result. As we discussed in section III.C.4.a.(1) of the proposed rule (81 FR 50834), we did 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 did 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 was not admitted to that hospital.

We sought comment on the proposal for AMI and CABG 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 resulted in an outpatient-to-inpatient transfer.

Table 7 included in the proposed rule (81 FR 50840) provided a summary of 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 related to the participation in the AMI or CABG models of hospitals providing initial AMI care.

TABLE 7—PROPOSED INITIATION AND ATTRIBUTION OF AMI AND CABG EPISODES THAT INVOLVE NO TRANSFER, OR OUTPATIENT-TO-INPATIENT OR INPATIENT-TO-INPATIENT TRANSFERS AT THE BEGINNING OF AMI CARE

Scenario	Proposed 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 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 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 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 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 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 episode is initiated.

The following is a summary of the comments received and our responses.

Comment: A number of commenters expressed support for the proposed AMI model transfer episode initiation and attribution policy that would initiate an AMI episode under the responsibility of an initial treating hospital that is an AMI model participant where the beneficiary is assigned to an AMI MS–DRG or PCI MS–DRG with AMI ICD–CM diagnosis code and the beneficiary is later transferred to another hospital and ultimately discharged from an AMI, PCI, or CABG MS–DRG. One commenter further recommended that CMS consider implementing this policy in the BPCI initiative and future episode payment models that are under development. Several commenters stressed the importance of beneficiaries receiving rehabilitation services in their home communities to improve adherence to the treatment plan, and acknowledged that CMS' AMI model transfer attribution proposal would encourage this care pattern. Another commenter pointed out that CMS should differentiate patient-directed presentation with AMI at a hospital emergency department versus emergency medical services-directed delivery to the hospital emergency department. The commenter explained that the usual practice in the case of STEMI identified in the field by emergency medical services would be to transport the beneficiary to a hospital with appropriate capacity to avoid any need for transfer that could delay treatment and impair outcomes. The commenter added that the trend nationally for emergency medical services delivery of patients with an AMI is for the patient to be taken to a facility that is capable of managing that patient rather than taking them to the closest hospital. Thus, the commenter believes the transfer issues should be only applicable to the minority of beneficiaries who present to the emergency department under their own power.

Other commenters who supported the proposed AMI model transfer episode initiation and attribution policy, including the proposal to cancel

episodes that contain a chained anchor hospitalization with a final discharge MS–DRG that is not an AMI, PCI, or CABG MS–DRG, however expressed concern that the proposal for a price MS–DRG payment adjustment does not go far enough to provide a level playing field for AMI episodes involving a chained anchor hospitalization. One of these commenters presented analysis showing that while only a minority of episodes involving a chained anchor hospitalization resulted in a final discharge MS–DRG other than an AMI, PCI, or CABG MS–DRG, the episode costs were very high in those cases because they were atypical. The commenter concluded that CMS' proposal to cancel these episodes was appropriate.

Additional analysis by the commenter demonstrated that hospitals that transfer AMI beneficiaries frequently are more likely to be smaller community hospitals with much higher episode spending, who would be penalized by the lack of a more robust transfer-adjustment methodology just because they do not have the most sophisticated cardiac care available. Several commenters stated that these hospitals often have no choice but to transfer their most complicated patients to larger, tertiary hospitals so that the patients can receive the most appropriate cardiac care and that hospitals should not be penalized for doing so. These commenters requested that CMS exclude the IPPS amount paid to the initial admitting hospital when calculating quality-adjusted target prices and actual episode spending to put these hospitals on a more level playing field with larger referral hospitals that offer comprehensive cardiac care in order to encourage the best provision of care to beneficiaries in AMI episodes. Additionally, the commenters recommended that CMS provide additional explanation of the framework for chained anchor hospitalizations in the final rule and include illustrative examples about how the methodology works.

One commenter expressed support for the second of the two alternatives considered by CMS for attributing AMI episodes in inpatient-to-inpatient transfer scenarios that would begin an AMI episode and assign episode responsibility to the hospital in the chained anchor hospitalization discharging the beneficiary under the most resource-intensive MS–DRG according to a hierarchy of CABG, PCI, and AMI MS–DRGs in descending order of inpatient hospital resource-intensity. The commenter reasoned that in comparison with CMS' proposal, this approach would provide a more direct association in the transfer policy between hospital episode responsibility and the hospital providing the highest level of care for the beneficiary with AMI during the chained anchor hospitalization. The commenter stated that if a hospital admits a beneficiary but then has to transfer the beneficiary to another hospital for more advanced cardiac care that the initial treating hospital cannot provide, it does not seem reasonable to make that initial hospital responsible for all follow up care post-discharge for that condition.

The majority of commenters opposed CMS' proposed AMI model transfer episode initiation and attribution policy, with the majority addressing the inpatient-to-inpatient transfer scenario where the initial treating hospital and the i-i transfer hospital are both AMI and CABG model participants. In general, the commenters believe the inpatient-to-inpatient transfer proposal was too complex and would be unmanageable for EPM participants. They stated that while CMS partially predicated its AMI model transfer episode initiation and attribution proposal on public input on the CJR model that beneficiaries often prefer to receive follow up care after hospital discharge in their community, the AMI and CABG models are sufficiently different from the CJR model that this perspective may not apply to the proposed models. In the AMI and CABG models, the commenters emphasized that beneficiaries would be more likely to require emergent care and, therefore, have less of an opportunity to seek care from a facility located outside of their region. Thus, the commenters believe that many AMI model beneficiaries experiencing a chained anchor hospitalization during their initial hospital treatment for AMI would remain in the same region as the i-i transfer hospital for post-acute care services, in contrast to primarily elective LEJR under the CJR model where procedures may be planned in advance and involve farther travel for the surgery. Thus, the commenters reasoned that the initial treating hospital and the i-i transfer hospital caring for a beneficiary in an AMI episode would be likely to be in the same region as one another and the beneficiary's home community. Thus, they concluded that CMS' interest in AMI model attribution policy for inpatient-to-inpatient transfers that could support beneficiary follow up in their own community following discharge could be met equally well through AMI episode attribution to the i-i transfer hospital as to the initial treating hospital.

Therefore, for inpatient-to-inpatient transfer scenarios for AMI model beneficiaries, many commenters who disagreed with CMS' proposal recommended CMS to adopt the first alternative considered for i-i transfers once an AMI episode is initiated at the initial treating hospital. Consistent with CMS' discussion of this alternative considered in the proposed rule (81 FR 50838), the commenters encouraged CMS to cancel the AMI episode initiated at the initial treating hospital every time an inpatient-to-inpatient transfer occurs, and base any AMI or CABG episode initiation on the MS–DRG for the final i-i transfer hospital admission in the chained anchor hospitalization if the i-i transfer is an AMI or CABG model participant. This would place financial responsibility for the episode on the i-i transfer hospital if the beneficiary went on to be discharged from acute care at that hospital and the hospital was an AMI or CABG model participant. The commenters claimed this approach would greatly simplify the initiation, attribution, and pricing methodologies under the AMI and CABG models.

The commenters favoring AMI episode initiation and episode assignment to the i-i transfer hospital contended that CMS' proposal to assign AMI episode responsibility to the initial treating hospital could encourage the initial treating hospital to either prematurely transfer patients who present to the emergency department with symptoms of AMI or not transfer AMI patients at all to retain control of the episode and its associated costs. The commenters speculated that while these hospital responses could be clinically appropriate, it is unclear whether this would be the best approach for beneficiaries and whether long-term this type of transfer policy within the AMI model could reduce the capacity of small and rural hospitals to effectively manage care for cardiac patients, while creating an overreliance on larger hospitals.

The commenters stated that CMS' proposal placed too much importance on the role of the local hospital and physicians associated with the initial AMI treatment and too little importance on the role of the hospital providing the majority of the AMI care. They maintained that the i-i transfer hospital would be more likely to influence the post-discharge plan and post-acute care the beneficiary receives and would be in a better position to retain financial responsibility for the beneficiary and assume final risk for the EPM episode. The commenters claimed that it is the

discharging i-i transfer hospital that would develop the discharge plan; make recommendations on the type of post-acute care services necessary and make arrangements with specific post-acute care providers; schedule follow up appointments; educate the beneficiary and caregivers about the beneficiary's clinical condition; and communicate post-discharge instructions.

In addition, several commenters pointed out that the initial treating hospital may not know the beneficiary's final MS–DRG until days after discharge from the i-i transfer hospital. They stated that this time lag makes it problematic to assign episode responsibility to the initial treating hospital because that hospital would not be able to identify and intervene with AMI model beneficiaries prior to their discharge from acute care, a care redesign strategy that the commenters believe is important for AMI model success. Some commenters stated that CMS failed to appreciate the complexity of accurate beneficiary identification and its impact on facilitating effective post-acute care services in the proposed AMI model transfer policy.

A number of commenters recognized CMS' intent to link transferring hospitals with larger, tertiary hospitals through the AMI model transfer episode initiation and attribution proposal in order to strengthen the quality and efficiency of health care within communities. The commenters agreed that there needs to be increased communication and collaboration among these hospitals in order to achieve better patient outcomes, yet they also believe that ongoing challenges with the timely communication of beneficiary information among providers and the current competitive healthcare landscape are not conducive to this type of collaboration.

In general, many commenters expressed concern that the complexity of the AMI model's proposed transfer attribution policies and the potential resulting confusion about beneficiary notification and hospital episode responsibility in an environment that lacks established electronic tracking programs that can communicate among many hospitals in different systems. Several commenters believe the proposed policy could focus an AMI model participant's limited resources on administrative issues that do not actually improve care and reduce episode costs for AMI beneficiaries. They stated that hospital time and resources would be better spent improving care, developing sharing arrangements among providers, and tracking beneficiary outcomes. The commenters emphasized that this is especially true since transfers are expected to occur in a small minority of AMI episodes.

The majority of commenters also expressed various concerns about potential beneficiary harm due to AMI model transfer policies under an EPM, whether those proposed or recommended by some of the commenters, that would establish new financial incentives for hospitals around transfers for beneficiaries with AMI in the absence of clear best transfer practices for hospitals with varying levels of cardiac care capacity. The commenters claimed that CMS' proposal did not include sufficient protections against EPM participants engaging in adverse patient selection to improve quality and cost performance in each type of transfer scenario (no transfer, outpatient-to-inpatient, and inpatient-to-inpatient). The commenters believe that inappropriate transfers and cost-shifting among competitors in a geographic market could occur under the AMI model, and they recommended to CMS to provide robust patient protections and transfer methodologies in the final rule.

Most commenters expressed support for CMS' proposal to initiate AMI episodes upon admission to the o-i transfer hospital in an outpatient-to-inpatient transfer scenario, as well as attribute responsibility for the episode to the o-i transfer hospital. The commenters agreed with CMS that this approach would not require potentially flawed assumptions about the relatedness of services preceding the hospital admission and, therefore, would result in clearly defined AMI episodes. However, several commenters recommended CMS to address the operational issues identified in the proposed rule (81 FR 50839) related to outpatient-to-inpatient transfers that would not allow CMS to begin AMI episodes when an initial treating hospital provides only outpatient emergency care prior to transfer to an o-i transfer hospital. The commenters believe it would be important to mitigate these concerns in order to avoid the potential unintended consequences of unnecessary and medically inappropriate outpatient-to-inpatient beneficiary transfers.

Due to the complexity of transfer scenarios and the lack of clarity about the best approaches to caring for beneficiaries with AMI under an EPM in communities with varying cardiac care capacity distributed among hospitals in the region, several commenters further recommended that CMS gather clinical expert advice through an advisory panel or other dialogue with stakeholders to further explore the AMI model transfer policy consequences on hospitals' willingness to transfer patients. Finally, many commenters recommended CMS to provide clarification and ongoing guidance and support to AMI model participants related to transfers and episode attribution and monitor for any unintended consequences of the final AMI model transfer episode initiation and attribution policies.

Response: We appreciate the variety of perspectives of the commenters on the proposed AMI model transfer episode initiation and attribution policies. We agree with the commenters that this area of policy is both complex and significant under the AMI model, given the variety of care patterns experienced by beneficiaries with AMI and the variation in cardiac care capacity among hospitals. The transfer policy has substantial implications for AMI and CABG model participants with varying cardiac care capacity, beneficiaries who experience transfers during emergency treatment of AMI, and CMS due to the potential for the AMI model transfer policy to result in changes in transfer patterns that do not improve the quality or efficiency of care for beneficiaries with AMI, both those beneficiaries included the model and those whose care is not included in the AMI model. We recognized the importance of considering the potential advantages and disadvantages of various approaches to AMI model transfer episode initiation and attribution for beneficiaries and hospitals in our extensive discussion in the proposed rule (81 FR 50838 through 50840) about alternatives considered for outpatient-to-inpatient and inpatient-to-inpatient transfer scenarios. We also continue to believe that collaboration among community hospitals and referral hospitals with more advanced cardiac care capacity is important to improving the quality and efficiency of health care in communities, especially for beneficiaries with conditions requiring emergency evaluation and treatment such as AMI.

We considered the analysis provided by some commenters and the commenters' different perspectives on the proposed AMI model transfer episode initiation and attribution proposal and the alternatives considered, including the potential for unintended consequences under any transfer policy we would establish for the AMI model. At this point in time, we appreciate that there are important advantages and disadvantages to each of the potential AMI model transfer

episode initiation and attribution policies that require ongoing consideration over the longer-term during AMI model implementation in order to optimize the interests of beneficiaries, hospitals, and CMS, while limiting the risk of unintended consequences that could create problems for beneficiaries, hospitals, and CMS. For example, several commenters stressed that changes to current AMI transfer patterns under transfer policies of the AMI model that encourage the initial treating hospital to either more quickly transfer patients who present to the emergency department with symptoms of AMI or not transfer AMI patients at all to retain control of the episode and its associated cost could be clinically appropriate but also could reflect premature transfers that were not medically necessary or a care pattern that poses a risk to beneficiaries' health. Thus, while we are finalizing a policy now to address transfer situations under the AMI model to allow for implementation of the model, we are also coupling this policy with heightened monitoring and evaluation of transfers of Medicare AMI beneficiaries to and from AMI and CABG model participants and may propose refinements to the policy or payment adjustments in the future depending on our findings.

With respect to the policy for outpatient-to-inpatient transfers of beneficiaries with AMI, we proposed to begin AMI and CABG episodes upon the first inpatient admission to a treating hospital that is an AMI or CABG model participant, rather than in the outpatient department of the initial treating hospital that did not admit the beneficiary. In the proposed rule (81 FR 50839), we also considered an overarching alternative policy that could begin every AMI and CABG episode at the first AMI or CABG model participant at which the beneficiary was either admitted for an AMI MS–DRG, PCI MS–DRG with an AMI ICD–CM diagnosis code, or CABG MS–DRG or presented to the emergency department for initial AMI care (including observation status) before being transferred to an o-i transfer hospital. However, we are not beginning AMI or CABG episodes with care furnished by an AMI or CABG model participant when the beneficiary is not admitted as an inpatient to that hospital. Given the commenters' concerns about our proposal to begin AMI episodes at the initial treating hospital under the circumstance of an inpatient-to-inpatient transfer, we believe that beginning AMI episodes at a hospital furnishing only emergency AMI care could interfere with the hospital's focus on emergency stabilization and transfer of the beneficiary. It could also place an undue burden on the initial treating hospital for long-term responsibility for the AMI episode in which the initial treating hospital had a role that was limited to stabilization prior to transfer for AMI treatment. We would not expect the initial treating hospital in these circumstances to be substantially involved in the beneficiary's AMI treatment after the initial emergency care. The commenters confirmed our concerns, as discussed in the proposed rule (81 FR 50839), that this approach would be complex, challenging to operationalize, and require assumptions about the relationship of care to the AMI based solely on administrative claims data that would be insufficient to ensure we could accurately identify related care.

Thus, we have concluded that it remains problematic to define the services to be included in AMI episodes if those services precede an inpatient hospitalization that would otherwise initiate the AMI or CABG episode. As we discuss in section III.C.4.a.(1) of this final rule, we are not beginning an 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 will not make an exception for transfers from the emergency department or observation status of the initial treating AMI or CABG model participant when the beneficiary with AMI is not admitted to that hospital. As discussed in sections III.G.4. through 6. and IV. of this final rule, we will be engaged in monitoring and evaluation specifically as they relate to the risks associated with this policy of adverse patient selections that could result in increased transfers of complex beneficiaries with AMI to other hospitals so that an AMI model participant can avoid high-cost episodes. Should we observe concerning outpatient-to-inpatient transfer patterns, we may engage in future rulemaking to refine the AMI episode initiation policy or to make a payment adjustment for this scenario.

With respect to the proposed policy for inpatient-to-inpatient transfers, we appreciate the detailed comments on the proposal as well as on the two alternatives considered in the proposed rule (81 FR 50838). In response to the commenters who contended that the proposal to assign AMI episode responsibility to the initial treating hospital in an inpatient-to-inpatient transfer scenario could increase premature transfers, we are unclear that this would be the case since we also proposed not to initiate AMI episodes based only on care in the outpatient department. Thus, we believe it would be more likely expected that AMI model participants pursuing early transfer would transfer the beneficiary prior to admission to the hospital. However, we are concerned that the proposal to assign AMI episode responsibility to the initial treating hospital could lead to beneficiaries not being transferred in circumstances where they need a higher level of cardiac care, as a number of commenters claimed.

We appreciate the support of the commenter for the second alternative we discussed in the proposed rule (81 FR 50838) for inpatient-to-inpatient transfer, which would assign AMI or CABG episode responsibility to the hospital in the chained anchor hospitalization discharging the beneficiary under the most resource-intensive MS–DRG according to a hierarchy of CABG, PCI, and AMI MS–DRGs in descending order of inpatient hospital resource-intensity. While we continue to believe that this alternative could have merit by placing AMI episode responsibility on the hospital that furnished the most intensive treatment to the AMI beneficiary during the chained anchor hospitalization, we are not adopting this policy due to concerns about the episode attribution complexity that it would present. Many commenters pointed out significant challenges for AMI model participants that would arise under our proposal to assign AMI episode responsibility consistently to the initial treating hospital that admitted the beneficiary regarding the ability of AMI model participants to meet the requirements of the model, such as timely beneficiary notification. They also raised concerns about the timeliness of the responsible hospital's identification of model beneficiaries especially if the hospital is not the one discharging the beneficiary from acute care and stated that a delay in beneficiary identification could seriously impede the hospital's ability to intervene with AMI and CABG model beneficiaries to begin coordinating care prior to hospital discharge. Thus, we believe that an inpatient-to-inpatient transfer policy that assigns AMI episode responsibility in some cases to the initial treating hospital and in other cases to the i-i transfer hospital depending on the different MS–DRGs during the chained anchor hospitalization would be even more

complex and could lead to even greater hospital confusion than our proposal.

We also considered the potential for making a payment adjustment while holding the initial treating hospital accountable for the AMI episode as recommended by a number of commenters, in order to put hospitals with lesser cardiac care capacity that more frequently need to transfer AMI beneficiaries on a more level playing field with hospitals that can themselves furnish comprehensive cardiac care. While this recommendation from the commenters would be operationally feasible and address some of the concerns raised by commenters about the transfer incentives inherent in our proposal, while maintaining the responsible hospital for the AMI episode in an inpatient-to-inpatient transfer scenario as the initial treating hospital that would be most likely to be in the beneficiary's community, this recommendation would add even greater complexity to the AMI model pricing methodology, already an area of significant concern to the commenters. This refinement also would not address the challenges for the initial treating hospital raised by other commenters related to timely beneficiary identification and notification. Therefore, we are not adopting this recommendation for the AMI model. However, we note that because we are changing the responsible hospital for AMI and CABG episodes that involve inpatient-to-inpatient transfers in our final policy as discussed later in this section, we believe the commenters' interest in creating a more level playing field among AMI model participants that transfer beneficiaries to variable degrees is addressed through that final policy.

Most commenters favored the first alternative we discussed in the proposed rule (81 FR 50838) for AMI model transfer episode initiation and attribution in the inpatient-to-inpatient transfer scenario. Specifically, this policy would cancel the AMI episode initiated at the initial treating hospital that is an AMI model participant when any inpatient-to-inpatient transfer occurs. The beneficiary would initiate a new AMI or CABG episode at the i-i transfer hospital if that hospital is an AMI or CABG model participant and the MS–DRG for that hospitalization is an AMI MS–DRG, PCI MS–DRG with AMI ICD–CM diagnosis code, or CABG MS–DRG. If the i-i transfer hospital is not an AMI or CABG model participant, then the beneficiary would not be included in any AMI or CABG episode regardless of the MS–DRG assigned. This approach would place financial responsibility for the AMI or CABG episode on the i-i transfer hospital if the beneficiary went on to be discharged from acute care at that hospital. Episode initiation and attribution in this way addresses the concerns of commenters about establishing a level playing field for AMI model participants that more frequently transfer beneficiaries for AMI treatment because it would not hold those hospitals accountable for AMI episodes with inpatient-to-inpatient transfers that are, on average, higher-cost than AMI episodes without transfers.

This approach also addresses the commenters' significant concerns about the potential burden our proposal would have placed on the initial treating hospital to track beneficiaries transferred to the i-i transfer hospital and determine if they were discharged from the i-i transfer hospital under an MS–DRG that would assign the beneficiary to an AMI episode for which the initial treating hospital would be responsible. The resources necessary for the initial treating hospital to coordinate with the i-i transfer hospital that was actually discharging the beneficiary around the discharge and follow up plan could be substantial, given that the i-i transfer hospital would hold the discharge planning responsibility for that beneficiary. It is not clear that the opportunity for the initial treating hospital to enter into financial arrangements to share upside and/or downside risk with the i-i transfer hospital as discussed in section III.I. of this final rule would have been sufficient to incentivize the degree of timely collaboration and coordination by the i-i transfer hospital that would be needed by the responsible initial treating hospital.

Therefore, we believe the most prudent final AMI model transfer episode initiation and attribution policy at this time is to cancel the AMI episode initiated at the initial treating hospital whenever an inpatient-to-inpatient transfer occurs, and base any new AMI or CABG episode initiation on the MS-DRG for the i-i transfer hospital admission if the i-i transfer hospital is an AMI or CABG model participant. This attribution approach is simple and unambiguous. It eliminates the need for us to adopt the concept of chained anchor hospitalization altogether, as well as the complex policy that would have established a price MS–DRG that could be different from the MS–DRG that was assigned to the hospitalization that initiates the AMI episodes as discussed in section III.D.4.b.(2)(a) of this final rule. We do not believe there is a need to make any additional pricing adjustments for inpatient-to-inpatient transfer scenarios that include more than one IPPS payment for continuous acute care services in the beginning of AMI episodes in order to ensure a level playing field for hospitals that more commonly transfer beneficiaries for AMI treatment. By making the hospital ultimately discharging the beneficiary from acute care responsible for the AMI or CABG episode and beginning the episode at that hospital, we reduce the hospital's uncertainty as much as possible around identifying beneficiaries in the model. In the inpatient-to-inpatient transfer scenario, the uncertainty about identification of beneficiaries who were transferred is no different than if all the care for the beneficiary occurred at a single hospital. We also do not hold a hospital financially responsible for inpatient or outpatient hospital and Part B services that precede the beneficiary's admission to the responsible hospital, services the responsible hospital would be unable to influence according to the commenters.

While we are finalizing this AMI model transfer episode initiation and attribution policy at this time for the AMI model that differs from our proposal for the reasons discussed, we continue to have some concerns about the care patterns that could be perpetuated and changes that could be incentivized by the policy. First, we recognize that this policy does not encourage any efficiencies in the transfer patterns of beneficiaries with AMI, while we know that episodes which include inpatient-to-inpatient transfers in the beginning of AMI care are costly for the Medicare program. A recent analysis by DataGen of 90-day episodes of care for AMI found that nationally, Medicare payments (that is, costs to the program) for AMI acute care transfers (not just those receiving PCI) were second only to the costs for patients going to long-term care.[71] This analysis is consistent with information provided by the commenters that AMI episodes that include inpatient-to-inpatient transfers are significantly more costly than AMI episodes that do not include such transfers. The analysis identified three scenarios for AMI care as follows:

- In hospitals that are licensed to perform PCIs, a patient who is admitted with AMI and needs a PCI receives his or her full treatment at that hospital. This results in one MS–DRG assignment and payment for the PCI.

[71] The Truth Behind Variation in Episode Payments; May 5, 2014. Accessed October 18, 2016 at *http://www.beckershospitalreview.com/finance/the-truth-behind-variation-in-episode-payments.html.*

• In hospitals not licensed to perform PCIs, a patient admitted with an AMI who needs a PCI is assigned an AMI MS–DRG at the initial treating hospital and then transferred to an i-i transfer hospital for the PCI. This results in two MS–DRG payments, one for the AMI care and one for the PCI. In this case, the inpatient acute care costs for the initial AMI treatment are substantially higher. The analysis found that the average length-of-stay at the initial treating hospital was 3 days, but it was not possible to determine from administrative claims whether that relatively long length-of-stay was due to patient stabilization or the need to wait for the PCI to be scheduled at the i-i transfer hospital.

• In hospitals that are licensed to perform PCIs, a patient who is admitted with an AMI and needs a PCI receives some care at the initial treating hospital and then is transferred to an i-i transfer hospital for the PCI. This also results in two MS–DRG payments and substantially higher inpatient acute care costs for the initial AMI treatment

In summary, medically unnecessary or inappropriate inpatient-to-inpatient transfers lead to inefficiencies in initial AMI treatment, yet both the second and third scenarios may provide opportunities for care redesign. However, the final AMI model transfer episode initiation and attribution policy is not able to test such opportunities at this time.

In addition to not creating incentives for transfer efficiency, the final AMI model policy may create additional incentives for an AMI model participant to transfer complex beneficiaries or beneficiaries with potentially avoidable complications resulting from AMI treatment who would be expected to result in high-cost episodes to i-i transfer hospitals. Transfers could occur to i-i transfer hospitals that are also participants in the AMI model where the costs of care at the initial treating hospital would not be included in the AMI episode initiated at the i-i transfer hospital or to hospitals outside the MSA that would not be participants in the AMI model. Such transfer patterns could ultimately result in either complex beneficiaries or those with complications resulting from the initial AMI treatment disproportionately not being the financial responsibility of the initial AMI model treating hospital or not being included in the AMI model at all.

Given these concerns about the potential missed opportunities and unintended consequences due to the final AMI model transfer episode initiation and attribution policy, we will be examining AMI transfers to and from AMI model participants very closely through our monitoring and evaluation activities as discussed in sections III.G.4. through 6. and IV. of this final rule, both of beneficiaries that ultimately are included in AMI episodes and those that are not. We may revisit the transfer policy or propose payment adjustments through future rulemaking if we see reduced AMI transfer efficiency; opportunities to increase transfer efficiency; disproportionate transfers of complex AMI beneficiaries suggesting that AMI model participants are engaging in adverse patient selection; high rates of transfers of beneficiaries with potentially avoidable complications of AMI treatment at the initial treating hospital; inordinate loss of beneficiaries from the AMI model due to transfer outside of the MSAs where the AMI and CABG models are being tested; or other patterns of concern.

The final policies for initiation and attribution of AMI and CABG episodes that involve no transfer, outpatient-to-inpatient transfer, or inpatient-to-inpatient transfers at the beginning of AMI care are summarized in Table 8.

Comment: One commenter requested that CMS establish a transfer attribution policy for the SHFFT model as well, because beneficiaries with SHFFT are occasionally transferred from the initial treating hospital to another hospital for SHFFT surgery. The commenter recommended that the SHFFT episode be attributed to the transfer hospital, that is, the hospital receiving the beneficiary upon transfer from the initial treating hospital.

Response: We appreciate the commenter's suggestion. However, we do not believe it is necessary to establish a specific transfer policy for the SHFFT model. A SHFFT episode would only be initiated in the hospital where the beneficiary had SHFFT surgery and where a SHFFT model MS–DRG is first assigned to the beneficiary's hospitalization. The initial treating hospital would only assign a SHFFT model MS–DRG to the beneficiary if the beneficiary received SHFFT surgery at that hospital and the transfer hospital could not assign a SHFFT model MS–DRG unless the beneficiary had surgery on the other hip, an unlikely scenario. Therefore, under the circumstances described by the commenter, without any special policies beyond the standard rules of SHFFT episode initiation, the SHFFT episode would be initiated at the transfer hospital, which would be responsible for the SHFFT episode. We note that if the SHFFT surgery was performed at the initial treating hospital where an episode was initiated and then the beneficiary was transferred to another hospital for additional care, the SHFFT episode would continue under the responsibility of the initial treating hospital. We note that we would apply the SHFFT model exclusion list to the transfer hospital MS–DRG to determine whether those inpatient services were included in the SHFFT episode.

Final Decision: After consideration of the public comments received, we are not finalizing our proposal to attribute AMI episodes to the initial treating hospital when an inpatient-to-inpatient transfer occurs during the anchor hospitalization. Instead, we are adopting a final policy to cancel the AMI episode initiated at the initial treating hospital when an inpatient-to-inpatient transfer occurs, and base any AMI or CABG episode initiation on the MS–DRG for the final i-i transfer hospital admission if the i-i transfer hospital is an AMI or CABG model participant. If the i-i transfer hospital is not an AMI or CABG model participant, the beneficiary's care is not included in any AMI or CABG episode. We are not using the terms chained anchor hospitalization and price MS–DRG in the final episode definition and pricing policies for the AMI model as discussed in sections III.C.4.a.(5) and III.D.4.b.(2)(a) of this final rule. Instead, the episode definition and pricing is determined only by the anchor MS–DRG for the AMI or CABG model episode.

The proposal for AMI episode attribution in circumstances that involve inpatient-to-inpatient transfers of beneficiaries with AMI was included in proposed § 512.240(a)(2). We no longer need a specific attribution provision for the AMI model because attribution of AMI and CABG episodes occurs in the usual manner to the AMI or CABG model participant that discharges the beneficiary under an AMI MS–DRG, PCI MS–DRG with AMI ICD–CM diagnosis code, or CABG MS–DRGs that initiates the AMI or CABG episode at that hospital. Therefore, we are renumbering proposed § 512.240(a)(3) (Cancellation of an AMI model episode) to § 512.240(a)(2), and revising proposed § 512.240(a)(3)(iii) which has been renumbered § 512.240(a)(2)(iii) to specify that an AMI model episode is canceled if the beneficiary is transferred during the anchor hospitalization to another hospital for inpatient hospitalization.

The final policies for initiation and attribution of AMI and CABG episodes that involve no transfer, outpatient-to-inpatient transfer, or inpatient-to-inpatient transfers at the beginning of AMI care are summarized in Table 8.

TABLE 8—FINAL INITIATION AND ATTRIBUTION OF AMI AND CABG EPISODES THAT INVOLVE NO TRANSFER, OR OUTPATIENT-TO-INPATIENT OR INPATIENT-TO-INPATIENT TRANSFERS AT THE BEGINNING OF AMI CARE

Scenario	Final episode initiation and attribution policy
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 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 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 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 nonparticipant): Beneficiary admitted to an initial treating hospital that is an AMI or CABG model participant for an AMI MS–DRG or PCI MS–DRG with AMI ICD–CM diagnosis code and later transferred to an i–i transfer hospital for an AMI, PCI, or CABG MS–DRG, where the i–i transfer hospital is not an AMI or CABG model participant.	Cancel AMI episode. No other AMI or CABG episode is initiated.
Inpatient–to–inpatient transfer (participant to participant): Beneficiary admitted to an initial treating hospital that is an AMI or CABG model participant for an AMI MS–DRG or PCI MS–DRG with AMI ICD–CM diagnosis code later transferred to an i–i transfer hospital for an AMI, PCI, or CABG MS–DRG, where the i–i transfer hospital is an AMI or CABG model participant.	Cancel AMI episode at the initial treating hospital. Initiate an AMI or CABG episode at the i–i transfer hospital. Attribute episode to the i–i transfer 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 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 episode is initiated.

b. Middle of EPM Episodes

Similar to the CJR model, we proposed 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 was canceled, we proposed 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 proposed 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 the proposed rule (81 FR 50834), 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 proposed 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 the proposed rule (81 FR 50868) for further discussion of our proposals addressing potential overlap of beneficiaries in the EPMs with the BPCI initiative. We also refer to section III.D.6.c.(3) of the proposed rule (81 FR 50869 through 50871) for discussion of our proposal to cancel EPM episodes for beneficiaries who become assigned to 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 Final Rule for LEJR episodes, 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 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.[72]

[72] 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.

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.[73] Several CMS programs use 30-day mortality measures for CABG and AMI as measures of hospital quality, and these measures were proposed for use in the pay-for-performance methodology for the CABG and AMI models as discussed in section III.E.3.f. of the proposed rule (81 FR 50880). 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.[74] Thus, we would expect that deaths during SHFFT episodes would be more common than in CJR episodes. Because beneficiaries in AMI, CABG, and SHFFT episodes would be at significant risk of death during these episodes that we proposed to extend 90 days post-hospital discharge, we considered 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, in the proposed rule (81 FR 50841) we discussed our belief that it would not be appropriate to exclude beneficiaries from AMI, CABG, or SHFFT episodes who die any time during the episode like we do in the CJR model. Instead, we proposed to maintain beneficiary episodes in the EPMs even if death occurred 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 believed this proposal would encourage EPM participants to actively manage EPM beneficiaries to reduce their risk of death, especially as death would often be preceded by expensive care for emergencies and complications. Because of the higher mortality rates for all of the EPM episodes than for LEJR episodes in the CJR model, we did not consider mortality following hospital discharge to be atypical and, therefore, we proposed to cancel EPM episodes only for death during the anchor hospitalization.

We further proposed that the following circumstances also would cancel an AMI episode in the circumstances of a chained anchor hospitalization when the beneficiary was 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 episode, regardless of whether the final transfer hospital was an AMI or CABG model participant (that is, the episode would be canceled if the final transfer hospital MS–DRG was any MS–DRG other than an AMI MS–DRG, PCI MS–DRG, or CABG MS–DRG).

While we proposed to begin an AMI 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 the proposed rule (81 FR 50836 through 50840), we also proposed to cancel AMI episodes under the circumstances when a beneficiary in an AMI episode was discharged from acute care under an MS–DRG from the final i-i transfer hospital in the chained anchor hospitalization that was not an AMI, PCI, or CABG MS–DRG that could initiate an AMI or CABG episode (that is, the episode would be canceled if the final transfer hospitalization MS–DRG was any MS–DRG other than an AMI, PCI, or CABG MS–DRG). Overall, this proposal treated the hospital that initiated the AMI episode and then transferred the beneficiary most similarly to a hospital that furnished all of the beneficiary's inpatient care itself, with respect to whether or not the beneficiary's care was ultimately included as an episode in the AMI model.

Finally, we did not propose to cancel an AMI episode altogether for a CABG readmission during the 90-day post-hospital discharge period or cancel the AMI episode and initiate a CABG episode because planned CABG readmission following an anchor hospitalization that initiates an AMI episode may be an appropriate clinical pathway for certain beneficiaries. Instead, we proposed 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 episodes. We refer to section III.D.4.b.(2)(c) of the proposed rule (81 FR 508520 for discussion of the adjusted AMI model-episode benchmark price that would apply in the case of CABG readmission during an AMI episode.

The proposals for cancellation of EPM episodes were included in proposed §§ 512.240(a)(3), (b)(2), and (c)(2). We sought comment on our proposals for cancellation of EPM episodes.

The following is a summary of the comments received and our responses.

Comment: With the exception of the proposal for cancellation of EPM episodes for death only during the anchor hospitalization, many commenters expressed support for the other proposed EPM episode cancellation policies, especially the proposal to cancel EPM episodes 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 episode. The commenters pointed out that when a transfer results in discharge from the final hospital in the chained anchor hospitalization under an MS–DRG that could not initiate an AMI or CABG episode, those episodes are disproportionately likely to reflect high-cost episodes that would not be conducive to care redesign due to beneficiary complexity and the need for atypical beneficiary care. Several commenters encouraged CMS to monitor cancellation circumstances because EPM participants could engage in gaming by discharging a dying patient from the hospital to garner a low-cost episode or encouraging beneficiaries to enroll in a Medicare Advantage plan.

A few commenters requested that CMS cancel EPM episodes when a beneficiary has an excluded readmission because the Part A and Part B services furnished following that readmission would be related to the clinical condition that was the basis for the readmission, and not the condition that was the focus of the EPM.

Response: We appreciate the support for our proposals to cancel an EPM episode when a beneficiary initiates an EPM episode but then fails to meet the general beneficiary care inclusion criteria sometime during the episode, which include enrollment in Medicare Part A and Part B; eligibility for Medicare not on the basis of end-stage renal disease; not enrolled in any managed care plan; not covered under a United Mine Workers of American health plan; have Medicare as their primary payer; and not to an ACO in the Next Generation ACO model or an ACO in a track of the Comprehensive ESRD Care Model incorporating downside risk for financial losses. In addition, we appreciate the support for our proposals to cancel an AMI episode when a beneficiary initiates any BPCI episode and when an AMI model beneficiary is discharged from the final hospital in a

[73] *https://www.medicare.gov/hospitalcompare/search.html.*

[74] 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.

chained anchor hospitalization under an MS–DRG that is not an AMI, PCI, or CABG MS–DRG, regardless of whether the final transfer hospital is an AMI or CABG model participant. As discussed in section III.C.4.a.(5) of this final rule, we are finalizing this proposal, but with modification to cancel all AMI episodes that begin at an initial treating hospital when an inpatient-to-inpatient transfer occurs after the AMI episode has begun.

In response to those commenters requesting that we cancel EPM episodes for the occurrence of an excluded readmission, we do not agree that all Part A and Part B services furnished following discharge from the excluded readmission but within the original 90-day post-discharge period for the EPM episode would be unrelated to the clinical condition that is the focus of the EPM. Instead, we believe care during that period would also be furnished for EPM beneficiary management and recovery following the AMI, CABG, or SHFFT hospitalization that initiated the EPM episode. The application of our exclusion list for readmissions and Part B services continues to identify those readmissions and Part B services that would be excluded from the EPM episode definition throughout the full post-discharge episode duration, regardless of the occurrence of an excluded readmission during the EPM episode.

Additionally, as discussed in sections III.G.4. through 6. of this final rule, we plan to monitor EPM participants' claims data and audit EPM participants' and their EPM collaborators medical records and claims as we deem appropriate and will include canceled EPM episodes in this monitoring to ensure that we do not observe patterns of cancellation suggestive of gaming of the EPM episode cancellation policies.

Comment: Several commenters expressed support for CMS' proposal to cancel EPM episodes for death during the anchor hospitalization but not for death during the 90-day post-discharge episode period. These commenters agreed that death during the inpatient hospitalization would be atypical and should result in EPM episode cancellation, whereas death within the 90 days following hospital discharge would not be rare for the clinical conditions in the EPMs and could appropriately be targeted for improvement through EPM care redesign. The commenters pointed out that CMS' proposals to use AMI and CABG mortality rates in the AMI and CABG model pay-for-performance methodologies was consistent with the opportunities for EPM care redesign to reduce mortality rates in the 30 days following discharge from the anchor hospitalization for AMI and CABG. A few commenters suggested that CMS should not cancel EPM episodes for any death once they are initiated, even for death during the anchor hospitalization, arguing that such cancellations could skew episode costs and that some in-hospital deaths may be preventable, which the EPMs should provide incentives to prevent.

However, many commenters, including MedPAC, recommended that CMS adopt the same policy as the CJR model and cancel episodes for death at any time during the EPM episode, including during the 90 days post-hospital discharge. Some of the commenters stated that episodes during which a beneficiary dies usually involve atypical courses of care, which may include extensive end-of-life care that hospitals should not be penalized for providing. MedPAC speculated that on the one hand, stays during which the EPM beneficiary dies could be exceptionally high-cost if the patient lives for most of the 90 days and receives end-of-life care. On the other hand, if the EPM beneficiary dies shortly after discharge from the hospital, the patient may receive little post-acute care services or end-of-life care, resulting in unusually low-cost episodes. They concluded that in either case, the episode spending would not be typical and, therefore, these stays should be excluded from calculating the target price and reconciliation payment for the EPM participant. They stated that excluding these episodes would make the spending data less ''noisy'' and better reflect the typical spending for the EPM participant's episodes. MedPAC also claimed that CMS has better tools than including in the EPMs beneficiaries who die in the 90 days following hospital discharge that encourage lower mortality rates, such as use of the AMI and CABG mortality rates in the HVBP Program, and care coordination, such as the Medicare Spending Per Beneficiary (MSPB) measure in the HVBP Program and the HRRP.

Some commenters further contended that the proposal to cancel SHFFT episodes only for death during the anchor hospitalization compared to CJR model episode cancellation for beneficiary death any time during a LEJR episode leads to a lack of consistency between hip fracture beneficiaries included in the CJR and SHFFT models. Under CMS' proposal, hip fracture beneficiaries treated with a SHFFT would be subject to one set of rules, while those treated with a hip replacement would be subject to another set, leading to confusion among the hospitals that would be participants in both the CJR and SHFFT models and inequitable treatment of beneficiaries with the same clinical condition of hip fracture. The commenters also believe that CMS' rationale for not canceling SHFFT episodes for beneficiaries who die following discharge from the anchor hospitalization due to a higher risk of death for hip fracture patients than patients receiving LEJR ignored the fact that a substantial portion of the hip fracture population is treated with a LEJR. These commenters concluded that this overlap of fracture beneficiaries between SHFFT and LEJR confounded the comparison CMS was trying to make between the higher mortality rate of beneficiaries following SHFFT versus LEJR and led to questions about its validity.

Response: While we appreciate that there may be some opportunities to reduce in-hospital deaths for beneficiaries treated with CABG or SHFFT, we believe that there are limited efficiencies that could be expected during the anchor hospitalization itself. Furthermore, we note that there are three separate MS–DRGs for beneficiaries who die during a hospitalization for AMI (MS–DRG 283 Acute Myocardial Infarction, Expired with MCC; MS–DRG 284 Acute Myocardial Infarction, Expired with CC; MS–DRG 285 Acute Myocardial Infarction, Expired without CC/MCC), and we did not propose that these MS–DRGs would initiate AMI episodes. Thus, there would be no situations when AMI episodes were canceled for death during an anchor hospitalization. Thus, we do not believe it would be appropriate to include beneficiaries who die during the anchor hospitalization in any of the EPMs.

While beneficiary deaths in the 90-days post-discharge from the anchor hospitalization would be expected to be more common in AMI, CABG, and SHFFT episodes than in the LEJR episodes included in the CJR model, we agree with the commenters that the costs of such episodes are likely to vary unpredictably across EPM participants. We also agree with the commenters' argument about the importance of policy consistency in similar episode payment models for deaths because adopting different cancellation policies for death under the CJR model than we proposed for the EPMs could be confusing for those hospitals that are participants in both the SHFFT and CJR models. While we continue to believe that reductions in mortality following discharge from a hospitalization for AMI, CABG, or SHFFT are a harmful

beneficiary outcome that should be targeted for improvement through care redesign incentivized by the EPMs for these clinical conditions, we agree with the commenters that it would be appropriate to cancel all EPM episodes for beneficiary death any time during the episode. We note that our use of 30-day AMI and CABG mortality measures in the pay-for-performance methodologies of the AMI and CABG models, respectively, as discussed in sections III.E.2.b. and c. of this final rule encourages AMI and CABG model participant to actively manage AMI and CABG beneficiaries to reduce this risk of death, to supplement existing incentives in other CMS programs that encourage lower mortality rates.

Comment: Several commenters requested that CMS clarify its administrative policies for identifying and informing EPM participants about beneficiaries whose episodes are initiated and then canceled. The commenters stated that CMS should inform EPM participants in a timely manner when an episode is canceled for any reason, with one commenter specifying at least quarterly notification. The commenters pointed out that an EPM participant's awareness of episode cancellation is important for several reasons, including the EPM participant's simultaneous calculation of EPM episode spending; beneficiary notification; provision of beneficiary engagement incentives; and determination of beneficiary eligibility for certain Medicare program rule waivers which is discussed further in section III.J. of this final rule. The commenters claimed that while the EPM participant is in the best position to know when the triggering procedures or services they have been providing will result in a MS–DRG that would initiate an EPM episode, the EPM participant will not always know when a patient meets certain exclusion criteria throughout the course of the EPM episode. The commenters emphasized that it is important for the EPM participant to know if beneficiaries they expect to be part of the EPM episode are going to be part of the EPM episode on a timely basis for cancellations or events that would serve to disqualify the beneficiary from a given hospital's attribution of an episode. Therefore, the commenters recommended that CMS inform EPM participant and CJR participant hospitals timely when an episode is canceled for any reason.

Response: We appreciate the interest of the commenters in conducting timely analysis of EPM episode spending, as well as ensuring that the requirements of the EPM are met in their treatment of Medicare beneficiaries. Given our plans for providing and updating episode claims data to EPM participants upon request as frequently as quarterly as discussed in section III.K.5 of this final rule, we will explore adding indicators to the beneficiary-identifiable claims data supplied to EPM participants that provide information about circumstances that could result in EPM episode cancellation, such as admission of a beneficiary to a hospital that initiates episodes under a BPCI model for care that could potentially cancel an EPM episode. To the extent adding such indicators to the claims data is feasible, providing this information through the claims data to EPM participants would ensure that EPM participants are informed as frequently as quarterly about beneficiary circumstances that could result in EPM episode cancellation. This information would not be real-time, however, and while our best estimate, would likely be incomplete even based on the best available information at the time. At a minimum, it would always reflect the time lag for the EPM episode claims to be submitted and processed and then reported back to the EPM participant in the updated claims data. We note that at reconciliation, complete information would be provided to EPM participants that have requested beneficiary-level claims data or summary beneficiary claims data reports about those episodes that were ultimately included in the EPM participant's reconciliation report as discussed in section III.D.5. of this final rule.

We note that we expect EPM participants to be actively managing all of their beneficiaries with conditions characterized by AMI, CABG, or SHFFT based on their care pathways developed for such beneficiaries, regardless of the model or program that may ultimately apply to the beneficiary under the uncommon circumstances of EPM episode cancellation. We also emphasize the importance of strong, ongoing communication among providers in a given geographic area caring for beneficiaries in similar models or programs where provider interests in delivering high quality, efficient health care should align.

Final Decision: After consideration of the public comments received, we are finalizing the proposals in §§ 512.240(a)(2), (b)(2), and (c)(2) for cancellation of EPM episodes, with modification to also cancel EPM episodes if the beneficiary dies during the episode.

We are canceling EPM episodes for the following circumstances:

- The beneficiary ceases to meet any of the general beneficiary inclusion criteria described in section III.C.4.a.(1) of this final rule, except the three criteria regarding inclusion in other episode payment model episodes.
- The beneficiary dies.
- The beneficiary initiates any BPCI model episode.

Additionally, in the AMI model we are canceling the AMI episode when a beneficiary is transferred during the anchor hospitalization for inpatient hospitalization at another hospital as discussed in section III.C.4.a.(5) of this final rule.

Because we are not finalizing the proposed AMI model transfer episode initiation and attribution policy, as discussed in section III.C.4.a.(5) of this final rule, we are not adopting the policy included in proposed § 512.240(a)(2). Therefore, we are renumbering proposed § 512.240(a)(3) to § 512.240(a)(2) to specify the final AMI episode cancellation policy. This includes renumbering proposed § 512.240(a)(3)(iii) to final § 512.240(a)(2)(iii) and revising the provision to specify the final inpatient-to-inpatient transfer policy that cancels an AMI model episode if the beneficiary is transferred during the anchor hospitalization for inpatient hospitalization at another hospital.

c. End of EPM Episodes

(1) AMI and CABG Models

We proposed a 90-day post-hospital discharge episode duration for AMI 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 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 AMI episodes. However, we believe the 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 episodes would continue to be provided as beneficiaries transition out of AMI 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 episodes), while the remaining 90 percent of CABGs for beneficiaries hospitalized with AMI were provided during the initial hospitalization (these beneficiaries would in CABG episodes). In contrast, fewer than 3 percent of those AMI model beneficiaries who received an inpatient or outpatient PCI during an AMI 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.[75] We refer to section III.D.4.b.(2)(c) of this final rule for further discussion of pricing adjustments and alternatives considered for setting EPM-episode benchmark prices for AMI 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 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 CABG episodes. However, we believe the 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 episodes would continue to be provided as beneficiaries transition out of CABG 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 proposed that the day of discharge from the anchor hospitalization counts as day 1 of the post-hospital discharge period (80 FR 73324). 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 episode. However, the hospital that initiated the AMI 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 final rule.

The proposals for the end of AMI and CABG episodes were included in proposed §§ 512.240(a)(1) and (b)(1), respectively. We sought comment on our proposals to end AMI and CABG episodes.

We received a number of comments on the proposed episode duration for the AMI and CABG models, although most commenters provide similar rationale and recommendations for the three proposed EPMs. Thus, we refer to the next section for a discussion of the comments regarding the proposed ending of EPM episodes, including SHFFT as well as AMI and CABG episodes.

(2) SHFFT Model

We believe that SHFFT model beneficiaries are similar to CJR model beneficiaries who undergo hip replacement for fracture. We believe that the same episode duration as the CJR model of 90 days is appropriate for SHFFT 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 proposed a 90-day post-hospital discharge duration for SHFFT episodes.

The proposal for the end of SHFFT episodes was included in proposed § 512.240(c)(1). We sought comment on our proposal to end SHFFT episodes.

The following is a summary of the comments received and our responses.

Comment: A number of commenters expressed support for the proposed 90-day post-discharge episode duration for the AMI, CABG, and SHFFT models. These commenters reasoned that 90 days following discharge from an inpatient hospitalization was the most clinically appropriate length for the proposed conditions and would enhance the commitment of EPM participants and their collaborators to caring for patients over time. They added that this duration would be sufficiently long to capture many complications of treating EPM clinical conditions and engage multiple providers in inpatient, outpatient, and post-acute care provider settings. The commenters believe that the proposed episode length would move providers closer to achieving long-term population health management. Several commenters pointed out that hospitals are well-prepared to assume responsibility for EPM episodes that continue for 90 days after hospital discharge.

Other commenters stated that the proposed 90-day EPM episode duration was too long, especially in the context of the proposals to include a broad array of related items services in EPM episodes. In general, the commenters who stated for a shorter episode duration believe that during the early stages of required bundled payment models, it would be more reasonable for hospitals to assume episode performance risk for 30 days post-discharge than 90 days as proposed and that CMS should adopt 30-days post-discharge as the standard EPM episode duration permanently or temporarily, such as for the first two model years, and then reevaluate.

Several commenters contended that in using an episode definition that

[75] 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 the proposed rule, that end in CY 2014.

includes 90-day post-discharge, CMS was, in effect, making hospitals managers of population health. These commenters believe that hospitals lack the resources, skill sets, and infrastructure to engage in the mission of managing population health, and stated that the requirements are much different and more complex and demanding than what is need for episode payments. Several commenters reasoned that since the proposed quality metrics for the EPMs were 30 days after discharge and they believe that hospitals are more effective managing the first 30 days of an episode, the episode duration should be shortened to 30 days so the quality and performance metrics would be aligned.

A number of commenters requested that CMS shorten the episode duration to 30 days because 30 days is a more appropriate duration for exacerbations of existing, unrelated chronic conditions to the condition that is the focus of the episode. Some commenters claimed that a post-surgical or post-event episode duration under the AMI, CABG, and SHFFT models longer than 30 days poses a greater risk for variability due to medical events outside the intended scope of the model and control of the hospital. They stated that this is particularly true for ill patients who are likely to have major complications or comorbidities when admitted and are at higher risk for developing new complications post-discharge. The commenters stated that because all the proposed models are urgent or emergent, rather than elective or time-sensitive, this danger poses greater concern than under other Innovation Center episode payment models, such as the CJR model and OCM. While such comorbidities contributing to all-cause readmission can be reasonably controlled in the immediate and 30-day post-operative or post-event period, the commenters contended that the most complex patients develop complications after discharge, which are highly varied and predominantly unrelated to the quality of care they receive. Therefore, they concluded that care for chronic conditions and other non-anchor MS–DRG-related conditions becomes much more prevalent in days 31 to 90 following hospital discharge. One commenter observed based on experience in its hospitals that after 30 days, an over 30 percent increase in readmissions to a hospital other than the original facility occurred, creating a need for additional strategies to coordinate episode care after 30 days. The commenters stated that hospitals do not have the time, money, skill set or recourse to develop the infrastructure to support episode care management during the 31- to 90-day post-discharge period. Finally, several commenters observed that Medicare beneficiaries may have more than one residence during the year, creating challenges with follow up for an episode that extends 90 day following hospital discharge.

Response: We appreciate the support of many commenters for the proposed 90-day post-hospital discharge EPM episode duration. We agree with the commenters that the episode duration should capture the majority of health care services that are related to the episode and be sufficiently long to include many complications and follow-up care to the anchor hospitalization. We believe that hospitalization is often a sentinel event for Medicare beneficiaries, representing an opportunity for increased care coordination and, in the case of the EPMs, improved care management of chronic conditions that may have led to the hospitalization for the cardiac event or cardiac or orthopedic surgery. This episode duration provides EPM participants with a substantial period of time in which to work to improve the quality and efficiency of EPM episode performance for beneficiaries who are hospitalized for the targeted conditions.

We have substantial BPCI Model 2 experience in testing AMI, PCI, CABG, and SHFFT episodes that include beneficiaries who are most similar to those who would be included in the proposed EPMs. Almost all BPCI Model 2 Awardees testing these episodes have selected the 90-day episode duration, compared to the 30-day and 60-day alternative durations that are available in BPCI Model 2. Ninety days post-hospital discharge is also the episode duration in the CJR model. Our goal in the EPMs is to incentivize efficient, high quality care that returns beneficiaries to the community in the best health possible, and we believe that a 90-day post-discharge duration reflects a full continuum of clinical services and transition of care for average SHFFT, AMI, and CABG model beneficiaries, at which time the beneficiary's functional recovery and stabilization of medical conditions are relatively complete so the beneficiary is able to resume most usual activities of daily living.

Similar to LEJR episodes under the CJR model, in our analysis of episode spending for the EPMs we observed the concentration of Medicare post-discharge episode spending in the earlier part of the episode following discharge from the anchor hospitalization in all the EPMs.[76] Specifically, in the first 30 days following anchor hospitalization discharge in AMI episodes, excluding those AMI episodes with readmissions for CABG for which we make a payment adjustment under the AMI model as discussed in section III.D.4.b.(2)(c) of this final rule, we found 61 percent and 54 percent of post-discharge episode spending for AMI MS–DRG-anchored and PCI MS–DRG-anchored AMI episodes, respectively. Similarly, in the 30 days following discharge, we observed 68 percent and 69 percent of post-discharge episode spending for CABG and SHFFT episodes. For all of the EPMs, about 60 to 70 percent of the remaining post-discharge spending occurred in days 31–60 post-discharge, and one-third in days 61–90 post-discharge. Thus, while the 90-day post-discharge episode duration increases the EPM participant's financial risk somewhat compared to episodes that extend only 30 days, because we found that significant services related to the clinical condition that is the focus of the models occurred during days 31–90 post-discharge, we believe there are significant opportunities for improved quality and efficiency in EPM episodes after 30 days and extending through 90 days post-discharge from the anchor hospitalization. If, as some commenters speculated, a post-surgical or post-event episode duration under the AMI, CABG, and SHFFT models longer than 30 days posed a significant risk of variability primarily due to medical events that are unrelated to the clinical condition that is the focus of the EPM episode, we would have expected to see an equal percentage of post-discharge episode spending in the periods of time from days 31–60 and 61–90. That was not the case in our analysis, because we continued to see EPM episode spending as a proportion of post-discharge spending drop off in relation to increasing time after discharge, suggesting that the EPM episode definitions are capturing related episode spending that declines, as would be expected, over the period of time post-discharge as the beneficiary recovers and returns to the community.

While we understand that uncommon events during the 90-day post-discharge episode duration may occur for an individual beneficiary, resulting in an unanticipated or unavoidable need for costly health care services, we believe

[76] 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 the proposed rule, that began in CY 2012–2014.

that our EPM episode definitions that exclude unrelated items and services and our payment policies, namely the adjustment for high payment episodes and stop-loss policies discussed in sections III.D.3.d., III.D.7.b.(1), and III.D.7.d. of this final rule, provide sufficient protections for EPM participants from undue financial responsibility for the care of unrelated clinical conditions as well as for unusual circumstances. We also believe that shorter episode durations may incur a higher clinical risk for beneficiaries if EPM participants delay services beyond the EPM episode, and the risk to beneficiaries of this response by providers to episode payment can be minimized by the longer 90-day episode duration that we proposed for the EPMs. We refer to sections III.G.4. through 6. of this final rule for discussion of our plans to monitor for access to care, quality of care, and delayed care.

In response to the commenters recommending a shorter episode duration in the earlier stages of bundled payment, as noted previously we have several years of experience with BPCI Model 2 where the majority of Awardee have selected a 90-day episode duration for episodes of a similar design to the EPMs that target the same clinical conditions. While entities choose to participate in the BPC models, we have also established a 90-day episode duration in the CJR model, which is the first episode payment model which has a geographic basis. Thus, we do not believe that it is necessary to adopt a shorter episode duration for the EPMs either permanently or temporarily.

Regarding those commenters who believe that the 90-day post discharge episode duration and broad episode definitions would make hospitals responsible for population health, we note that the EPMs are not total cost-of-care models. As discussed in section III.C.3.b of this final rule, we exclude items and services that are unrelated to EPM episodes, namely those that are not directly related to the EPM episode or the quality or safety of the EPM episode care that is included in the EPM episode; for chronic conditions that are generally not affected by the EPM episode care; and for acute clinical conditions not arising from existing EPM episode-related chronic clinical conditions or complications of EPM episode care. We agree with the commenters in favor of the proposed 90-day post-discharge episode duration for the EPMs who stated that the proposed EPMs of this episode duration move providers closer to long-term population health management. Given the diversity of commenters' views on hospitals' readiness to assume responsibility for episodes of the proposed duration, we appreciate that EPM participants in models where participation is required are in various stages of readiness for managing the quality and cost performance of episode, based on their prior experience, resources, and infrastructure. We believe that all EPM participants have substantial opportunities to increase their capacity to manage the quality and cost of EPM episodes and achieve significant financial rewards from good performance, regardless of their starting point. We note that many of the EPM policies such as data sharing, financial arrangements, the phase-in of two-sided risk, and stop-loss limits afford hospitals the opportunity to learn about EPM episode care patterns, collaborate with others who have expertise in care redesign, and implement their initial EPM care plans for their beneficiaries in an initial environment of limited financial risk.

We do not believe that the measurement period for the quality measures and the duration of the EPM episodes must necessarily align, although we note that we sought comment in the EPM proposed rule about potentially using quality measures that examine patient outcomes over a period that extends at least as long as the EPM episode (81 FR 50901). We proposed to use existing AMI and CABG outcome measures that assess outcomes over a 30-day period following discharge, at least initially, because they are in wide use and have gained acceptance among hospitals and because the AMI and CABG mortality measures have been reviewed and endorsed by the National Quality Forum. However, we believe that 90 days is a period over which hospitals have substantial ability to influence the quality and efficiency of care that EPM beneficiaries receive. Rather than shorten EPM episodes to align with the existing 30-day quality measure timeframe as some commenters recommended, we believe it would be more appropriate to seek to adapt the existing measures or to develop new related measures to assess outcomes over a longer timeframe, including timeframes at least as long as the EPMs. We refer to section III.E.4 of this final rule for further discussion of our plans regarding future quality measures that could be incorporated into the EPM pay-for performance methodologies.

Finally, we appreciate the perspective of the commenters who believe that a 30-day episode duration would be more appropriate because a longer episode duration poses a greater risk for variability due to events outside the intended scope of the model and control of the hospital, including readmissions to a different hospital, and that this risk is higher for the EPMs than other Innovation Center bundled payment models due to the urgent or emergent clinical conditions included in the EPMs. We agree with the commenters that the EPMs test different clinical scenarios than the CJR model that targets LEJR, which is primarily elective, and that the complexity of many EPM beneficiaries requires new approaches to redesigning and coordinating care for the 90 days post-hospital discharge. While EPM beneficiaries may be more likely to develop a variety of complications requiring more related services following discharge than those in the CJR model, we continue to believe that complications most commonly have patterns and bear a significant relationship to the quality of care and effectiveness of care coordination following hospital discharge. Even though some EPM beneficiaries may be medically complex and fragile, we continue to believe there are substantial opportunities to improve the quality and efficiency of their care under the EPMs where EPM participants have quality and cost performance responsibility for episodes that extend 90-day post-discharge from the anchor hospitalization. We also agree with the commenters that EPM participants who are required to participate in the EPMs be protected from undue financial risk. We refer to section III.D.4.b.(2) of this final rule for further discussion of risk adjustment under the EPMs.

Final Decision: After consideration of the public comments received, we are finalizing the proposals in §§ 512.240(a)(1), (b)(1), and (c)(1) for the end of AMI, CABG, and SHFFT episodes, respectively, based on an EPM episode duration that extends 90 days following discharge from the anchor hospitalization, with modification to revise § 512.240(a)(1) to eliminate proposed paragraphs (a)(1)(i) and (ii) and incorporate the 90-day post-discharge episode duration in the general provision. We no longer need to specify the episode duration separately for an AMI episode that includes an inpatient-to-inpatient transfer after an AMI episode has been initiated because we are not adopting the proposed policies for chained anchor hospitalizations. As discussed in section III.C.4.a.(5). of this final rule, we are not finalizing the AMI model transfer episode initiation and attribution proposal that would have required us to

identify chained anchor hospitalizations.

D. Methodology for Setting EPM Episode Prices and Paying EPM Participants in the AMI, CABG, and SHFFT Models

1. Background

a. Overview

We proposed 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, our proposed rule provided the following definitions of terms that were used in sections that precede their technical definition and cross-references to other sections of the 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 that was described in III.D.4.b.(2)(i) of the proposed rule.
- 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 the proposed rule) prior to the application of the effective discount factor, as described throughout sections III.D.4.b through e. of the 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 the 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 the 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 the 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 proposed 5 performance years (PYs) for the EPMs, which would include EPM episodes for the periods displayed in the following Table 9:

TABLE 9—PROPOSED 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 9, 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. As we noted in our proposed rule, 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 were concerned whether an EPM with fewer than 5 performance years would be sufficient for these purposes.

We considered extending the first PY, for example, to 18 months. As discussed further in section III.D.2.c. of the proposed rule, however, we instead proposed 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). As stated in our proposed rule, 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 sought comment on this proposal.

The following is a summary of the comments received and our responses.

Comment: Many commenters requested that CMS delay implementation of the models; typically, for at least 6 months to a year—or a year from the final rule's issuance—so that participants would have a sufficient time to prepare for the new models. Some commenters recommended delaying the models entirely until CMS had additional time to consider evaluation results for BPCI or the CJR model. Other commenters recommended a phased-in approach for implementing the models, for example, by (1) first implementing the SHFFT model no sooner than January 1, 2018 and then implementing the cardiac EPM models no sooner than 6 months later as well as additional time if the final rule is delayed beyond January 1, 2018 or (2) conversely delaying the SHFFT model, given that hospitals are in the early stages of building infrastructure for the CJR model and having to do so for the SHFFT model as well could be too great a burden. A commenter recommended that CMS delay the start date to January 1, 2018 as it would better align with private payers' regulatory and business models, which are also developing and rolling out bundled payment models. In their view, this synchronization would reduce burden by simplifying record keeping requirements, performance metric submission, and financial tracking by both CMS and private payers.

Among the reasons cited for a delay, some commenters expressed concern with the rapid pace of implementing additional models—particularly, geographic-based models, which a number of commenters have said they oppose. For example, commenters expressed concerns that CMS was moving forward with new models in the absence of empirical results from the CJR model or promising results from BPCI. Specifically, results from the evaluation of year 2 results for BPCI showed no statistically significant difference in Medicare payments and an increase in mortality for the cardiovascular surgical episodes between the BPCI participants (which were voluntary), and comparison groups. Further, while there was a significant reduction in utilization of institutional post-acute care settings, there were instances where BPCI patients exhibited less functional improvement. As one commenter noted, CMS has not yet been able to ensure that the quality of care and beneficiary outcomes under the model are at least equivalent, if not better than, those in traditional fee-for-service Medicare.

Commenters also pointed to the pre-implementation efforts that would be needed for participants to be successful with episode payment bundles, which they believe would take more time than would be granted under the proposal. For example, hospitals need more time than proposed to better understand the models' requirements and clinical and financial risk of their patient populations; build the clinical, legal, financial and quality infrastructure; analyze and understand the clinical and cost factors that affect their performance; and identify changes to care pattern to be successful. Moreover, there is considerable variation in hospital preparedness and capabilities to implement these models without a delay as well as challenges in doing so while simultaneously fulfilling the requirements of multiple models including the CJR model, MACRA, and the end of the grace period for ICD–10.

A commenter noted that, given the broad-based clinical experience with continuity-of-care across episodes, appropriate workforce capacity and technology infrastructure, and significant investment by both the public and private sectors needed to be successful, the cardiac models could be particularly challenging. Further, these challenges could be especially acute for small hospitals that often have limited financial resources, have low case volume across which to spread financial experience, have high amounts of uncompensated care or are located in lower income geographic regions, do not yet have experience with episode-based payments, or lack existing networks with physicians and other providers. In addition to provider readiness, a commenter questioned whether CMS has the administrative and personal resources to manage the complexities of the newly proposed and expanded models in a way that would meet hospitals' needs to be successful under the models. Another commenter believed that, despite CMS proposing certain waivers under the models, insufficient protections existed with regard to regulatory and legal risk.

Response: We appreciate the concerns commenters expressed on our proposed start date as well as their requests to delay the proposed models. Our general goals for the proposed models are to improve care quality for Medicare beneficiaries and efficiency in service delivery to better control growth in Medicare spending. Hence, we wish to move forward in implementing the proposed models as quickly as is reasonably possible. Many commenters expressed concerns about their readiness to participate in the models under our proposal; particularly, with the requirement to assume downside risk within 6 months of the models being implemented. We understand these concerns and share in hospitals' desire to be successful in improving care and increasing efficiencies under the models so that they earn reconciliation payments and Medicare and its beneficiaries realize improvements in care and efficiency. Thus, while we are not proposing to delay implementation of the models, as discussed in section III.D.2.c. of this final rule, we are modifying our proposal requiring participants to assume downside risk in the second quarter of PY2 so that they would have an additional 9 months of experience in the models without assuming downside risk. EPM participants would not be required to assume downside risk for episodes until PY3, but could voluntarily elect to do so in PY2. We believe that delaying the requirement for participants to assume downside risk under the models appropriately balances our interests in implementing the models in a timely way with the concerns and interests of participants with respect to their readiness to participate successfully in the models as well as accommodate to the proposed requirements in conjunction with other requirements under the Medicare program. As such, we do not believe it is also necessary to further delay or phase-in the models. Likewise, we do not believe it is necessary to delay our models so that they are better aligned with private payer models. We would further note that, beginning in PY2, our proposed models would already follow the period suggested for this alignment to occur.

We do not agree with commenters that the models should be delayed until additional BPCI or CJR model results are considered or in light of the BPCI year 2 results. The currently proposed models will test geographic-based bundled payments with a broader, more diverse, and different group of participants or episodes than is the case

with BPCI or the CJR model, which will expand our understanding of these models with a broader and more complex array of conditions and procedures. We also do not believe that the unique challenges that could be presented under the cardiac models is a reason to delay the models. Rather, among other things, we would expect these models to assist us in empirically identifying what challenges there may be as well as the steps needed to overcome them. We also share commenters' concerns that smaller hospitals be successful under the models. Accordingly, our proposed rule included additional protections to limit financial risk for certain hospitals, including rural hospitals and sole community hospitals, through more generous stop loss thresholds, which we finalized in section III.D.7.c.(1) of this final rule. Also, as discussed further in section III.D.7.c.(1) of this final rule, we are extending these protections to hospitals determined to have a low volume of episodes under an EPM.

We appreciate the comment on whether CMS is prepared administratively and with respect to personnel resources to implement the models, and note that the proposed models would not be implemented in the absence of our readiness to do so. Finally, we have considered and made final a range of waivers of program rules and provisions for financial arrangements that we believe are necessary and sufficient to facilitate participation in the models through allowing additional flexibilities in care delivery and giving participants to the tools to align the financial incentives of other providers, suppliers, and ACOs with the goals of the EPMs (see sections III.I. and III.J. of this final rule).

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to establish five performance years beginning with EPM episodes that start on or after July 1, 2017 as displayed in Table 10.

TABLE 10—FINAL 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.

b. Retrospective Payment Methodology

Consistent with the CJR model (80 FR 73329), we proposed to apply a retrospective payment methodology to the proposed EPMs (81 FR 50844). 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 would be compared to quality-adjusted target prices (which account for the level of EPM episode quality), as described in section III.D.5.a. of the proposed rule (81 FR 50864 through 50865). 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 (80 FR 73329), we believed 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. Moreover, we continued 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 sought comment on this proposal. The following is a summary of the comments received and our responses.

Comment: Most of the comments supported CMS' proposal to use a retrospective payment methodology. Commenters agreed with CMS' view that this would be the most administratively feasible and straightforward payment option since it uses the existing payment system infrastructure and processes. Some of these commenters reported that alternatively applying a prospective payment methodology, which would make one lump sum payment to the hospital for the episode, would be challenging to implement given the administrative and infrastructure changes it would entail for hospitals, other participating providers and Medicare. One commenter expressed concern that our proposed models would, in fact, require all payments be made to the responsible hospital so that other providers would have to submit bills for services they provided under an EPM episode to that hospital, which the commenter believed could result in both decreased access to care and increased administrative complexity.

Response: We appreciate the comments we received that were in support of our proposed retrospective payment methodology, and concur with commenters' views on some of the benefits of this model. We would clarify that, as stated previously in this section, 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. As such, providers would submit claims for payment as they always have and would not submit claims to the responsible hospital.

Comment: While not opposing the proposal, a commenter expressed the view that a retrospective model should be viewed as a stepping stone toward rather than the destination to requiring greater levels of financial risk. In their view, disadvantages of a retrospective model include their potential to reduce spending within an episode of care but not the volume of the episodes themselves, which could encourage a greater number of bundled procedures;

fragmentation of care delivery due to the existence of multiple bundled payment programs designed around different disease states or procedures; and the potential that the considerable cost and effort expended to organize people and systems around each bundled episode could cause the total cost of these programs combined to be higher than the cost associated with operating a single program covering the full population and the full spectrum of care. As such, the commenter supported the proposed bundled payments for a limited time and for the purpose of stimulating efforts to full population based efforts.

Response: We understand the commenter's view that bundled payments could be a stepping stone toward other models that establish greater risk for providers and recognize the various limitations of a fee-for-service system with respect to higher volume of services and less coordinated delivery of care. In contrast to the commenter, however, we believe in and hence are empirically testing within our proposed models the potential to improve upon these dimensions as well as assist in lowering the cost of services within a fee-for-service rather than capitated framework.

Comment: Some commenters opposed the proposed retrospective methodology. For example, a commenter reported their view that the proposed retrospective payment model would limit the possibility for real, innovative care redesign because it (1) offered no upfront incentive dollars to invest in new care delivery models and services that could deliver true value and (2) confined innovation care redesign by what the FFS structure will reimburse. That is, while participants would be held financially accountable for ensuring that care is delivered below the quality-adjusted target price, they could do little to affect the costs for the episode within their own setting as they continue to receive a MS–DRG payment for the diagnosis regardless of whether the patient stays a longer or shorter period of time, additional services are offered, or care coordination is provided. Thus, if a participant seeks to reduce costs, it is limited to reducing readmissions, improving care transitions, or reducing post-acute care costs—either by reducing the length of stay within a SNF (as it is paid on a per diem) or through substitutions of care (for example, directly discharging the patient home with or without services). In this commenter's view, significant care redesign would be better facilitated through providing a group of provider partners with a prospective payment.

Similarly, a commenter suggested that participants are impeded in their ability to plan for the delivery of services if they do not know how much money will be available to support those services. As such, participants should have a risk-adjusted budget for the condition or episode in advance rather than after care has already been delivered. Further, payment amounts should be based on the actual costs of all of the services being delivered, not just the amounts that would have been paid under the fee-for-service system for the subset of services that would have been separately billable. As such, the commenter recommended that participants and their collaborators be paid for high-value services that are not currently billable as part of condition-based and episode-based payment models if providers have agreed to be accountable for overall spending related to a condition or episode.

Another commenter recommended that CMS determine payment benchmarks through negotiated rates or competitive bids (rather than fee-for-service claims) as it would foster more rapid transformation in cost and resource use as well as encourage competition among providers to achieve the best outcomes for the lowest cost. In their view, a prospective negotiated rate would offer providers more opportunity to innovate in how they deploy professional staff, choose technology, and engage with outpatient and home-based services. Also, a prospectively negotiated case rate would foster collaboration among all clinicians involved in patient care and provide predictable pricing.

Response: We appreciate the concerns and challenges raised by these commenters, but are not persuaded to change our methodology. Rather, we believe that participants are capable of innovative care redesign in the absence of upfront incentives dollars and within the constraints of fee-for-service Medicare payment requirements. While our proposal did not provide participants with an up-front budget or a capitated payment amount, we would be providing them detailed information on their benchmark and likely quality-adjusted target prices as well as their financial performance both historically and during their participation in the models (see section III.K. of this final rule). We believe this information should be sufficient to enable participants' abilities to assess their performance as well as determine and plan changes in their practices to make them successful. Also, where appropriate, we have offered participants improved flexibilities under the models by waiving certain Medicare requirements and allowing for financial arrangements, which should facilitate their participation under the models (see sections III.I. and III.J. of this final rule). To the extent, we identify additional adjustments, we could consider them through future rulemaking. Finally, while we wish to explore and test a range of payment models, which could include capitated or competitive bidding models, the purpose of the proposed models is to examine ways in which to improve health care quality and reduce costs in a fee-for-service framework.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification to implement a retrospective payment methodology. Also, we would like to clarify that when referring to Medicare claims data for services furnished to EPM beneficiaries, as we have stated immediately here and throughout this section, we mean any payment from the Part A or Part B trust fund on behalf of a beneficiary that is not specifically excluded as specified in section III.C. or III.D.6 of this final rule. Consistent with this, we have made conforming changes to our regulatory text—specifically, to our definition of actual episode payments as well as to § 512.305(c)(1) and § 512.307(a)(1).

c. Two-Sided Risk EPMs

As we did for the CJR model (80 FR 73229 through 7333), we proposed to establish two-sided risk for EPM participants (81 FR 50844). 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. 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 differed from CJR in that we proposed 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 referred to the two portions of performance year 2 as either having no downside risk (NDR) or having downside risk (DR); specifically—

- Performance Year 2 (NDR) or PY 2 (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 PY 2 (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.

Our proposed rule noted our continued belief 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, and 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. 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 thought that it was 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 proposed to phase-in this repayment responsibility beginning in the second quarter of EPM performance year 2 as displayed in Table 11 (81 FR 50844 through 50845).

TABLE 11—PROPOSED STOP-LOSS THRESHOLDS AND DISCOUNT PERCENTAGE RANGES FOR MEDICARE REPAYMENTS BY PY

Performance year	PY1	PY2 (NDR)	PY2 (DR) (%)	PY3 (%)	PY4 (%)	PY5 (%)
Stop–loss threshold	n/a as no downside risk in PY1 or first quarter of PY2		5	10	20	20
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.

We refer to section III.E.3.f. of this final 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 under the models.

We sought comment on this proposal. The following is a summary of the comments received and our responses.

Comment: A number of commenters supported CMS' proposal to phase-in downside risk noting that doing so would allow providers with little or limited experience and who were not ready to take on risk additional time to prepare to do so. However, nearly all of the commenters on this proposal urged CMS to extend the period of time during which participants would not be subject to downside risk as 6 months would not be an adequate timeframe in which to begin managing episodes that will be subject to downside risk. A number of commenters noted that because of the way that episodes are defined during a performance year, participants would actually have only 6 months before episodes that will incur downside risk begin. This is because the models would begin on July 1, 2017 and downside risk would begin for episodes *ending* April 1, 2018 and later. However, episodes that end April 1, 2018 would have begun over 90 days earlier, or prior to January 1, 2018. Therefore, participants would actually only have from July 1, 2017 until about January 1, 2018 before episodes that will incur downside begin.

Most of the commenters requested a 12-month period during which participants would not be required to assume downside risk with some commenters requesting longer periods, for example, up to 2 years. In some cases, commenters requested that CMS delay the requirement to assume downside risk, but to allow participants flexibility to assume risk earlier if they wished to do so. A commenter requested that CMS stagger downside risk across the models, for example, allow a longer period without downside risk for AMI episodes than for CABG episodes as the commenter believed there was greater complexity and uncertainty associated with the former than the latter. Additionally, several commenters opposed the proposal to require downside risk altogether or asking that CMS make this requirement contingent upon also further risk-adjusting target prices and financial performance data.

The reasons offered for delaying downside risk often paralleled those for delaying the models in general—that is, additional time is needed to develop infrastructure and expertise with the models. Some commenters raised concerns about the effects of the proposal on beneficiary access; particularly, for smaller hospitals and academic medical centers. As such, a commenter expressed support for CMS' plans to monitor access and recommended that CMS publish data and consider alternatives if this is found among complicated AMI or CABG cases.

A commenter suggested that CMS completely waive downside risk for certain protected hospitals such as SCHs, MDHs, RRCs, and low-volume hospitals. Another commenter stated that participants should not have to take on additional risk given they are already facing payment reductions through other efforts such as those for the HRRP. If participants must face downside risk through the proposed models, the commenter requested that CMS exclude conditions under the model from the HRRP. Some commenters pointed to delays in receiving performance data from CMS as well as time need to review these data needed to assist them in assessing and adjusting care patterns. Commenters also noted that because not all participants have had experience with bundled payment models, they are likely not ready to assume downside risk.

In addition to comments requesting that CMS delay downside risk, commenters also requested that EPM participants be permitted to voluntarily adopt downside risk sooner, for example, to fulfill one of the requirements to qualify as participating in an Advanced APM.

Response: We appreciate comments supporting our proposal to phase-in downside risk. We are also persuaded by commenters that delaying the date by which participants would be required to

assume downside risk would improve participants' ability to successfully achieve the goals of the models. Accordingly, we are revising our proposal so that participants in the proposed models would not be required to assume downside risk until PY3—that is, episodes ending on or after January 1, 2019, with anchor discharges that occur on or after October 4, 2018. We believe that this delay period appropriately balances participants' desire for additional experience under the models in the absence of downside risk with our desire to establish appropriate incentives for improved care quality and cost control. Given we believe this delay period is sufficient for all models, we do not believe it necessary to stagger downside risk separately by model. We also disagree with comments opposing our proposal to require downside risk or asking that CMS make this requirement contingent upon our also further risk-adjusting target prices and financial performance data. First, we believe downside risk is necessary for purposes of establishing appropriate provider incentives. Second, as discussed in section III.D.4.b.(2). of this final rule, we plan to explore additional risk-adjustment options that could be implemented beginning in PY3 and would thus apply to episodes that would be subject to downside risk for all participants.

While we are delaying the requirement to assume downside risk under the models, we have decided to allow EPM participants, including those seeking to qualify as participating in an Advanced APM, to voluntarily begin to assume downside risk for episodes ending on or after January 1, 2018, with anchor discharges that occur on or after October 4, 2017. Table 12 presents our final policies for phasing-in downside risk for all participants, along with associated stop-loss limits and discount percentages, for participants that voluntarily assume risk on this accelerated schedule.

We appreciate the concerns raised on the potential effects of our proposal on beneficiary access to care, and would note that we have made final a range of quality measures (see section III.E. of this final rule), monitoring activities (see section III.G. of this final rule), and compliance efforts (see section III.F. of this final rule) that would address beneficiary access issues. We disagree with the suggestions to waive downside risk for certain protected hospitals such as SCHs, MDHs, RRCs, and low-volume hospitals or given that hospitals are already facing payment reductions through other efforts. We believe that the additional protections we included, which limit total financial risk under the models for these protected hospitals, are sufficient (see section III.D.7.c.(2). of this final rule). We also recognize that while a participant could experience payment reductions under both the proposed models and the HRRP, we disagree that they should be held harmless from either of these potential reductions. The payment reductions participants would potentially face under the proposed models are not dissimilar to the potential reductions hospitals already simultaneously face for programs such as the HRRP, HAC, and EHR incentives without exemption.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, with modification, to phase-in downside risk. Accordingly, we are delaying the requirement to assume downside risk by 9 months so that episodes ending on or after January 1, 2019 would assume downside risk as compared to our proposal that would have required this for episodes that ended on or after April 1, 2018 and beyond. Also, we are allowing participants to voluntarily elect downside risk for episodes ending on or after January 1, 2018. Table 12 presents our final policies on this in conjunction with modified stop-loss thresholds and discount percentages by performance year. These final policies are further discussed in sections III.D.7.b.(1), III.D.7.c.(1) and III.E.3.f of this final rule, respectively.

TABLE 12—FINAL STOP-LOSS THRESHOLDS AND DISCOUNT PERCENTAGE RANGES FOR MEDICARE REPAYMENTS BY PY

	PY1	PY2 (%)	PY3 (%)	PY4 (%)	PY5 (%)
Downside Risk for All Participants—DR effective for episodes ending on or after 1/1/2019 (anchor discharges occurring on or after 10/4/2018)					
Stop-loss threshold	n/a as no downside risk in PY1 and PY2 without election of voluntary downside risk for PY2		5	10	20
Stop-loss threshold for certain hospitals*			3	5	5
Discount percentage (range) for Repayment, Depending on Quality Category			0.5–2.0	0.5–2.0	1.5–3.0
Voluntary Downside Risk—DR effective for episodes ending on or after 1/1/2018 (anchor discharges occurring on or after 10/4/2017)					
Stop-loss threshold	n/a as no downside risk in PY1	5	5	10	20
Stop-loss threshold for certain hospitals*		3	3	5	5
Discount percentage (range) for Repayment, Depending on Quality Category		0.5–2.0	0.5–2.0	0.5–2.0	1.5–3.0

* Including rural and sole-community hospitals, rural referral centers, Medicare Dependent Hospitals and hospitals determined to be EPM volume protection hospitals within an EPM.

3. Adjustments to Actual EPM-Episode Payments and to Historical Episode Payments Used To Set Episode Prices

a. Overview

Using Medicare payments for Parts A and B claims for services included in the EPM episode definitions, we proposed to calculate historical episode payments (3 years of historical Medicare payment data grouped into EPM episodes), EPM-quality-adjusted target prices, and actual EPM-episode payments according to the EPM episode definitions as discussed in sections III.C.3. and III.C.4. of the proposed rule (81 FR 50829 through 50843) as we did for the CJR model. As was the case for the CJR model (80 FR 73330 through 73336), we also proposed 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 (81 FR 50846). We also proposed to additionally include an adjustment for reconciliation payments and Medicare repayments when updating EPM participant episode benchmark and quality-adjusted target prices (81 FR 50847). We refer to section III.D.6. of the proposed rule for discussion of adjustments for overlaps with other Innovation Center models and CMS programs (81 FR 50867 through 50872).

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 Graduate Medical Education (GME) and 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 (80 FR 73333), we proposed 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 (81 FR 50846). Our proposed rule noted our view that in applying this methodology to exclude these payments from our calculations, we would best maintain appropriate incentives for both the 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 noted 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 were not intending to test under the models. In addition to the various incentives, enhanced payments, and add-on payments, we noted that 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 referred 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 proposed to exclude these special payments from EPM-episode calculations using the CMS Price Standardization methodology at § 512.300(e)(2). We sought comment on our proposal to exclude special payments using the CMS Price Standardization methodology.

The following is a summary of the comments received and our responses.

Comment: Commenters generally supported the proposal to adjust actual and target spending amounts for various special payments such as IME and DSH.

Response: We appreciate the comments we received supporting our proposal to exclude special payments from EPM-episode calculations using the CMS Price Standardization methodology. We wish to clarify that like CJR, we will follow the CMS Price Standardization methodology with modifications as necessary to be consistent with our episode definition in section III.C of this final rule and to ensure timely reporting of reconciliation

results, for the performance year reconciliations, which begin 2 months after the conclusion of a performance year. We will account for the information available at the time due to claims run-out, payment system updates, and the calculations necessary to fully implement the standardization methodology. We will utilize the methodology, consistent with our episode definition, for the target price calculations and subsequent reconciliation calculations 14 months after the conclusion of the performance year, in which we incorporate full claims run-out and further account for overlap with other models. This approach will provide feedback and reconciliation payments, as available, to hospitals in a timely manner and as accurately as feasible, while ensuring the standardization approach is utilized for the subsequent reconciliation calculation for a performance year.

Comment: Commenters requested more clarity on whether IPPS capital payments are included, and requested that we exclude these costs. A commenter noted that these capital costs are not included under the BPCI models, hospitals need stability in capital cost reimbursement to plan for major capital expenditures, and thus these costs should not be placed at risk because of models affecting only cardiovascular and orthopedic services.

Response: To clarify, as is the case with CJR, IPPS capital payments will be included in EPM-episode calculations. As we stated in the CJR Final Rule (80 FR 73333), these payments are included in Medicare FFS payments, which we use to calculate benchmark and actual expenditures. Further, including IPPS capital payments affords participants an opportunity to achieve greater reconciliation payments if they are able to achieve efficiencies for the costs that the capital portion of IPPS payments would cover, which may or may not actually be capital costs.

Comment: A commenter requested that CMS exclude outlier payments EPM-episode calculations. The commenter expressed concern that because CMS proposed a limited risk-adjustment methodology, hospitals that treat the least healthy beneficiaries such as academic medical centers would be penalized for longer lengths of stay that result in receiving outlier payments for the index admission, particularly as financial targets transition to regional pricing.

Response: We disagree that outlier payments should be excluded from our calculation. First, we expect the models to encourage more efficient care that should result in lower costs and potentially the frequency for which outlier payments are needed. Second, as discussed in section III.D.3.d. of this final rule, we are finalizing policies to cap high-cost episodes with payments 2 standard deviations or more above the mean calculated at the regional level for purposes of determining benchmark prices and actual expenditures, which should assist in protecting participants from higher costs associated with outlier payments. Third, as discussed in section III.D.4.b.(2). of this final rule, we will be exploring options to further risk-adjust costs and payments under the models with the goal of making them effective for episodes ending after January 1, 2019, with anchor discharges occurring on or after October 4, 2018. These further adjustments for risk would offer additional financial protections to participants with high-cost episodes.

Comment: Several commenters recommended that costs for chronic care management, cardiac rehabilitation, and intensive cardiac rehabilitation services be excluded from payment calculations. With regard to the former, the commenter noted that chronic care management services were not paid under Medicare until January of 2015 and therefore was not a payable service during two of the years used to set target prices for the first two performance year. Further, in this commenter's view, many physicians currently are not billing for these services, but the commenter anticipates the volume will increase. With regard to the latter, commenters noted that if the proposed efforts to encourage CR utilization are successful, spending for CR/ICR services in AMI and CABG episodes would increase and could cause participants' spending to exceed their targets making them either ineligible to receive reconciliation payments or at risk for making Medicare repayments. As such, this would penalize hospitals for improving CR/ICR utilization, which would impede, if not completely defeat, CMS' efforts to encourage CR and ICR utilization. Accordingly, these commenters recommended that the cost of CR and ICR services be excluded from episode payment calculations.

Response: As we noted in section III.C.3.b. of this final rule, we do not believe that it would be appropriate to exclude other specific Part B services, including chronic are management services, cardiac rehabilitation, intensive cardiac rehabilitation services that are related to the clinical conditions that are the basis for EPM episodes, just because they are underrepresented in the baseline period upon which benchmark episode prices are set. Likewise, we do not believe it is appropriate to exclude the costs of these included services from our financial calculations. To the extent that care redesign under the EPMs increases utilization of these services to improve episode quality and efficiency, periodic updates to the 3 years of historical data used to establish EPM-episode benchmark prices, as is discussed in section III.D.4.b.(3) of this final rule, would result in greater representation of these services that reflect more recent care patterns.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to exclude certain special payments from EPM-episode calculations using the CMS Price Standardization methodology. Our final policy for excluding special payments is included in § 512.300(e)(2).

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 proposed 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 (81 FR 50846). We believed these methodologies would most accurately account for spending within EPM episodes under the EPMs. The methodologies for prorating payments under the EPMs were included in § 512.300(f). We sought comment on our proposed methodologies for prorating payments.

The following is a summary of the comments received and our responses.

Comment: We received comments requesting greater clarity on how we would prorate payments for services that straddle episodes. We also received a comment requesting greater clarity for ''prorated'' payments for ''straddled'' episodes with the presence of an AMI diagnosis treated with CABG.

Response: Following are the steps we use for the CJR model that we proposed to apply when prorating payments under the proposed EPMs, and that were specifically cited in our proposed rule (80 FR 73333 through 73335).

These steps have been updated to reflect our methodology as applied to an AMI episode involving a CABG.

In general, assuming we have a beneficiary in an EPM episode who is admitted to a SNF for 15 days, beginning on Day 86 post-discharge from the anchor EPM hospitalization, the first 5 days of the admission would fall within the episode, while the subsequent 10 days would fall outside of the episode. Under our proposal, to the extent that a Medicare payment for included episode services spans a period of care that extends beyond the episode, these payments would be prorated so that only the portion attributable to care during the episode is attributed to the episode payment when calculating actual Medicare payment for the episode.

For non-IPPS inpatient hospital (for example, CAH) and inpatient post-acute care (for example, SNF, IRF, LTCH, IPF) services, we would prorate payments based on the percentage of actual length of stay (in days) that falls within the episode window. Prorated payments would also be similarly allocated to the 30-day post-episode payment calculation in section III.D.7.e. of this final rule. In the previous example, one-third of the days in the 15-day length of stay would fall within the episode window, so under the proposed approach, one-third of the SNF payment would be included in the episode payment calculation, and the remaining two-thirds (because the entirety of the remaining payments fall within the 30 days after the episode ended) would be included in the post-episode payment calculation.

For HHA services that extend beyond the episode, the payment proration would be based on the percentage of days, starting with the first billable service date (''start of care date'') and through and including the last billable service date, that fall within EPM episode. Prorated payments would also be similarly allocated to the 30-day post-episode payment calculation in section III.D.7.e. of this final rule. For example, if the patient started receiving services from an HHA on day 86 after discharge from the anchor hospitalization and the last billable home health service date was 55 days from the start of home health care date, the HHA claim payment amount would be divided by 55 and then multiplied by the days (5) that fell within the EPM episode. The resulting, prorated HHA claim payment amount would be considered part of the EPM episode. Services for the prorated HHA service would also span the entirety of the 30 days after the EPM episode spends, so the result of the following calculation would be included in the 30-day post-episode payment calculation: HHA claim payment amount divided by 55 and then multiplied by 30 days (the number of days in the 30-day post-episode period that fall within the prorated HHA service dates).

There may also be instances where home health services begin prior to the EPM episode start date, but end during the EPM episode. In such instances, we would also prorate HHA payments based on the percentage of days that fell within the episode. Because these services end during the EPM episode, prorated payments for these services would not be included in the 30-day post-episode payment calculation discussed in section III.D.7.e. of this final rule. For example, if the patient's start of care date for a home health 60-day claim was February 1, the anchor hospitalization was March 1 through March 4 (with the EPM episode continuing for 90 days after March 4), and the patient resumed home care on March 5 with the 60-day home health claim ending on April 1 (that is, April 1 was the last billable service date), we would divide the 60-day home health claim payment amount by 60 and then multiply that amount by the days from the EPM admission through April 1 (32 days) to prorate the HHA payment. This proposed prorating method for HHA claims is consistent with how partial episode payments (PEP) are paid for on home health claims.

For IPPS services that extend beyond the episode (for example, readmissions included in the episode definition), we would separately prorate the IPPS claim amount from episode target price and actual episode payment calculations as was made final in the final CJR rule (80 FR 73334 through 73335), called the normal MS–DRG payment amount for purposes of this final rule. The normal MS–DRG payment amount would be pro-rated based on the geometric mean length of stay, comparable to the calculation under the IPPS post-acute care transfer policy at § 412.4(f) and as published on an annual basis in Table 5 of the IPPS/LTCH PPS Final Rules. Consistent with the IPPS post-acute care transfer policy, the first day for a subset of MS–DRGs (indicated in Table 5 of the IPPS/LTCH PPS Final Rules) would be doubly weighted to count as 2 days to account for likely higher hospital costs incurred at the beginning of an admission. If the actual length of stay that occurred during the episode is equal to or greater than the MS–DRG geometric mean, the normal MS–DRG payment would be fully allocated to the episode. If the actual length of stay that occurred during the episode is less than the geometric mean, the normal MS–DRG payment amount would be allocated to the episode based on the number of inpatient days that fall within the episode. If the full amount is not allocated to the episode, any remainder amount would be allocated to the 30 day post-episode payment calculation discussed in section III.D.7.e. of this final rule. The proposed approach for prorating the normal MS–DRG payment amount is consistent with the IPPS transfer per diem methodology.

More specifically, if a beneficiary has a readmission for MS–DRG 234—coronary bypass with cardiac catheterization without major complications or comorbidities—into an IPPS hospital on the 89th day after discharge from an EPM anchor hospitalization, and is subsequently discharged after a length of stay of 5 days, Medicare payment for this readmission would be prorated for inclusion in the episode. Based on Table 5 of the IPPS/LTCH PPS Final Rule for FY 2017, the geometric mean for MS–DRG 234 is 8 days, and this MS–DRG is indicated for double-weighting the first day for proration. This readmission has only 2 days that falls within the episode, which is less than the MS–DRG 234 geometric mean of 8 days. Therefore, the normal MS–DRG payment amount associated with this readmission would be divided by 8 (the geometric mean) and multiplied by 3 (the first day is counted as 2 days, and the second day contributes the third day), and the resulting amount is attributed to the episode. The remaining five-eighths would be captured in the post-episode spending calculation discussed in section III.D.7.e. of this final rule. If the readmission occurred on the 82nd day after discharge from the EPM anchor hospitalization, and the length of stay was 10 days, the normal MS–DRG payment amount for the admission would be included in the episode without proration because length of stay for the readmission falling within the episode (9 days) is greater than or equal to the geometric mean (8 days) for the MS–DRG. We would also clarify that, consistent with how we would prorate payments for services that extend beyond the episode when establishing benchmark prices for an AMI episode without a CABG, in instances of an AMI episode with CABG readmissions, we would establish the benchmark price based on prorated amounts for both the AMI episode and the CABG readmission.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without

modification, to prorate payments for services that straddle episodes. Our final policy for prorating payments is included in § 512.300(f).

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 proposed to apply 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 (81 FR 50846). We proposed to apply the ceiling according to the following groupings that align with our proposed EPM price-setting methodology.

First, for SHFFT model episodes, we proposed 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 proposed to calculate and apply the ceiling separately for each price MS–DRG at the regional level.

Third, for CABG model episodes, we proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 believed that the proposed 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 were included in § 512.300(e)(1). We sought comment on our proposal to cap high payment EPM episodes.

The following is a summary of the comments received and our responses.

Comment: Commenters supported the proposal for capping high payment episodes. A commenter noted that the proposal does not separately address an episode where Medicare accepts a beneficiary's appeal of Medicare Provider Non-Coverage after the discharging physician determined not to certify that patient for care. The commenter noted that under such a scenario, in contradiction with the hospital's clinical judgment on appropriate level of care, the proposed policy would not cap spending unless it reached the proposed threshold. The commenter recommended that CMS create additional flexibilities or protections for hospitals where a Medicare appeal overturns a hospital's decision that is based on clinically-directed, evidence-based discharge criteria.

Response: We appreciate comments in support of our proposal to cap high payment EPM episodes. We disagree with the suggestion to include protections in addition to what we have proposed to address scenarios where a Medicare appeal contradicting a hospital's discharge decision increases the costs of an episode. We believe our proposal offers sufficient protection under such circumstances. Further, if a hospital's discharge decision was overturned upon appeal, we would have to believe the final decision was correct and any additional costs that resulted from the appeal would be appropriately included as an episode cost.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, with modification, to cap high payment EPM episodes. Specifically, we are not finalizing our proposal 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 with respect to AMI model episodes with MS–DRG 231–236, and instead will simply apply ceilings separately for each MS–DRG at the regional level as we would with MS–DRGs 280–282 or 246–251 without readmission for CABG MS–DRGs. Our final policy for capping high payment EPM episodes is included in § 512.300(e)(1).

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 the 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 proposed to include both reconciliation payments and Medicare repayments when calculating historical EPM-episode payments to update EPM-episode benchmark and quality-adjusted target prices (81 FR 50847). We concurred 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.B. of the proposed rule (81 FR 50950 through 50951), we also proposed 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 believed this option would not achieve our intention of more fully capturing the costs of care under the EPM. We further noted 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 proposed to include BPCI Net Payment Reconciliation Amounts in our calculations when updating EPM-episode benchmark and quality-adjusted target prices. We noted, 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 proposed 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 proposed 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 the 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 was included in § 512.300(c)(8). We sought 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.

The following is a summary of the comments received and our responses.

Comment: Multiple commenters supported the proposal to include reconciliation payments when calculating target prices in order to more fully recognize the costs of care under the models. A number of commenters expressed the view that the proposal will help avoid participants from constantly competing against their prior success and better ensure that target prices decrease at a slower rate, which is critical for those providers that are already efficient, allow more viable financial targets for the participating providers that are better aligned with effective patient care. A commenter requested that CMS include these reconciliation payments and repayments in PY2 rather than PY3. Another commenter requested that CMS exclude Medicare repayments given that the targets would fall for hospitals that increased their spending to improve care, which then caused them to exceed their target prices.

Response: We appreciate the comments supporting our proposal to include reconciliation and Medicare repayments when calculating historical EPM-episode payments to update EPM-episode benchmark and quality-adjusted target prices. We disagree with comments suggesting that we accelerate their inclusion to PY2 or to exclude Medicare repayments for these purposes. We would further note that since the historical data for determining PY1 and PY2 benchmarks is based on 2013 to 2015 expenditure data, the effects of a reconciliation determination for PY1, which is based on 2017 expenditure data, would not pertain to the data used to determine target prices for PY2. Moreover, given that reconciliation determinations are made 2 months after the completion of a performance year, it would not be possible to apply the PY1 reconciliation results to the PY2 benchmark data even if we were to adjust our timeframe for determining historical payments.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to include both reconciliation payments and Medicare repayments when calculating historical EPM-episode payments to update EPM-episode benchmark and quality-adjusted target prices. The final policy for including reconciliation payments and Medicare repayments is included in § 512.300(c)(8).

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 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 were further discussed in section III.E.3.f of the proposed rule (81 FR 50887 through 50893), this section of the proposed rule discussed the approach to establishing EPM-episode benchmark and quality-adjusted target prices (81 FR 50847 through 50864).

For the purposes of price-setting, any references in our proposed rule to AMI ICD–CM diagnosis codes meant 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 the proposed rule to intracardiac ICD–CM procedure codes meant 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 proposed 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 the 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 proposed to generally apply the CJR model methodology to set EPM-episode benchmark and quality-adjusted target prices (80 FR 73337 through 73338), 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. The price-setting methodology incorporated 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 the proposed rule, 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 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 both our proposed rule and this final rule.

We also proposed 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 stated our belief 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 was included in § 512.300(c)(9). We sought comment on our proposal to prospectively communicate these prices.

The following is a summary of the comments received and our responses.

Comment: Commenters supported the proposal to establish and prospectively communicate benchmark and quality-adjusted target prices. Commenters also expressed concerns about how far in advance the information would be made available and the level of detail that would be included in the information. Commenters indicated that knowing the target price prior to the relevant performance period is essential for participants to be able to implement efficient care redesigns linked explicitly to established payment rates. As such, commenters requested that CMS provide this information 60 to 90 days prior to the start of the relevant performance period. Other commenters requested that CMS make all of the components necessary to calculate the target price for both the CJR model and proposed EPMs available to participants so they can verify that CMS accurately calculated the target price as some CJR participants have reported an inability to replicate the target price calculation due to CMS' use of ''black box'' inputs for certain national factors.

Response: We appreciate the comments and support we received for our proposal to prospectively communicate benchmark and quality-adjusted target prices, agree with commenters on the importance of having this information in advance of each performance year, and intend to make as much information available as we deem appropriate to participants as far in advance of the models' implementation as is possible.

Comment: Several commenters recommended that CMS annually reevaluate and update the price-setting assumptions through a notice and comment process. One of these commenters reported that the proposal to make historical claims data available before implementation of the models would still not give hospitals an opportunity to comment on problems with the methodology until after the models had begun. Another commenter based their request on significant and unexplained changes in prices reported under BPCI and the Pioneer ACO model.

Response: We appreciate these comments and suggestions. We believe the information we provided in both our proposed and this final rule is sufficiently detailed for participants to understand our assumptions and methodology for setting target prices. In the event we intend to materially change our price-setting assumptions or methodology, we would make those proposed changes available through a notice and comment process.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to prospectively communicate quality-adjusted target 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 proposed generally to apply the episode pricing methodology that was applied to the CJR model to develop the EPM-episode benchmark prices, which we referred to as the standard EPM-episode benchmark price (81 FR 50848). In addition, for each EPM participant, we proposed 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 the proposed rule (81 FR 50848 through 50864). For purposes of the proposed rule, risk-stratification meant 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 proposed to set the price MS–DRG equal to the anchor MS–DRG. We proposed 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 (80 FR 73337 through 73358) with risk stratification according to the anchor MS–DRG.

Similarly, for AMI model episodes without chained anchor hospitalizations and without readmissions for CABG MS–DRGs, we proposed to set the price MS–DRG equal to the anchor MS–DRG. We proposed 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 (80 FR 73337 through 73358) with risk stratification according to the anchor MS–DRG. We proposed to apply the CJR model payment methodology separately to AMI model episodes with anchor AMI MS–DRGs 280 through 282 and anchor PCI MS–DRGs 246 through 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 proposed 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 the proposed rule.

For AMI model episodes without chained anchor hospitalizations and with readmissions for CABG MS–DRGs, we proposed 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 the 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 proposed 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 the proposed rule.

For CABG model episodes, we proposed 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 (80 FR 73337 through 73358) 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 the proposed rule.

Finally, we proposed 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 the proposed rule.

The following is a summary of the comments received and our responses.

Comment: One commenter commended CMS for attempting to create a target price methodology that accounts for the variations in episode spending that are characteristic of these specific clinical scenarios while other commenters noted that the complexity of the proposals made it difficult to evaluate them. Several commenters disagreed with the proposal to base prices on MS–DRGs or anticipated that they could result in unintended consequences. For example, commenters noted concerns that it would be challenging to generate sufficient savings where a sizeable portion of episode costs are embedded in the MS–DRG costs attributed to the initial hospitalization and cannot be changed by hospitals' performance. Other commenters noted that the higher payments associated with higher-weighted MS–DRGs could serve as a disincentive to participants from making quality improvements or to reduce complications because they would be paid more when there are complications that raise the MS–DRG, but paid less when quality improvements they made resulted in a lower cost MS–DRG where only CMS rather than the hospital benefitted from the reduced costs. Likewise, several commenters claimed that participant coding behavior could result in similar unintended consequences. As such, several commenters recommended that CMS consider a price-setting methodology that removes the MS–DRG payment from the target price or mitigates coding effects from the calculations or differentially weights cost components that would be ''locked in'' to the episode spending.

Response: The purpose of our models is to test EPMs within the existing parameters and payment systems of FFS Medicare. As we noted in section III.A.1.c. of this final rule, issues such as those commenters raised are generally present for every episode payment model that sets a price Medicare will pay for an episode-of-care. While our models are not intended to change these existing FFS payment systems, we intend that by incorporating both the MS–DRG payment and Part B services furnished during the anchor inpatient hospitalization, the EPMs will create incentives for increased care coordination and efficient care delivery from the time of inpatient admission through 90 days after discharge. Moreover, we hope the EPMs can identify the effectiveness of a bundled payment model within those parameters as well as the factors that could impede success. As discussed further in sections III.G.4. through III.G.6. of this final rule, we will monitor access to care, the quality of care, and delayed care under the EPMs and may take actions against EPM participants if we find evidence that supports concerns in these areas. In addition, the evaluation as discussed in section IV. of this final rule will analyze beneficiary outcomes and their relationship to clinical pathways under the EPMs.

Comment: Several commenters addressed EPM payments under the SHFFT model. One commenter noted that the proposed SHFFT model would include 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. As these procedures are emergent rather than elective, they would have more risk to manage than would an elective LEJR and would more often require a SNF stay and non-weight bearing status for weeks, which results in higher costs than for an elective procedure. The commenter questioned whether such non-elective procedures would have a higher benchmark price and expressed concerns that bundled payment models are potentially less successful for non-elective procedures which they believe require more time for planning and rehabilitation.

Other commenters suggested that the differences in severity and fracture type for episodes under the SHFFT model are not adequately represented by the three MS–DRGs we proposed. One of these commenters requested additional separate target prices as CMS had done for the CJR model, which would serve as a rough form of risk-adjustment and would make it easier for hospitals to devise protocols and strategies best suited to fracture type. Another commenter suggested that since patients who experience SHFFT episodes often require lengthier and more complicated care, and typically require longer post-acute care than those receiving joint replacement, the calculation of target prices should also take into account the proportion of SHFFT episodes included in the bundle in order to most accurately capture the risk of SHFFT episodes. One commenter recommended that CMS adopt transfer mechanisms within the SHFFT model, including price adjustments, which are similar to those proposed for inpatient-to-inpatient hospital transfers under the AMI model but that the receiving hospital would bear the risk if a SHFFT patient is transferred to that hospital.

Response: We proposed to set prices based on anchor MS–DRGs, which implicitly adjust payments based on their relative weights with respect to the IPPS resources required for that MS–DRG. For example, average episode expenditures for historical SHFFT episodes increases from roughly $36,000 in episodes with anchor MS–DRG 482 to more than $52,000 for episodes with anchor MS–DRG 480.[77] Further, our benchmark prices would reflect the historic costs of post-acute care associated with these MS–DRGs. If historic post-acute care costs for the emergent MS–DRG are higher than those for a similar elective MS–DRG, then those higher resources would be reflected in and produce a larger increase in the benchmark amount than would be the case for the elective procedure. We would also note that as discussed in section III.D.4.b.(2) which follows, we will be exploring additional options to adjust benchmark prices and performance payments to better account for cost variation associated with risk. These adjustments, which we intend to be effective beginning in PY3, should further account for some of the potential variation in costs across episodes as has been highlighted. We disagree with the view that a bundled payment would be any less effective with an emergent than an elective procedure. Our proposed models are intended to encourage changes and improvements in participants' care practices, in general, with respect to the episodes covered under the models, which we believe would apply regardless of whether the episode is elective or emergent.

As discussed in section III.D.4.b.2.(a), we are not finalizing our proposal with regard to inpatient-to-inpatient transfers for AMI episodes. For AMI model episodes alone, we will cancel the AMI episode that begins at the initial treating hospital when an inpatient-to-inpatient transfer occurs during the anchor hospitalization. For CABG and SHFFT model episodes, once the episode begins and an inpatient-to-inpatient transfer occurs, the episode will continue and

[77] Episodes for SHFFT 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.

the hospitalization at the transfer hospital will be included or excluded from the CABG or SHFFFT episode based on whether or not the MS–DRG for the admission at the transfer hospital is excluded from the CABG or SHFFT episode definition.

Comment: One commenter stated that the proposed EPMs do not adequately account for research and teaching functions and that CMS should adjust payments to account for the overhead associated with these functions.

Response: We disagree that our proposed models should include additional payment adjustments for research and teaching function beyond the payments Medicare already makes for these purposes under the IPPS. In contrast, we believe that participants should seek improved care quality and efficiencies as broadly as is possible, including any that can be attained with research or teaching activities.

Comment: A commenter noted their view that all providers should have EHR capability, including the ability to share EHR data across sites of service in order to speed decision-making and eliminate duplication of effort. The commenter suggested that CMS include incentive funds to assist post-acute care providers in implementing a robust EHR system and tools to share the data with other providers. Similarly, a commenter suggested that the proposed models will require technology and services for monitoring care during a post-acute care stay, and that CMS should incentivize the use of such technology and services. The commenter recommended that CMS should pay for remote patient monitoring using the CPT-code 94040, which is similar to what is done in certain state models.

Response: We agree that EHR capability and monitoring technologies can be useful tools toward improving care coordination and care quality; however, our models are based on incentives to improve care quality and efficiency, with a goal of improving control of cost growth. We do not believe that adding funding to encourage further adoption of technologies under the models is consistent with our goals. However, we would note that to the extent a participant establishes sharing arrangements with post-acute care collaborators under the models, those collaborators could choose to use such shared funds for purposes of improving their EHR or monitoring capacities.

Comment: As discussed in section III.C.3.b. of this final rule, one commenter pointed to evidence demonstrating that the use of drug-eluting stents (DESs) results in better long-term outcomes in many patients and fewer repeat procedures for in-stent restenosis than do less costly non-drug eluting stents. The commenter expressed concern that while the costs of these more expensive stents would be captured in the episode cost calculation, the long-term benefit for patients both in terms of outcomes and costs would not be fully captured in the 90-day post-discharge episode period and hence discourage the appropriate use of DES by causing fewer patients to receive them, resulting in poorer outcomes and increased cost growth. The commenter requested that CMS consider various means so to ensure the 90-day post-discharge episode target price does not discourage the longer term outcomes that are better for Medicare beneficiaries and potentially overall savings for CMS. Another commenter requested an adjustment or additional financial protection for costs associated with the implantation of an Implantable Cardioverter Defibrillator (ICD) given strong empirical support and its Class I recommendation for prevention of sudden cardiac death for certain patients.

Similarly, another commenter recommended that CMS include a payment adjustment such as an additional outlier or add-on payment for using new technology, having higher cost cases, or adopting a breakthrough/high cost treatment in advance of other providers.

Finally, one commenter recommended that CMS coordinate with the device industry to create a process wherein the use and associated cost of new technologies can be added to episodes of care definitions on a routine basis and modify the proposal to ensure that providers have financial incentives to provide optimal care for high-risk patients with severe coronary artery disease even if the initial treatment episode has a higher cost. The commenter expressed concern that insufficient data were available at this time to inform a clinical guideline recommendation with regard to the optimal timing of non-culprit vessel PCI, and the proposed payment bundles could encourage procedures that may not provide the best clinical outcomes for Medicare beneficiaries but instead have financial benefits with respect to the target price. As guidelines change based on available data, CMS should consider potential adjustments to reconciliation to the episodes quality adjusted target prices based on guideline changes.

Response: As we noted in section III.C.3.b. of this final rule, Medicare payment for coronary stents, whether bare metal or DES, used during a PCI performed during a hospitalization are included in the IPPS payment for the inpatient hospitalization. While they are not paid separately by Medicare, payment for the required resources would be included in AMI episodes because the IPPS services for the anchor hospitalization are included in the episodes. We propose to risk-stratify EPM-episode prices based on MS–DRG as discussed in section III.D.4.b.(1) of this final rule and there are separate MS–DRGs for PCIs that use DES (246 and 247) and non-DES (248 and 249) for which there would be separate AMI episode prices. Therefore, we do not believe that the financial incentives under the AMI model encourage the use of any specific coronary stent because the episode prices take into consideration the IPPS payment for the specific MS–DRG that applies to the AMI model beneficiary. We do not expect the AMI model to discourage the appropriate use of DES. We would also note, as stated in section III.D.4.b.(2), we will be exploring additional mechanisms to risk adjust payments that should become available beginning in PY3. We believe that these adjustments will provide participants further protections that should help mitigate the concerns commenters raised.

Likewise, we do not agree with comments requesting payments in addition to those currently made available when participants adopt specific or new technologies, provide services for high-cost cases, or adopt breakthrough technologies. The purposes of the proposed models are to improve care quality and efficiency while better controlling Medicare cost growth within a FFS framework. As such, the models seek to achieve these goals to the greatest extent possible within the regulatory framework that applies within FFS Medicare, and are not intended to create new or substitute payment mechanisms or processes for establishing new payments under FFS Medicare.

Comment: A commenter recommended that when establishing episode target payments, price calculations should incorporate clinical practice guidelines and appropriate use criteria that are endorsed by all stakeholders to ensure that patients are not receiving inadequate care.

Response: We disagree with the recommendation that prices should include clinical practice guidelines as, to the contrary, they are based on Medicare FFS payments and their historical utilization for services included in the EPMs, and should not

include specifications reflecting normative criteria regarding clinical practice guidelines, which could be overly prescriptive for EPM participants and provides and suppliers treating EPM beneficiaries. That said, we would assume that EPM participants would be following clinical practice guidelines as we would expect should also be the case for services and paid under the Medicare FFS program.

Comment: We received a comment suggesting that CMS make payment adjustments for cases where a beneficiary receives the majority of their post-acute care in a different MSA from the MSA in which the anchor hospitalization occurred. The commenter presented an example where a beneficiary with an anchor hospitalization in Massachusetts receives post-acute care in Florida. In their view, the MSA in Florida could have higher service utilization and spending than the Massachusetts MSA given different care practices. Further, the commenter believed it was unlikely that the hospital in Massachusetts could have influence on a provider in another distant MSA. The commenter recommended a payment adjustment to both avoid penalizing hospitals in the initiating MSA and to help in not deterring tertiary care facilities from accepting patients that could not receive necessary care in their own distant MSA.

Response: As noted in section III.C.4.a. of this final rule, we recognize that in occasional circumstances, EPM participants may have limited ability to coordinate care, but that we generally expect that much of the subsequent coordination of post-acute care services and other related services for EPM beneficiaries during the 90 days post-discharge can be accomplished through telecommunications that do not require the patient to remain within the geographic proximity of the hospital responsible for the EPM episode. In that section, we also noted that the design of the EPMs does not preclude hospitals from coordinating care with other providers outside of their immediate service area, that most EPM participants have the tools to engage in effective remote care coordination that results in high quality episode care, and that we finalized several waivers of Medicare program rules, as discussed in section III.J. of this final rule, to facilitate efficient and effective episode care coordination for beneficiaries in remote or distant locations outside of the EPM participant's immediate community. We also finalized policies for financial arrangements in section III.I. of this final rule that allow EPM participants to share upside and downside financial risk with a variety of individuals and entities who collaborate with the EPM participant in redesigning care and caring for EPM beneficiaries, regardless of the geographic proximity of these individuals and entities to the EPM participant. Through financial arrangements, EPM participants could align the financial incentives of providers in the EPM beneficiary's home community with the goals of the EPM participant to improve the quality and reduce the cost of EPM episodes. Therefore, we do not believe it is necessary to make a payment adjustment when a beneficiary receives post-acute care in a different MSA from the MSA in which the anchor hospitalization occurred. However, we plan to monitor these occurrences and could consider modifying our policy should that be determined appropriate.

Comment: Several commenters requested that CMS include more flexibility with respect to payments for post-acute care services under the models. For example, some commenters noted that while Medicare payments for inpatient rehabilitation facility or long-term care hospital services are based on a prospective amount, payments for skilled nursing facility services are less ''encompassing'' and are based on a per diem amount. Commenters suggested that these differences can create an unequal playing field and prevent efficiencies that are realized from being reflected in payments. As such, commenters requested that CMS identify flexibilities so that payments among a broader array of post-acute care providers could more closely reflect any efficiencies that are realized, for example, through payments on a per diem basis or at a reduced rate.

Response: We appreciate the suggestions commenters offered to better align payments across post-acute care providers. We will not be adopting these suggestions for purposes of these models as, to the greatest extent possible, we want to test the effects of bundled payments within the existing FFS Medicare framework. We will consider the applicability of the suggestions offered, however, as we explore future models that involve payments for post-acute care services.

(2) Adjustments To Account for EPM-Episode Price Variation

We also 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 (80 FR 73338 through 73339), we stated our belief that no standard risk adjustment approach that is widely-accepted throughout the nation exists for the proposed EPM episodes. Thus, we did not propose to make risk adjustments based on beneficiary-specific demographic characteristics or clinical indicators. Likewise, we questioned whether CMS Hierarchical Condition Categories (HCC) used to adjust for risk in the Medicare Advantage program would 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 did not propose to risk-adjust EPM-episode benchmark or quality-adjusted target prices using HCC scores for the EPMs. We referred to the CJR Final Rule for additional discussion of our assessment of risk-adjustment options for the CJR model, which informed our views on their appropriateness for the EPMs (80 FR 73338 through 73340).

We also noted, however, that there are circumstances that could account for spending variation in EPM episodes where certain pricing adjustments could be appropriate. We 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 the 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. We also recognized 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 proposed specific policies and payment adjustments in recognition of the systematic, consistent variation in EPM-episode spending that could result from such circumstances.

The following is a summary of the comments received and our responses.

Comment: While one commenter supported the proposal to risk-stratify episode costs based largely on MS–DRGs with additional adjustments for scenarios including chained anchor hospitalizations, readmissions, and CABG, many commenters expressed concerns that no further risk-adjustment was proposed beyond the risk-stratification inherent in the MS–DRGs and CMS' proposed adjustments for such scenarios as chained anchor hospitalizations or episodes involving readmissions or CABG. These commenters noted their views that the absence of further risk-adjustment would penalize hospitals treating the sickest, most complicated, and most vulnerable patients for factors that are beyond the hospitals' control. One commenter reported that adequate risk-adjustment is especially important as CMS considers additional clinical groups for bundling programs, such as cardiac care or SHFFT patients, that are more clinically heterogeneous than CJR patients. MedPAC noted that it has ''consistently found that chronic conditions and advanced age play a major role in explaining variation in spending across beneficiaries. CMS proposes no further risk-adjustments beyond the DRG/subgroups but provides no data to assess whether the proposed stratification is sufficient to adjust for differences in spending across beneficiaries within each episode type. The Commission urges CMS to evaluate whether additional risk adjustment strategies, such as comorbidities and age, would improve the accuracy of the benchmarks.''

Many of the commenters pointed to a recent study noting that the use of region-based target pricing can lead to reduced reconciliation payments for hospitals.[78] However, reconciliation payments would substantially increase for hospitals that treat patients with high complexity and be reduced for hospitals that treat patients with low complexity when CMS–HCC scores are applied. Some commenters cited additional data in support of their views that the absence of risk-adjustment ignores the substantial variation in episode payments that exists, penalizes hospitals for assuming the risk of higher-cost/higher-risk patients, or potentially impedes access to high quality care.

A number of commenters related the absence of further risk-adjustment to concerns with the proposal to phase-in regionally determined target prices. For example, commenters noted that the use of a regional spending component will hold all hospitals in a region to the same target price, even though they would have different clinical capabilities and different risk profiles that results in their treating patient populations with differing levels of severity and costs, which further buttressed the view that substantial variation in episode payments exist within each target price category, not just between the target price categories. Some commenters expressed concerns that differences in clinical capabilities, and therefore, differing rates of more costly transfer episodes, could penalize smaller hospitals that do not have the most sophisticated cardiac care available.

Some commenters expressed the view that the absence of risk adjustment would particularly affect hospitals that typically treat more complex patients, for example, tertiary hospitals or hospitals that are academic medical centers because the absence of risk adjustment would not account for the complexity of their patients, which often included multiple co-morbidities, longer lengths of stay, and higher costs. As hospitals could view these patients as increasing their financial risk under the EPMs, commenters expressed concerns that patients who suffer from multiple chronic conditions or comorbidities may find it more difficult to find participating hospitals willing to serve them.

Other commenters expressed concern that hospitals serving communities with a high percentage of lower income patients could be adversely affected by the absence of risk-adjustment. Moreover, the lack of further risk-adjustment could create a risk-adverse environment with the possibility of withholding appropriate care to patients with moderate to high-risk profiles, for example to women, due to their older age at cardiac presentation and minorities due to increased frequency of clinical renal disorder. These commenters noted that such patients could have higher costs due to their age or presence of multiple co-morbidities. Further, by not providing an adjustment factor, there could be a greater chance of transfer abuse whereby smaller providers might shift risk for these patients to tertiary providers by transferring emergency room patients that are at greater risk for complications or readmissions.

Commenters also noted that CMS appeared to be inconsistent and contradictory in not proposing to apply CMS–HCC scores for the proposed models or for the CJR model when it does so for similar programs and applications. Specifically, commenters observed that CMS–HCC scores are applied to quality measures such as Medicare Spending per Beneficiary (MSPB), 30-day mortality and readmission, as well as for the quality measures proposed to be included under the proposed models. Commenters remarked that this gives the impression of poor harmonization of efforts within CMS, which leads to fragmented programs.

Thus, the commenters requested that CMS apply some kind of additional risk-adjustment to the proposed models and the CJR model at the latest before downside risk begins. One commenter noted that even if not ideal, further risk-adjustment would be at least as good as CMS' proposal, but simpler and easier to understand than the 75 different target prices CMS proposed. Other commenters recommended that CMS explore and incorporate additional risk-adjustment to address socio-demographic factors, in addition to clinical factors, to more accurately reflect the level of risk associated with such beneficiary characteristics as income and employment status. Further, another commenter reported that socio-demographic factors such as the availability of primary care, physical therapy, easy access to medications and appropriate food, and other supportive services, which are beyond providers' control, affect hospitals' performance on outcome measures.

Several commenters recommended that CMS apply the CMS–HCC scores. In their view, some benefits of these scores is that they capture the severity of a patient's level of underlying illness, better match hospital's payment to the complexity of their patients, appropriately account for the expected increase in utilization of health care services, reduce the likelihood of a Medicare repayment, and should be administratively simple to apply given their use for other efforts and programs under Medicare. One commenter offered that these codes could, at a minimum, serve as a basis for CMS to begin to construct an appropriate risk-

[78] Ellimoottil C, Ryan AM, Hou H, et al. Medicare's New Bundled Payment For Joint Replacement May Penalize Hospitals That Treat Medically Complex Patients. Health Affairs. 2016: 35(9):1651–1657. doi: 10.1377/hlthaff.2016.0263.

adjustment for CJR episodes, as well as for SHFFT episodes if it re-proposes their implementation in the future. Another commenter suggested that CMS identify a means to adjust the CMS–HCC codes so that they could better apply to a 90-day episode. Moreover, while encouraging further risk-adjustment as soon as possible within the period of the model, this commenter also suggested that the proposed models could be an opportunity to obtain the data needed to develop EPM risk-adjusters.

One commenter encouraged the use of physician-defined patient condition categories to ensure effective risk stratification in condition-based payment models. This commenter reported that alternative payment models that are designed to control overuse need to incorporate effective risk adjustment or risk stratification components in order to protect patients against underuse and to avoid penalizing physicians for delivering and ordering services that patients need. In their view, CMS–HCCs and other claims-based regression models are not adequate for risk adjustment in condition-based payment models. Rather, condition-based payment models must be risk stratified based on the clinical characteristics and functional status of patients that are most relevant to the types of conditions being managed.

Some commenters urged CMS to improve the risk-adjustment methodology by collaborating with the clinical community and relevant medical specialty societies such as the cardiovascular community that have experience with the different risks facing patients who will be treated within these episode models. Other commenters recommended that CMS review risk adjustment methodologies used by other's bundling models or to incorporate data from the STS Risk Calculator into the risk-adjustment methodology or to use multiple model to better predict the cost of care.

Commenters requested that CMS expand risk-adjustment to other provider types or measures factors in addition to the patient alone. For example, one commenter expressed concern that CMS has no risk-adjustment methodology in place for patients' transitions into the post-acute and long-term care sector and that many factors contribute to cost variation in these milieu are outside of the control of the facilities themselves. The commenter requested CMS to clearly define risk stratification indices and develop a cost-to-risk algorithm based on previous utilization data and incorporating specific, patient characteristics, including functional status, age, and frailty, to accurately evaluate EPM performance. Another commenter recommended that CMS examine whether the CMS–HCC model would be an appropriate way to measure the resource use of geriatricians as well as serve as a risk-adjustment mechanism. Finally, one commenter urged CMS to modify the risk-adjustment policy to reflect the relative riskiness of the procedures as well as the beneficiary-specific demographic characteristics and clinical indicators.

Response: We appreciate the comment supporting our proposal to risk-stratify episode costs based largely on MS–DRGs with additional adjustments for scenarios including chained anchor hospitalizations, readmissions, and CABG as well as the many comments expressing concerns about our proposal, data cited in support of these concerns, requests for additional measures to adjust for risk, and suggestions on approaches to consider for this purpose. We share commenters' interests in ensuring that payments under the models are well aligned with costs and adequately recognize cost variation associated with either the services provided or beneficiary characteristics so that participants are encouraged and able to be successful under the models, which includes providing access to high quality care to Medicare beneficiaries. In particular, we share commenters' concerns that episode payments be more closely aligned with costs when all EPM participants will assume downside risk and have their payments determined more fully based on regional pricing.

Based on the comments we received, we are persuaded to explore additional measures with which we could adjust EPM episode payments for risk to complement our proposals to stratify and adjust episode payments based on type and combination of anchor MS–DRGs included in an episode. As such, we plan to examine a range of options such as CMS–HCC scores, beneficiary factors, clinical factors, pathways including planned readmissions after discharge for an acute cardiac event, and other measures that potentially further explain variation in costs, including socio-demographic factors such availability of primary care services. As discussed in section III.D.7.c.(2) of this final rule, CMS will also consider and potentially incorporate results from studies conducted under the Improving Medicare Post-Acute Care Transformation ''IMPACT'' Act of 2014 (Pub. L. 113–183) with respect to factors, including socio-demographic factors, that could affect resource use under Medicare and the EPMs.

While we are optimistic that we will be able to identify factors that explain more variation in episode expenditures than risk stratification alone, we acknowledge that no combination of adjustments will account for all variation in episode expenditures. Still, we intend to proceed with the models and as discussed elsewhere in this rule are finalizing other financial protections like an extended period of no downside risk (see section III.D. 2.c.), capping high payment episodes (see section III.D.3.d.), and more generous stop-loss protections for certain hospitals (see III.D.7.c.(1)). We also intend to engage with and seek input from stakeholders as we examine this range of options prior to rulemaking.

Our goal is to make our refinements to the pricing methodology to reflect risk adjustment effective beginning in PY3, which we would establish based on a notice and comment rulemaking process. As such, the additional measures would apply to episodes ending on or after January 1, 2019 and that had anchor discharges occurring after October 1, 2018 and thus be in place at the time downside risk is required.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to risk-stratify episodes based on adjustments to recognize the combination of MS–DRGs and pathways associated with an episode. We will also explore and plan to implement additional adjustments to account for risk through rulemaking to be effective in PY3.

(a) Adjustments for Certain AMI Model Episodes With Chained Anchor Hospitalizations

In section III.C.4.a.(5) of the proposed rule, we stated 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 stated that 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 indicated 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 proposed 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 occurred 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 proposed that the AMI model episode would begin with and be attributed to the first hospital, and we proposed 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 was an AMI or PCI MS–DRG, we proposed 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 the proposed rule. If the price MS–DRG is a CABG MS–DRG, we proposed 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 13 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 13—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 stated our belief 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 stated our view 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. In our view, 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 noted that 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 were not convinced this approach would ultimately improve care quality and efficiency under the AMI model.

First, we were 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.[79] Beneficiaries

[79] Barreto-Filho J, Wang Y, Rathore SS, et al. Transfer Rates From Nonprocedure Hospitals After Initial Admission and Outcomes Among Elderly

Continued

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 believed 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 believed 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 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 believed 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 recognized 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 noted our belief 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 believed that 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 the proposed rule, we proposed 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 believed 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 were included in § 512.300(c)(7)(i). We sought comment on our proposals for pricing AMI episodes involving chained anchor hospitalizations and the alternative proposals we considered. We also sought 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 sought 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 sought 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.

The following is a summary of the comments received and our responses.

Comment: As discussed earlier in Section III.C.4.a. of this final rule, many commenters expressed concerns and opposed the proposal 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. Similarly, many commenters expressed concerns with respect to the pricing of episodes in the case of these chained anchor hospitalizations that generally paralleled the comments discussed in section III.C.4.a. of this final rule.

Response: As discussed in section III.C.4.a., we were persuaded by commenters to not finalize our proposal that once an AMI model episode is initiated at an AMI model participant, the AMI model episode would continue under the responsibility of that specific participant when a beneficiary is transferred to another hospital for further medical management of AMI or revascularization through PCI or CABG during a chained anchor hospitalization. Instead, we are finalizing a policy that for an episode involving an inpatient-to-inpatient transfer, the episode would be attributed to the transfer hospital rather than the initial hospital.

Accordingly, we are also not finalizing our proposed pricing methodology for these episodes, which would have 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-

Patients With Acute Myocardial Infarction. JAMA Intern Med. 2014;174(2):213–222. doi:10.1001/jamainternmed.2013.11944.

anchor admission with the highest IPPS weight. Instead, we are finalizing a policy where an episode's price will be determined only by the anchor MS–DRG for the AMI or CABG model episode as determined by the transfer hospital in the same manner as we would for any other AMI episode that does not involve a transfer.

Since we are not finalizing our original proposal, we also will not be finalizing the terms ''chained anchor hospitalization'' or ''price MS–DRG'' as all episodes under the model will be priced based on their assigned anchor MS–DRG. Accordingly, we will be deleting these terms from our proposed regulations.

Final Decision: After consideration of the public comments received, we are not finalizing the proposal to make payment adjustments for AMI episodes involving a chained anchor hospitalization, but will instead attribute the episode to the final hospital and calculate prices for these episodes based on the anchor MS–DRG for that episode determined by the transfer hospital. As such, we are replacing the term ''price MS–DRG'' with ''MS–DRG'' and deleting references to ''chained-anchor hospitalizations.'' Also as discussed in section III.C.4.a.(5) of this final rule, given our concerns about the potential missed opportunities and unintended consequences due to the final AMI model transfer episode initiation and attribution policy, we will be examining AMI transfers to and from AMI model participants very closely through our monitoring and evaluation activities as discussed in sections III.G.4. through 6. and IV. of this final rule, both of beneficiaries that ultimately are included in AMI episodes and those that are not. We may revisit the transfer policy or propose payment adjustments through future rulemaking if we see reduced AMI transfer efficiency, opportunities to increase transfer efficiency, disproportionate transfers of complex AMI beneficiaries or those with potentially avoidable complications suggesting that AMI model participants are engaging in adverse patient selection or providing poor quality care, inordinate loss of beneficiaries from the AMI model due to transfer outside of the MSAs where the AMI and CABG models are being tested, or other patterns of concern.

(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).[80] 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.[81] 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.[82]

Thus, for CABG model episodes, we proposed 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 proposed to calculate the CABG anchor hospitalization benchmark price by following the general payment methodology that was applied to the CJR model (80 FR 73337 through 73358), with expenditures limited to those that occurred during the anchor hospitalization and risk stratification according to the price CABG MS–DRG.

We also proposed to calculate the CABG post-anchor hospitalization benchmark price by following the general payment methodology that was applied to the CJR model (80 FR 73337 through 73358), with 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).

We proposed 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. of the proposed rule.

The proposals to establish pricing for CABG model episodes were included in § 512.300(c)(7)(ii). We sought comment on our proposals to establish pricing for CABG model episodes.

The following is a summary of the comments received and our responses.

Comment: One commenters suggested that CMS create a separate target price for CABG episodes where a patient has a previous history of CABG.

Response: We appreciate the commenter's suggestion, but believe the existing MS–DRGs that apply under the IPPS, which similarly do not distinguish CABG MS–DRG discharges based on whether or not a beneficiary had a previous history of CABG, our proposed pricing adjustments for CABG episodes, and additional risk-adjustments that we anticipate will be effective in PY3 should appropriately recognize the potential costs for beneficiaries within CABG episodes whether or not they had a previous history of CABG.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to establish pricing for CABG model episodes. Our final policy for establishing CABG model episodes is included in § 512.300(c)(7)(i).

(c) Adjustments for Certain AMI Model Episodes With CABG Readmissions

In section III.C.4.b of the proposed rule, we discussed AMI model episodes where a beneficiary is discharged from an AMI model participant under an AMI

[80] 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.

[81] 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.

[82] 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.

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 CABG 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 proposed 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 proposed 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 proposed 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 proposed 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 did 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 was included in § 512.300(c)(7)(iii). We sought comment on our proposal for adjusting episodes involving CABG readmissions.

The following is a summary of the comments received and our responses.

Comment: Several commenters expressed concerns about the proposal for adjusting episodes involving CABG readmissions—specifically, that the proposal does not sufficiently account for the increased post-acute care that a beneficiary typically receives after a CABG, but which they would not receive after only an AMI. One of the commenters presented data supporting their concern suggesting that post-discharge spending for certain MS–DRGs with a CABG readmission was substantially higher than for those same MS–DRGs without a CABG readmission. The commenters requested that CMS modify the methodology to account for the increased post-acute care that a beneficiary typically receives after a CABG.

Response: We appreciate the concerns raised by the commenters and have conducted further analysis of our proposal with respect to how well our proposal would account for post-acute care costs for AMI episodes involving CABG readmissions. While we agree that spending after discharge from the anchor stay for AMI episodes with CABG readmissions is substantially higher than for episodes without these readmissions, we disagree with suggestions that our proposal inadequately adjusts for these differences. Rather, based on our analysis, on average, the proposed adjustments account for the overwhelming majority of additional spending that occurs in AMI episodes with CABG readmissions relative to episodes without CABG readmissions. Additionally, the number of episodes for many of the affected MS–DRGs is relatively small, which we believe would impede our ability to establish reliable prices that would be an improvement over our current proposal in terms of payment accuracy. Accordingly, we are not persuaded to modify our proposal.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to adjust episodes with CABG readmissions. Our final policy for adjusting episodes with CABG readmissions is included in § 512.300(c)(7)(ii).

(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 set 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 involved 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 believed that this would be 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 noted 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 indicated that this approach would give 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 expressed interest 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 sought 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 sought 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 proposed 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 the proposed rule, would not bear undue financial risk and to mitigate any incentives to avoid caring for high-complexity patients. In addition, we sought comment on whether and how our methodology linking quality performance to payment under the 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.

The following is a summary of the comments received and our responses. The comments we received typically recommended that we consider either population-based models or capitated models, which we have addressed in section III.D.2.b. of this final rule; however, we are providing some specific examples that were recommended in the following comments.

Comment: A commenter recommended that we consider a population-based model that was tied to an ''event'' such as a beneficiary's initial Medicare enrollment in a selected geographic area such as a county or MSA; however, we should exclude Medicare Advantage enrollees or enrollees participating in other Medicare payment reform efforts. The model would include multiple quality measures reflecting both a clinical perspective and a beneficiary perspective. The model could include two tracks: Full financial accountability and partial financial accountability. Under the first track, we would pay participating providers a monthly, all-inclusive, beneficiary-risk-adjusted premium based on regional historical expenditures and the provider would assume full risk for all Part A and Part B expenditures. Under the partial financial accountability track, we would continue to provide the plan administration (allowing provider organizations without claims-payment and risk-assumption capabilities the opportunity to participate). Model participants would receive a monthly, beneficiary-risk-adjusted target budget for Medicare Part A and Part B services and their actual expenditures would be compared against their target budget at the end of each year for reconciliation. If costs exceeded the target, then the participant would repay CMS an agreed upon amount. If costs were below the target, then CMS would pay the participant an agreed upon amount. Both tracks could be eligible for Advanced APM designation under the Quality Payment Program, if they had a certified Electronic Health Record technology requirement for participants.

Another commenter, who had suggested that CMS adopt a model including prospective negotiated rates rather than retrospective reconciliation of fee-for-service claims, suggested that a capitated model would allow providers to experiment with services, in addition to telehealth consultations, that do not generate a fee-for-service claim. In their view, hospitals and surgeons have more opportunity to innovate in how they deploy professional staff, choose technology, and engage with outpatient and home-based services when they have full flexibility within a budgeted payment amount, and would encourage collaboration between all clinicians involved in patient care as well as provide predictable pricing. Also, the commenter believes that using prospectively determined negotiated rates or competitive bids would result in a more rapid transformation in cost and resource use. In their view, using target prices based on a provider's historical costs or the region's average costs is inconsistent with the goal of implementing innovative payment models. Moreover, current practice patterns should not be used to set a total cost for care, given the unnecessary care, excessive costs and cost variations that result from this payment approach. As such, this commenter recommend that providers competitively bid their episode price to encourage competition among providers to achieve the best outcomes for the lowest cost.

A commenter recommended that CMS design EPMs that would allow providers two options; specifically to (1) organize themselves in the manner most efficient to accept a prospective bundled payment from Medicare, and allocate it among the participating providers or (2) if other providers find it easier to continue billing under current payment systems, then retrospectively reconcile those payments against a prospectively defined budget. In this commenter's view, jointly-governed teams should have the flexibility to determine which organizational approach and retrospective or prospectively-determined payment model best works for their particular circumstances.

Another commenter suggested that CMS consider a model that pays specialists for management of specific conditions and combinations of conditions using the same payment model concepts being used with primary care physicians in the Comprehensive Primary Care Plus initiative. Under this model, CMS should focus accountability on services directly related to the condition, rather than total spending on all of the patients' health care needs and for which the physician may be unable to control. Further, the model would encourage the use of physician-defined patient condition categories to ensure effective risk stratification in condition-based payment models. These models would be risk stratified based on the clinical characteristics and functional status of patients that are most relevant to the types of conditions being

managed. Patients could designate the physician who would be managing care for their condition(s) but would be required to use the team of providers chosen by that physician for delivery of services related to the condition(s). Further, target spending amounts would be set for condition-based payments and episode payments prior to the beginning of the performance period. Finally, physicians and other providers could be for high-value services that are not currently billable as part of condition-based and episode-based payment models that use retrospective reconciliation.

Another commenter noted that while not recommending a specific framework, CMS should consider additional geographic-based models that include other costly procedures that vary in total episode costs, for example, spine surgery.

Response: We appreciate the comments and suggestions that were offered and that while not adopting these suggestions for these models, we will take them into consideration as we explore similar models in the future.

(e) Summary of Final Pricing Methodologies for AMI, CABG, and SHFFT Model Episode Scenarios

Tables 14 through 16 summarize our final standard pricing methodologies and the adjustments that will occur that are in sections III.D.4.b.(1) and (2) of this final rule for AMI, CABG, and SHFFT model episodes.

TABLE 14—AMI MODEL PRICING SCENARIOS

AMI pricing scenario	Price
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.
An AMI MS–DRG or PCI MS–DRG (with AMI diagnosis) anchored episode with CABG readmission.	Episode benchmark price is the sum of the standard episode benchmark price corresponding to the anchor MS–DRG and the CABG anchor hospitalization benchmark price corresponding to the CABG readmission MS–DRG.

TABLE 15—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 16—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 (80 FR 73340 through 73341), we proposed 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 (81 FR 50854). 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 the proposed rule). 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 EPMs was included in § 512.300(c)(1).

We sought comment on our proposal for 3 years of historical data updated every other year.

The following is a summary of the comments received and our responses.

Comment: Some commenters requested that CMS apply more trend data than the 3 years we proposed. A commenter expressed concern that in the absence of several years of historical data, target setting would not fully reflect case mix and behavior changes in addition to historical claims patterns.

Further, an impact of a focus on short-term costs may be a shift away from new technologies proven to improve outcomes and reduce costs. Another commenter requested an additional 2 years of trend data for Program Year 1, to bring the data up from 2015 to the 2017 program level and another 3 years of trend data to bring the 2015 claims up to the 2018 level. A commenter requested that the process be open and transparent so as to insure that all impacted collaborators are given the information and opportunity to comment and adjust.

Response: We continue to believe our proposed period for 3 years of historical data updated every other year is appropriate for the models. We disagree that including additional years of data beyond those we proposed would be necessary or helpful. Instead, rather than improving our historical data, the request for additional years of data could result in more heterogeneous historical data that is less reflective of a participant's most recent performance.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification 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. The final policy for using 3 years of historical EPM episodes for calculating benchmark prices is included in § 512.300(c)(1).

(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 proposed to apply a national trend factor to each of the years of historical EPM-episode payments (81 FR 50855) as we do with the CJR model (80 FR 73341 through 73342). Specifically, we proposed 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 proposed 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 noted our belief that 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 believed 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 was included in § 512.300(c) (11). We sought comment on our proposal for trending historical data.

The following is a summary of the comments received and our responses.

Comment: A few commenters addressed the use and trending of historical data. A commenter expressed their general agreement with the proposed trending methodology, but recommended that CMS update prices every other year rather than annually to limit the extent that participants would face increasingly more difficult targets. Another commenter recommended that CMS trend the initial 3 years of historical data for the full five years of the models. A commenter suggested that CMS apply more trend data to each performance year and expressed concerns that while CMS would trend data to the end of the benchmark 3-year period, CMS would not be trending data from the end of the benchmark period to match the time period for which the prices will be applied to pay providers.

Response: We appreciate the comments we received on our proposal to trend data and would like to clarify that their application would be on a semi-annual basis when we update target prices rather than annually. We disagree with the suggestion to apply

the 3 initial years of trend data to all five performance years as our intention is to establish target prices for the models using more recent performance data so as to maintain incentives for participants to continuously improve. Similarly, we disagree with the suggestion to expand the number of years used to trend data or to permanently relate trend data for a given performance year to those data for the initial 3-year benchmark period as doing so would result in data that are less representative of a participant's most recent performance.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to trend data. Our final policy for trending data is included in § 512.300(c) (11).

(5) Update Historical EPM-Episode Payments To Account for Ongoing Payment System Updates

As previously mentioned, we proposed 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 (81 FR 50855), 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 proposed 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 final rule for further discussion on the definition of EPM performance years.

We proposed 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-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 would 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 would 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 the proposed rule. Also, as discussed further in sections III.D.4.c. through d. of the proposed rule, 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. of the proposed rule.

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-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 referred to the CJR Final Rule (80 FR 73342 through 73446) for further discussion of our specific methodology and considerations for adopting this methodology for updating historical EPM-episode payments for ongoing payment system updates.

The proposal for updating episode payments for ongoing annual Medicare payment updates was included in § 512.300(c)(10). We sought comment on our proposal for updating episodes payments for ongoing annual Medicare payment updates. We received no specific comments on our proposal for updating historical EPM-episode payments to account for ongoing payment system updates. However, we wish to highlight that, as we do for the CJR model (80 FR 73343 through 73344), where an equation is used to calculate update factors for payment systems that apply annual updates to their rates effective October 1 of each year such as for inpatient acute, SNF, and IRF services, in lieu of calculating the update factors using the values applicable at the end of the latest historical year used to calculate target prices, we use a blend of the values applicable during the latest historical

year. This blend is intended to account for the payment systems that update payment rates on a fiscal year cycle, and ensure we are calculating update factors based on the payment rates that apply to a given period to the extent feasible, and result in more accurate target price calculations.

Final Decision: We are finalizing the proposal, without modification, to update episode payments for ongoing annual Medicare payment updates. The final policy for updating episode payments for ongoing annual Medicare payment updates is included in § 512.300(c)(10).

(6) Blend Hospital-Specific and Regional Historical Data

We proposed to calculate EPM-episode benchmark prices using a blend of EPM-participant-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 was discussed further in section III.D.4.b.(7) of the proposed rule (81 FR 50856). Specifically, we proposed to blend two-thirds of the EPM-participant-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 EPMs (CYs 2017 and 2018). For performance year 3 of the EPMs (CY 2019), we proposed to adjust the proportion of the EPM-participant-specific and regional historical EPM-episode payments used to calculate the EPM-episode benchmark prices from two-thirds EPM participant-specific and one-third regional to one-third EPM participant-specific and two-thirds regional. Finally, we proposed 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 participant-specific and regional historical EPM episode payments.

Consistent with our methodology for the CJR model (80 FR 73544), we proposed two exceptions. First, we proposed to use only regional historical EPM-episode payments to calculate EPM episode-benchmark prices for EPM participants with low historic EPM-episode volume). 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 thresholds for low historic volume in this final 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 proposed 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.[83]

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 proposed 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 referred to the CJR model Final Rule (80 FR 73346 through 73349) for further discussion on alternatives to and reasons for adopting this methodology for the CJR model, which informed our proposal with respect to the EPMs.

The proposal for blending payments when establishing participants' benchmark and quality-adjusted targets and certain exceptions was 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 final rule. We sought comment on our proposal for blending payments when establishing participants' benchmark and quality-adjusted targets as well as the exceptions.

The following is a summary of the comments received and our responses.

Comment: Commenters expressed different views on the proposal to base prices initially on a blend of participant-specific and regional historical data, while phasing in full regional pricing. Their perspective commonly related to the proposal to determine regional prices based on U.S. Census Divisions, which is discussed in section III.D.4.b.(7) that immediately follows. Some commenters appreciated the proposal of moving to regional pricing because it would help attenuate the effect of participants having to compete against their own best performance and where the most efficient participants in a region could be rewarded. Moreover, some of these commenters recommended that CMS even accelerate regional pricing or allow efficient participants the option to transition from historic to regional target prices at an accelerated rate. A commenter viewed the proposal as a way to incentivize both historically efficient and less efficient hospitals to provide high quality, efficient care.

Response: We appreciate the comments supporting our proposal to blend payments when establishing participants' benchmark and quality-adjusted targets and agree with their perceived benefits of the proposal. We do not agree with suggestions to accelerate regional pricing or allowing flexibility for hospitals to accelerate their transition to regional prices. We continue to believe our proposed phase-in period for regional pricing would generally be most protective of participants as they adjust to the models because their performance would be compared to their own historical performance rather than hospitals in their region. We are also concerned that allowing certain hospitals the option to accelerate toward regional pricing as was suggested could affect our estimates

[83] 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.

and possibly generate inflated reconciliation payments due to potential selection issues if historically efficient hospitals were to opt earlier for a more generous regional price. Allowing certain hospitals the option to select regional pricing earlier would also increase administrative complexity under the models.

Comment: Several commenters opposed proposed regional pricing policy, asking that CMS slow its phase-in period, asking that CMS phase-in regional prices to something less than 100 percent, for example, to only a 50–50 blend of participant-specific and regional pricing, or relying solely on participant-specific performance data. Some commenters suggested that hospitals might not be prepared to compete relative to regional pricing while others expressed concern that hospitals would be penalized for factors beyond their control, for example, hospitals with a disproportionately large population of high-cost or vulnerable beneficiaries. Thus, several commenters suggested that CMS also account for these factors.

Response: As we stated in the CJR Final Rule (80 FR 73348), we believe that only using participant-specific pricing would not reward already efficient participants for maintaining high performance and participants already delivering high quality and efficient care would find it challenging to improve upon their own historical performance to quality for reconciliation payments. We appreciate the concerns raised about participants being penalized for factors beyond their control once regional prices are phased-in. As discussed earlier in section III.D.4.b.(2) of this final rule, we will be exploring additional methods for further risk-adjusting episodes under the models that we intend to make effective by PY3. We believe that these additional adjustments in tandem with our general methodology for risk stratification, caps on high-payment episodes, and limits on Medicare repayments will offer sufficient protections to participants so that they are not penalized once regional pricing is phased-in.

Comment: Some commenters noted that even when regional pricing is fully phased-in, CMS and participants will see diminishing returns over time, beginning with providers in low-spending areas where more limited opportunities for additional gains in efficiency exist and target prices could not be further constrained without putting the quality of care at risk. Thus, these commenters requested that CMS use the *higher* of national or regional historical episode payments when calculating the target price to help ensure that appropriate incentives are provided to participants in both high- and low-spending areas. A commenter recommended that CMS vary pricing based on whether the participants is in a MSA with higher or lower than average historical prices. For example, for participants in MSAs with costs well above the national average, target prices would be based on a blend of participant-specific data and MSA historical data to help level the playing field while continuing to allow program savings. For participants in MSAs already below the national average, CMS should use a 5-state regional benchmark that would allow high performing MSAs to drive improvement and achieve savings for CMS and providers. Alternatively, some commenters recommended that CMS adopt a bifurcated transition whereby it uses a lower weight for the participants determined to have spending higher than their region similar to the Shared Savings Program.

Response: As we stated in the CJR Final Rule (80 FR 73348), we believe that using the higher of regional and participant-specific prices would not sufficiently incentivize inefficient participants to become more efficient. That is, participants with historically high episode expenditures would have less of an incentive to become more efficient over the course of a model if they can quality for reconciliation payments by improving only slightly relative to their own performance while still being less efficient than their regional peers.

We appreciate the suggestions to adopt a bifurcated transition or to vary pricing based on whether the participant is in a MSA with higher or lower than average historical prices—that is, to base target prices on a blend of participant-specific data and MSA historical data in MSAs with higher than average costs and a 5-state regional benchmark for hospitals in MSAs with lower than average costs, but do not believe these would materially improve upon our proposed methodology. We believe the protections we are offering participants are sufficient and obviate further adjustments such as the ''bifurcated'' transition or weighting adjustments recently adopted for the Shared Savings Program. Further, we believe the latter proposal would decrease incentives for all participants by potentially making it too difficult to achieve success for participants in higher-spending regions while relaxing standards for those in lower spending regions.

Comment: Some commenters recommended that, in lieu of regional pricing targets, CMS adopt national targets. In its comments, MedPAC noted that national prices are used in other Medicare FFS payment systems and that it believes the EPMs should transition to national prices. Further, in 2013, MedPAC reported that risk-adjusted spending on post-acute care and readmissions varied about 30 percent between high- and low-spending MSAs for SHFFT episodes. Transitioning to regionally-based benchmarks, as opposed to nationally-based benchmarks, will continue to allow large differences in spending across the country. In markets with long-term care hospitals (LTCH) and inpatient rehabilitation facilities (IRF), these high-cost settings will raise the participants' benchmarks. In markets without these providers, on the other hand, post-acute care is delivered in lower-cost settings and participants' benchmarks will be lower. MedPAC recommended that CMS ultimately transition to national benchmarks to exert pressure on high-cost regions to bring their spending in line with spending in other markets. Another commenter seemed to suggest that applying nationally-based benchmarks would help in addressing their concern with disparate device costs depending on whether a participant was in a rural or metropolitan area. In their view, participants in rural areas would be disadvantaged by higher costs for these items.

Response: We agree with MedPAC on the benefits of national prices as well as their view that national prices should ultimately be adopted if the EPMs were fully integrated into Medicare on a national basis. We also continue to believe that our proposal to phase-in regional pricing from participant-specific prices offers the most appropriate balance of incentives and protections for purposes of testing the proposed EPMs. In particular, we are concerned that immediately moving toward national pricing could impede the chances for success among participants in high cost regions. As a result, we are reluctant to adopt national pricing at this time. We also do not agree with the suggestion that moving toward national pricing would benefit participants in rural areas with respect to device costs. This is because financial performance, including spending on devices, during the performance years would be generally compared to a participant's historical costs or to the historical costs of providers in their region. In either case, the costs for

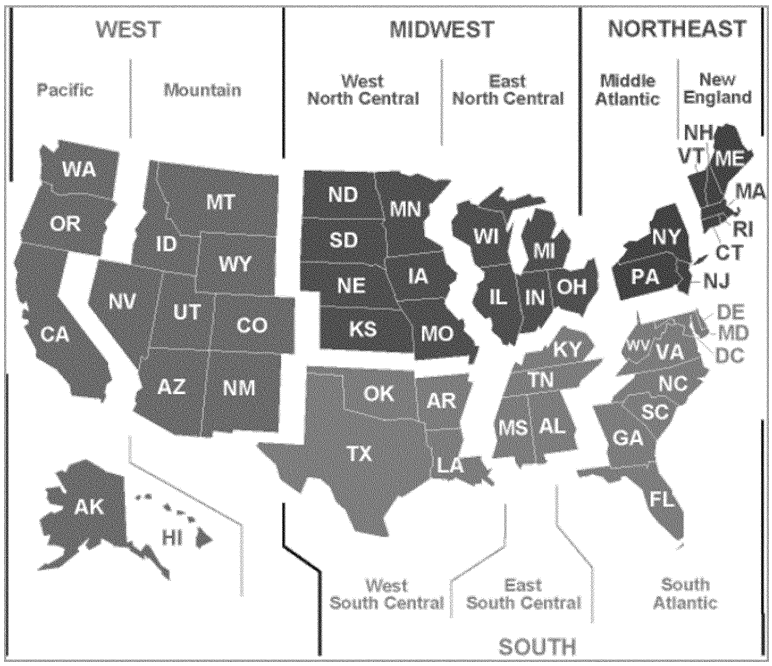
devices should be relatively more comparable than if comparisons were made to a national measure.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to blend payments when establishing participants' benchmark and quality-adjusted targets. We would note that our final policy would also include § 512.300(c)(5) in conjunction with § 512.300(c)(2), (3), and (4). Thus, the final policy for blending payments when establishing benchmark and quality-adjusted targets is included in § 512.300(c)(2), (3), (4), and (5).

(7) Define Regions as U.S. Census Divisions

As we did for the CJR model (80 FR 73349 through 73350), for all 5 performance years, we defined ''region'' as one of the nine U.S. Census divisions [84] in Figure 1 (81 FR 50857).

FIGURE 1: U.S. CENSUS DIVISIONS[85]



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 participant-specific utilization patterns. Our proposed rule also clarified 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 would 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 was included in § 512.300(c)(2). We sought comment on our proposal to define region in this manner.

The following is a summary of the comments received and our responses.

Comment: Many of the commenters on the proposed regional definition expressed concerns about the proposal to blend participant-specific and regional pricing. In general, the commenters expressed concerns that, given the size and diversity of the proposed U.S. Census divisions with respect to health conditions and costs, a single regional price would potentially not be an accurate measure of a participant's costs. As a result, those participants that treated sicker patients would be penalized in particularly large and diverse regions. Thus, many of these commenters requested that CMS set prices based on a narrower and more cohesive geographic area, for example, at the MSA level, IPPS wage index level, or based on MAC regions. A commenter recommended that CMS not base benchmark prices fully on a regional average but consider taking into account a participant's relative mix of patients with respect to CCs and MCCs.

Another commenter suggested that while some financial risk is captured based on CMS-HCC scores, the best way to remove unintended consequence is by comparing participants with similar patient populations, instead of using Census Divisions to calculate target prices. In their view, using Census Divisions to set target prices penalizes high acuity hospitals for existing in the same multi- state ''region'' as lower-acuity hospitals, even if those hospitals are more capable at caring for sicker patients. As such, many hospitals are funneled the most complex AMI, CABG, or fracture cases, which may increase average costs in a way that is consistent with providing the highest-quality care. As such, this commenter recommended that CMS instead compare hospitals against other hospitals with similar patient populations for the purpose of calculating target prices. As high-acuity

[84] 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.

[85] *http://www.eia.gov/consumption/commercial/census_maps.cfm.*

referral centers are most at-risk given that they treat the most ill patients in the nation for all of the proposed EPMs, the commenter recommended that CMS group together such high-acuity referral centers and treat them as their own ''Peer group'' cohort rather than by region or within each region for the purpose of calculating target price. This would ensure that locations systematically treating the most complex cases are being compared appropriately. Another commenter suggested this concept be expanded more broadly so that peer groups might be formed around characteristics such as urban teaching hospitals, suburban hospitals, or small rural hospitals.

Response: We appreciate the comments and concerns raised on our proposal to base regional pricing on U.S. Census Divisions as well as the suggested alternatives. Our proposal intended to balance our goal of identifying relatively cohesive, homogeneous, and meaningful groups for purposes of establishing benchmark prices with what was administratively feasible. While we appreciate the suggested alternatives that were offered and could consider them for future models, we continue to believe, as we stated in the CJR Final Rule (80 FR 73350), that 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 would also note that as discussed earlier in section III.D.4.b.(2), we will be exploring additional methods for further risk-adjusting episodes under the models that we intend to make effective by PY3. We believe that these additional adjustments will make comparisons of financial performance among participants more comparable regardless of a region's diversity.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to define a region as one of the nine U.S. Census divisions. Our final policy for defining regions is included in § 512.300(c)(2).

(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 area 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 proposed to normalize for wage indices at the claim level for both historical EPM-episode payments and actual EPM-episode payments (81 FR 50858). As discussed in section III.D.3.b. of the proposed rule (81 FR 50845 through 50846), we 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 proposed to reintroduce the participant-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 proposed to use the following algorithm to create a wage normalization factor: 0.7 * IPPS wage index + 0.3. The 0.7 approximates the 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. through III.D.4.e. of the proposed rule (81 FR 50862 through 50864). We also referred 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 was included in § 512.300(c)(12). We sought comment on our proposal to normalize for these variations.

We received no specific comments on our proposal to normalize for provider-specific wage adjustment variations other than one in support of the proposal.

Final Decision: We are finalizing the proposal, without modification, to normalize for provider-specific wage adjustment variations. Our final policy for normalizing provider-specific wage adjustment variations is included in § 512.300(c)(12).

(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 proposed generally to follow the process from the CJR model (80 FR 73352 and 73353) to calculate severity factors, EPM participant-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 (81 FR 50858 through 50861). Where the CJR Final Rule referred to anchor factors, however, for the purposes of the proposed rule, we referred 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 proposed 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 proposed 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 specific average episode payment would be calculated by multiplying such participant's 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 participant weights and the participant-specific pooled historical average episode payments would be comparable to how case-mix indices are used to generate case-mix adjusted Medicare payments. The participant 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 as for hospital-specific weights and hospital-specific pooled average payments. Instead of grouping episodes by the attributed hospital as 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 participant-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. of the proposed rule 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 proposed to follow an analogous procedure to the SHFFT model with the following modifications. First we proposed to group episodes with price MS–DRGs 280–282 separately from episodes with price MS–DRGs 246–251 for the calculations. Second, we proposed 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 proposed 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 proposed 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 proposed 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 of the proposed rule 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 proposed 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 proposed 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 proposed 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 proposed to calculate participant-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 proposed 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 proposed 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 proposed 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 proposed 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 the proposed rule would result in the quality-adjusted target prices for CABG model episodes.

For episodes in the AMI model with CABG readmissions, we proposed to perform no additional blending of participant-specific and regional-specific episode payments. We proposed to calculate the AMI model episode benchmark and quality-adjusted target prices for such episodes as described in section III.D.4.e. of the proposed rule.

The proposals to combine episodes to set stable benchmark and quality-adjusted target prices were included in § 512.300(c)(13). We sought comment on our proposals for combining episodes for these purposes.

We received no comments on our proposals for combining episodes.

Final Decision: We are finalizing the proposal, without modification, to combine prices for episodes. Our final policy for combining episodes is included in § 512.300(c)(13). We would note that since we did not finalize our proposal for price MS–DRGs, the term price MS–DRG is excluded and replaced with the term anchor MS–DRG.

(10) Effective Discount Factor

As discussed in section III.D.2.c. of the proposed rule, we proposed to make EPM participants partly or fully accountable for EPM-episode payments in relationship to the EPM quality-adjusted target price (81 FR 50844). As part of this, in setting an episode quality-adjusted target price for an EPM participant, we proposed to apply an effective discount factor to an EPM participant's participant-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 were 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 proposed 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 the proposed rule (81 FR 50887 through 50893) 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.

As discussed in section III.D.2.c. of the proposed rule (81 FR 50844), because of the proposed phase-in of repayment responsibility 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 exceeded 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 than would otherwise result from this calculation.

Also, as discussed in section III.E.3.f of the proposed rule (81 FR 50801), we proposed to apply an ''applicable discount factor'' to repayment amounts in performance years 2 and 3 while this repayment responsibility was being phased-in. We refer to section III.E.1. and specifically Tables 20 through 28 in our proposed rule for further illustration of the discount percentages that would apply for reconciliation payment and Medicare repayment over the 5 EPM performance years (81 FR 50888 through 50892). 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 was included in § 512.300(d). We sought comment on our proposal to establish discount factors that apply to the quality categories.

The following is a summary of the comments received and our responses.

Comment: Most commenters suggested that the ability to achieve savings under the proposed models (most notably for the cardiac models and the CABG model in particular) was more limited than for the CJR model, and that these limitations would become more significant as target prices decline further over time. For example, commenters opined that while about half of CJR episode spending is attributable to the initial hospitalization, CMS noted that about three-quarters of CABG episode spending is attributable to the initial hospitalization. As such, there are fewer opportunities to achieve efficiencies within the inpatient hospital payment amount because it is a predetermined per-discharge payment based primarily on the patient's condition, not on services provided. Further, some portion of CABG and AMI costs outside the initial hospitalization is attributable to readmissions; however, these costs are already declining due to hospitals' responses to the HRRP and any remaining readmissions are more likely to be clinically appropriate and necessary. As such, it would be difficult to achieve efficiencies within the remaining percentage of spending that occurs outside the initial hospitalization. Thus, commenters requested that CMS implement a smaller discount factor than what was proposed—typically a 1 percentage point reduction.

Response: We appreciate the comments and concerns raised with respect to our proposed discount factor. We recognize that, as compared to episodes under the CJR model, opportunities to achieve improved efficiencies under the proposed models would be different and potentially more challenging for participants under the proposed models. However, we do not believe the increased efficiencies needed to be successful as was proposed under the models are unattainable. Given our policy to phase-in full regional pricing over time, participants' performance will increasingly be compared to that of peers within their region; thus, for the more efficient participants, target pricing would likely be higher than if we relied on participant-specific pricing alone. Further, as discussed in section III.D.4.b.(2), we plan to explore and implement additional adjustments for risk beginning in PY3, which should facilitate successful participants' ability to achieve savings under the models. We would also note that our final policy to include reconciliation payments when updating target prices for successful participants under the models should ease the decline in pricing over time, which should facilitate their ability to be rewarded for improved efficiencies.

Comment: A commenter encouraged CMS to provide participants with protection against having to make repayments that result from adverse events beyond their control, similar to the protections offered under the Medicare Shared Savings Program. Specifically, during risk-bearing periods of the program, instead of setting a repayment target price equal to historical payments minus some percentage, the commenters recommended that CMS should instead set a symmetric target price equal to historical payments plus or minus some percentage. Under this proposal, participants with historical payments falling between, for example, 97 percent and 103 percent of historical payments would neither receive reconciliation payments nor be held responsible for repaying Medicare.

Response: We appreciate the suggested alternative the commenter offered, but would note that the proposed models are intended to test a bundled payment rather than a shared savings model, which is being tested through Innovation Center and Shared Savings Program ACO efforts.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, with modification, to establish discount factors that would apply to the quality categories. Specifically, for repayment amounts in performance year 2, our final applicable discount factor would apply only to participants that elected downside risk in that year. Also, in conformance with our final policy for phasing-in repayment responsibility, the applicable discount factor is extended so that it will apply to all EPM participants in performance year 4. Our final policy for the discount factor is included in § 512.300(d).

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 the proposed rule with respect to SHFFT model episodes and AMI model episodes without a CABG readmission (81 FR 50862 and 50863).

- 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 the 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 the proposed rule.

• Step 2—Remove the effects of special payment provisions (section III.D.3.b. of the proposed rule) and normalize for wage index differences (section III.D.4.b.(8). of the 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 the 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 the 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 the 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-specific weights (section III.D.4.b.(9) of the 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-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-specific and region-specific weighted update factors (section III.D.4.b.(5). of the proposed rule). Multiply each EPM participant-specific and region-specific pooled historical average episode payment by its corresponding EPM participant-specific and region-specific weighted update factors to calculate EPM participant-specific and region-specific updated, pooled, historical average episode payments.

• Step 8—Blend together each EPM-participant-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 the 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 final rule to reintroduce geographic variation. For purposes of the proposed rule, we defined 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 the 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 the proposed rule. For purposes of the proposed rule, we defined 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

We would note that because our final policy for inpatient-to-inpatient hospital transfers for AMI episodes does not include chained anchor hospitalizations, the one change to our proposed approach for combining pricing features for all SHFFT model episodes and AMI model episodes without CABG readmissions is to replace the term price MS–DRG with the term anchor MS–DRG.

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 the proposed rule with respect to CABG model episodes (81 FR 50863 through 50864).

(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 the 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 the 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 the proposed rule, we defined the output of this step as CABG anchor hospitalization benchmark prices for CABG model episodes with price MS–DRGs 231–236.

We would note that because our final policy for inpatient-to-inpatient hospital transfers for AMI episodes does not include chained anchor hospitalizations, the one change to our approach for combining pricing features for CABG model episodes is to replace the term price MS–DRG with the term anchor MS–DRG.

(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 the 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 the 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 the 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 the proposed rule, we defined the output of this step as CABG post-anchor hospitalization benchmark prices for CABG model episodes corresponding to the groups described in this step.

We would note that because our final policy for inpatient-to-inpatient hospital transfers for AMI episodes does not include chained anchor hospitalizations, the one change to our approach for combining pricing features for the post-anchor hospitalization portion of CABG model episodes is to replace the term price MS–DRG with the term anchor MS–DRG.

(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) of the proposed rule. For purposes of the proposed rule, we defined 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 the proposed rule. For purposes of the proposed rule, we defined 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.

We would note that because our final policy for inpatient-to-inpatient hospital transfers for AMI episodes does not include chained anchor hospitalizations, the one change to our approach for combining CABG anchor hospitalization benchmark prices and CABG post-anchor hospitalization benchmark prices is to replace the term price MS–DRG with the term anchor MS–DRG.

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 the proposed rule with respect to AMI model episodes with a CABG readmission (81 FR 50864).

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 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 the proposed rule. For purposes of the proposed rule, we defined 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).

We would note that because our final policy for inpatient-to-inpatient hospital transfers for AMI episodes does not include chained anchor hospitalizations, the one change to our approach for combining pricing features for AMI model episodes with CABG readmissions is to replace the term price MS–DRG with the term anchor MS–DRG.

5. Process for Reconciliation

a. Net Payment Reconciliation Amount (NPRA)

Consistent with the CJR model (80 FR 73381 through 73383), we proposed to conduct reconciliation for each EPM by calculating an EPM-specific NPRA for each EPM participant (81 FR 50864 through 50865). After the completion of an EPM performance year, we proposed 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 the proposed rule and the payment policies applicable to calculating actual EPM-episode payments as discussed in the subsections of section III.D.3 of the proposed rule.

We proposed to compare each EPM participant's actual EPM episode payments to its quality-adjusted target prices. We proposed, as discussed in section III.D.4. of the 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 proposed 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 proposed 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. and III.D.7.c.(1) of the proposed rule.

b. Payment Reconciliation

We proposed 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 (81 FR 50865 through 50867). 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 participants responsible for repayment, as applicable, in quarter 2 of that calendar year.

We also proposed 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 the 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 that 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. and III.D.7.c.(1) of the 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 discussed in section III.D.7.e. of the proposed rule, 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 the 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 the 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 proposed 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 the proposed rule, following the rules and processes for all other Medicare debts. Table 17 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 17—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
Participant 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 A's aggregated episode payment was $50,000 below the sum of quality-adjusted target prices for all of Participant 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 Participant 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 EPMs and other CMS models and programs as discussed in section III.D.6.b of the proposed rule, and would also involve updating performance year EPM-episode claims data. We also noted 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 18 displays the reconciliation timeframes for the EPMs.

TABLE 18—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
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 proposed this approach in order to balance our goals of providing reconciliation payments in a reasonable timeframe, while being able to account for overlap and all Medicare claims attributable to 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 noted 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 also noted our recognition that by

pulling claims 2 months after the end of the performance year to conduct reconciliation, we would not have complete claims run-out. However, we believed that the 2 months of claims run-out would be an accurate reflection of 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. Otherwise, the alternative would be to wait to reconcile until we have full claims run out 12 months after the end of the performance year, but we were concerned that this approach would significantly delay earned reconciliation payments under the EPMs.

However, we proposed 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 were included in § 512.305 and § 512.307. We sought comment on these proposals for an annual reconciliation and subsequent calculation.

The following is a summary of the comments received and our responses.

Comment: A number of commenters supported the proposal for reconciliation payments, including the waiver of deductibles and copays with respect to reconciliation payments and Medicare repayments. While one commenter indicated that the proposed timeframes for reconciliation were reasonable, most of the commenters requested that CMS provide reconciliation payments or estimates of what reconciliation payments would be on a more frequent basis than annually. In most cases, these commenters recommended reconciliation payments on a quarterly basis (some noted this would be similar to BPCI and recommended the BPCI true-up process whereby we would make an initial reconciliation with three revisions (or ''true-ups'') in order to include additional claims run outs and any other changes that might have occurred with the third (final) true-up occurring 9 months after the initial reconciliation rather than 12 months later than the subsequent reconciliation as is the case for the EPMs and CJR. Another commenter recommended quarterly reconciliation determination with the option of an annual reconciliation for those hospitals preferring such while another recommended the opposite. Commenters favoring more frequent reconciliations suggested that doing so would provide hospitals with better cash flow that could be used to invest in the changes needed to be successful as well as more immediate feedback that would enable participants to better assess their performance and determine which of their approaches are effective as well as what changes might be needed to improve their performance. Further, if hospitals had more up front funding, they could in turn provide more frequent financial rewards to downstream collaborating providers, which would better maintain incentives on a more consistent basis to promote care coordination, with improved quality and efficiencies. One commenter suggested that the proposed annual reconciliation payment schedule could impede care redesign efforts and undermine gainsharing.

In addition to comments on the frequency of reconciliation, a commenter recommended that reconciliation occur at the beneficiary episode level rather than in aggregate across beneficiary episodes, as we proposed, because the former would better focus financial incentives on each episode as hospitals would recognize that they bear risk for every episode individually rather than in aggregate. In this commenter's view, CMS' proposal will more likely encourage gaming across episodes where a hospital tries to offset losses from one episode through savings on another.

Response: We appreciate the comments we received supporting our proposal for an annual reconciliation with subsequent calculation as well as the suggestions for more frequent reconciliations or estimated reconciliation amounts. We are not persuaded to make reconciliation payments or estimated payment amounts available more frequently than on an annual basis. We are concerned that, particularly for small hospitals, the number of cases included in quarterly data would limit the representativeness of the data, which could produce somewhat misleading results. For similar reasons, do not believe that making more frequent reconciliation payments available than annually would advantage participants based on the expectation that additional resources would enhance their ability to develop infrastructure or gainsharing arrangements. Last, we are not persuaded to adopt the suggestion to determine reconciliations at the episode level. The commenter suggested that the proposed policy will result in hospitals ''gaming'' payments by offsetting losses for one episode with savings in another; however, we question this view. Rather, we believe the issue raised in this comment and our proposal for determining reconciliation payments under the models is similar and analogous to the basis under which Medicare makes payments under its FFS prospective systems in general. That is, for Medicare FFS prospective payments, an ''average'' payment is typically determined for a specific procedure or set of services where participants might ''gain'' or ''lose'' for a specific case but, on average and in aggregate across all cases, are paid that average amount. Given their recognition of this, we would not anticipate that Medicare providers and suppliers ''game'' their payments to offset losses on a case-by-case basis. Likewise, we would not expect that EPM participants would be any more or less encouraged to ''game'' episode payments depending on whether they received reconciliation payments at the episode level or in aggregate across all episodes.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to make an annual reconciliation with subsequent calculation. Our final policies for an annual reconciliation and subsequent calculation are included in § 512.305 and § 512.307.

We would also note that since we have delayed the requirement to assume downside risk to performance year 3, except for participants that elect downside risk in performance year 2, we will not be performing two separate aggregations, as we had proposed, to separately create one NPRA for the period in performance year 2 without downside risk and another NPRA for the period where downside risk would apply.

Thus, in contrast to our proposal, unless the EPM participant elected downside risk in performance year 2, we would calculate an EPM participant's NPRA for the performance year 1 and 2 reconciliation processes, 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 or performance year 2.

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 discussed in section III.D.7.e. of the proposed rule, 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 the 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 the 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. Though the NPRA for performance year 2 will be subject to a stop-loss limit of 0 percent, except for EPM participants that elected downside risk in performance year 2, it is still possible that EPM participants not electing downside risk for performance year 2 could owe a repayment amount because of the subsequent reconciliation calculation, post-episode spending calculation, and ACO overlap calculation for performance year 1. For example, when we conduct reconciliation for performance year 3 in early 2020, we would calculate the performance year 3 NPRA and the subsequent reconciliation calculation, post-episode spending, and ACO overlap calculation for performance year 2. 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 and the stop-loss limit of 0 percent for NPRA for the second performance year (except for EPM participants that otherwise elected downside risk),during the reconciliation process for performance year 3, the subsequent reconciliation calculation amount (for performance year 2) would be compared against the performance year 2 NPRA to ensure that the sum of the NPRA calculated for performance year 2 and the subsequent reconciliation calculation for year 2 is not less than zero.

For an EPM participant that elected downside risk in performance year 2 and all participants in performance years 3 through 5, 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 the proposed rule, following the rules and processes for all other Medicare debts.

Also, we would note that this final rule corrects proposed § 512.305(d)(iii) so that it refers to § 512.460(b) rather than § 512.460(b)(5).

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 proposed to annually issue to EPM participants a reconciliation report (81 FR 50867), similar to the CJR Reconciliation Report we make available to CJR participants (80 FR 73408). We proposed 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 final 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 proposed 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 the 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 was included in § 512.305(f). We sought 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.

The following is a summary of the comments received and our responses.

Comment: As noted previously in section III.D.5.a. and b. of this final rule, some commenters requested that reconciliation payments or estimates of what reconciliation payments would be more frequently than on an annual basis. A commenter requested that, given the many adjustments to costs, including various value-based payments such as HRRP, CMS make publicly available and to the CJR model participant hospitals and EPM participants documentation of the various adjustments that would allow participants to verify or validate the adjustments and calculations. This commenter was concerned that providers who are taking on risk could otherwise be penalized multiple times for readmissions in the bundled payment program as well as other value-based payment programs.

Response: For the reasons previously articulated in this comment and response section, we are not persuaded to make reconciliation reports available for frequently than on an annual basis.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to annually issue a reconciliation report. Our final policy for issuing a reconciliation report is included in § 512.305(f).

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 established our proposal for provider overlap at § 512.100(b) and § 512.230(g). We established our proposal for beneficiary overlap at

§ 512.230(f), § 512.230(h), and § 512.230(i). We established our proposal for payment reconciliation at § 512.210 and § 512.305. We sought comment on our proposals to account for overlap between EPMs and other CMS models or programs.

The following is a summary of the comments received and our responses.

Comment: We received numerous comments related to overlap between EPMs and other CMS models or programs.

Response: For further discussion of comments related to model and program overlap, we refer readers to the specific sections later in this section of this final rule.

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 proposed for the EPMs 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 from which it was previously excluded. As we stated in the proposed rule, we believe this proposal promotes accountable care by ensuring beneficiary coverage by BPCI or an EPM in selected areas.

We established 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 sought comment on this proposal. The following is a summary of the comments received and our responses.

Comment: Overall, we received considerable support from commenters for our proposal to continue to give precedence to existing BPCI models where the EPM participant was also participating in a BPCI model that overlapped with a SHFFT, AMI, or CABG EPM. Several commenters requested that existing precedence rules should continue for any similar voluntary models implemented after September 2018 when the current BPCI model is scheduled to end.

Response: We appreciate the many comments of support received for this aspect of the model. We wish to clarify that the current order of precedence for model overlaps pertains only to the currently existing models. CMS shall evaluate how to handle model overlaps for any future models at the time of implementation based on experience and knowledge gained through previous models.

We also recognize that this policy could indirectly impact clinicians with financial arrangements with an EPM participant, therefore, we refer to section III.A.2 for discussions of the ability for eligible clinicians to become qualifying APM participants (QP) as affiliated practitioners of EPMs that meet the Advanced APM criteria under the Quality Payment Program. Specifically, we are referring to the policy that eligible clinicians can meet program thresholds through participation in multiple Advanced APMs. We further discuss the considerations for a new alternative bundled payment model, and in particular the consideration for such a program to qualify as an Advanced APM, in section III.A.3.

Comment: Several commenters recommended that in order to minimize overlap with existing BPCI models, CMS exclude MSAs where there are existing BPCI models. A commenter recommended that BPCI participating hospitals be exempt from having to participate in multiple models even if there were no overlap in the episodes covered under each model. For example, a hospital participating in BPCI for SHFFT episodes would be exempt from having to participate in CABG or AMI EPMs.

Response: In identifying eligible MSAs where the EPMs could be implemented, we proposed to explicitly factor in the number of non-BPCI eligible cases when considering the relevant minimum volume of cases in an MSA. We refer readers to sections III.B.4., ''Geographic Unit of Selection and Exclusion of Selected Hospitals'' and IIII.B.5., ''Overview and Options for Geographic Area Selection for AMI and CABG Episodes'' of this final rule for a more detailed discussion of the factors considered in the selection of MSAs for EPMs. We do not believe it is appropriate to exempt hospitals from participating in EPMs solely because they are participating in a BPCI model for another non-overlapping episode. To do so would limit the potential volume of cases for evaluation purposes and could lead to patient steerage in areas where some hospitals in the same market may be participating in the EPM and others may not. Moreover, while we acknowledge the potential for some operational differences for those hospitals implementing multiple models, hospitals already participating in BPCI may, in fact, already have some of the infrastructure in place and be well positioned to succeed in implementing EPMs as well.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, for handling overlap situations between EPM and BPCI participating hospitals. That is, 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 only for episodes anchored by EPM MS–DRGs that would not otherwise be a BPCI episode. BPCI episodes would take precedence over EPM episodes.

(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 EPMs. We proposed that if a beneficiary is admitted to an EPM participant for an episode anchored by EPM MS–DRGs that is also 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 an episode that has already been initiated or never initiate the EPM episode in the first place. 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 established the proposal for BPCI PGP episode initiators in hospitals participating in EPMs at § 512.230(g). We sought comment on this proposal.

The following is a summary of the comments received and our responses.

Comment: Many commenters supported our proposal to give precedence to situations where there was overlap between an episode attributed to a PGP voluntarily participating in BPCI and one that could otherwise have been attributed to an EPM participating hospital. However, we received several comments that expressed disagreement with this policy. These commenters believed that the hospital participant should have priority for having responsibility and financial accountability for the episode. A commenter expressed the specific concern that PGPs participating in BPCI could potentially select lower intensity cases and steer higher intensity and potentially more costly cases to non-BPCI, EPM participant hospitals. Concern was also expressed by some commenters that attributing episodes to BPCI in these situations would lower the volume of episodes available to the hospital and potentially make it less cost effective for the hospital to implement operational changes necessary to better manage episodes.

Response: We acknowledge the potential for overlap between PGP initiated BPCI episodes and hospital attributed EPM episodes in those MSAs selected for EPM participation where there are also PGP BPCI initiators. CMS will monitor admission and transfer patterns and trends to identify any inappropriate patient steerage that may be occurring. On balance, however, we believe it is important to maintain CMS' commitment to existing models for which participants have volunteered and in which they are already actively involved. As these models end and CMS has the opportunity to evaluate their performance, including the impact of overlaps, we will incorporate the findings in the design of future models.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, for handling overlaps between BPCI PGP episodes and episodes initiated in hospitals participating in EPMs.

(c) Beneficiary Overlap

(1) Beneficiary Overlap With BPCI

As we stated in the proposed rule, we also need to account for instances where a different model's episode could initiate during an ongoing EPM episode. We proposed 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. As stated in the proposed rule, 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 BPCI, we proposed to give precedence to episodes covered under BPCI Models 2, 3 and 4 initiated on or before September 30, 2018.

In the proposed rule, we acknowledged that this proposed 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 have been managed.

As we stated in the proposed rule, 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 established the proposal for beneficiary overlap with BPCI at § 512.230(h). We sought comment on this proposal.

The following is a summary of the comments received and our responses.

Comment: As with the previously described overlap situations, we received numerous comments in support of giving precedence to the BPCI initiated episode. However, many commenters did express concern over how EPM participant hospitals would be able to know whether a presenting patient is already covered by a BPCI episode or if an EPM episode is subsequently cancelled. Several commenters stated that it was unrealistic to expect hospitals or other providers to identify such patients in ''real-time'' and requested CMS clarify its administrative policies for identifying and informing EPM participants about beneficiaries whose episodes are initiated and then cancelled for any reason. A commenter requested at least quarterly notification. The commenters pointed out that EPM participant awareness of episode cancellation is important for several

reasons, including EPM participant calculation and monitoring of episode spending; beneficiary notification; provision of beneficiary engagement incentives; and determination of beneficiary eligibility for certain rule waivers. In addition, these commenters expressed concern about the potential for beneficiary confusion and dissatisfaction with multiple coordinators of care, as well as costly duplication of services when multiple entities believe they are accountable for the episode.

Response: We acknowledge the potential for confusion for providers participating in markets where there are BPCI participants or in situations where patients may travel out of area to receive services that result in cancelling EPM episodes. We also appreciate the interest of the commenters in conducting timely analyses of EPM episode spending, as well as ensuring that the requirements of the EPM are met in their treatment of Medicare beneficiaries. The potential for this to occur makes it important for EPM participants to become familiar with the range of models operating in their market and to maintain ongoing relationships with their patients after discharge, as well as to develop collaboration arrangements with physicians. Even with this, we acknowledge that EPM participants and their staff may not know when all overlaps occur. Given our plans for providing and updating episode claims data to EPM participants upon request as frequently as quarterly as discussed in section III.K.5. of this final rule, we will explore adding additional data elements to the beneficiary-identifiable claims data provided to EPM participants that would indicate potential for episode cancellation such as admission of a beneficiary to a hospital or post-acute care facility that initiates episodes under BPCI or receipt of inpatient services by a physician in a BPCI PGP. To the extent adding such indicators to the claims data is feasible, providing this information through the claims data shared with EPM participants would ensure that EPM participants are informed as frequently as quarterly about beneficiary circumstances that could result in EPM episode cancellation. This information would not be real-time, however, and while based on the best available information at the time, it would be subject to change due to the lag-time for the relevant claim to be submitted and processed and then reported back to the EPM participant. We note that at reconciliation, complete information would be provided to EPM participants about those episodes that were ultimately included in the participant's reconciliation report as discussed in section III.D.5. of this final rule.

We note that we expect EPM participants to be actively managing all of their beneficiaries with conditions characterized by AMI, CABG, or SHFFT based on their care pathways, regardless of the model of program that may ultimately apply to the beneficiary under the uncommon circumstances of EPM episode cancellation. We also want to emphasize the importance of strong, ongoing communication among providers in a given geographic area caring for beneficiaries in similar models or programs where provider interests in delivering high quality, efficient health care should align.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, for handling situations in which a beneficiary eligible for coverage under an EPM is already covered by a BPCI episode or subsequently becomes eligible for coverage under a BPCI episode during the EPM episode period. Recognizing the limitation on available data, CMS will work to provide better, more timely informational resources to participants, where feasible, to assist them in identifying episodes that may be ineligible or cancelled due to overlaps.

(2) Beneficiary Overlap With the CJR Model and Other EPMs

As discussed in section III.C.4. of the 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;
- The 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.

As stated in the proposed rule, 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 established the proposal for beneficiary overlap with the CJR model and other EPMs at § 512.230(i). We sought comment on this proposal.

We received no comments related to our proposed overlap policy that gave precedence to the ongoing episode when there was the potential for overlap between CJR and EPM episodes that were not otherwise excluded from the first episode's definition.

Final Decision: Given that we received no public comments on the proposed policy for beneficiary overlap with the CJR model and the EPMs, we are finalizing the proposal, without modification, to give precedence to an ongoing EPM episode over subsequent episodes initiated during the post-hospital discharge period, except where the second admission is explicitly excluded from the initial episode.

(3) Beneficiary Overlap With Shared Savings Models and Programs

We explained in the proposed rule our expectation that many beneficiaries in an AMI, CABG or SHFFT model episode will also be assigned to a

Shared Savings Program ACO 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 proposed to attribute savings achieved during an EPM episode to the EPM participant, and to include EPM reconciliation payments for ACO-aligned beneficiaries as ACO expenditures. In order to address comments received during rulemaking for CJR, we proposed to test an alternative strategy to address ACO overlap. Specifically, we proposed 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 model in tracks with downside risk for financial losses. We did not propose to exclude beneficiaries assigned to Shared Savings Program ACOs in Tracks 1, 2, or 3. However, we sought comment on excluding beneficiaries from EPMs that are prospectively assigned to Shared Savings Program Track 3 ACOs 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 for all Shared Savings Program ACOs at this time prior to a test with a smaller population. As we stated in the proposed rule, we plan to monitor and learn from the test of excluding beneficiaries prospectively assigned to an ACO from risk tracks and to consider these results and comments in future rule-making.

Several strong considerations drive us to otherwise follow CJR precedent for addressing ACO overlap. As we stated in the proposed rule, CMS continues to avoid double payment of savings and double recoupment of losses, which is an important principle of successful payment reform. Further, 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 the proposed rule.

Therefore, we proposed 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 and CEC models 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 proposed 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 assigned 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 proposed 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 assigned 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 assigned 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 the proposed rule, would examine overlap in such situations and the potential effect on Medicare savings.

We note that our proposed policy as outlined in the 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 assigned to 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 assigned to ACOs in the Next Generation ACO model and ESCOs in the Comprehensive ESRD Care model 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 the 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.[86] [87] As we discussed in the proposed rule certain considerations

[86] 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*.

[87] 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*.

weigh against exclusion of all ACO-assigned 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 assignment algorithms do not support a blanket exclusion. It is more operationally feasible to identify and exclude beneficiaries who are prospectively assigned to ACOs. In retrospective assignment models, beneficiaries may be assigned to an ACO at the end of the performance year, before the performance year, or preliminarily assigned to one ACO before the performance year and subsequently assigned to a different ACO after all qualifying services are considered. In retrospective assignment, there will be significant numbers of beneficiaries assigned at final reconciliation to a given ACO who were not identified as preliminarily assigned to that ACO prior to the performance year. That is, they were identified either as unassigned to any ACO or assigned to a different ACO. In prospective assignment models and tracks, the list of assigned beneficiaries is available prior to the start of the performance year and a beneficiary's assignment 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 share in both savings and losses, they have stronger incentives than those in one-sided risk arrangements that share only in savings to reduce total cost of care. 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 explained our belief that pursuing a blanket exclusion from EPMs of assigned beneficiaries from all ACOs would inappropriately disadvantage EPM participants that carry significant financial risk under EPMs.

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 model 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 III.I. of the proposed rule which describes opportunities for gainsharing allowed under these models.

As we stated in the proposed rule, this policy tests the effects of such an ACO-assigned 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 recommended this test be limited to the AMI, CABG, and SHFFT, and CJR models, and ACO models being conducted under CMS' Innovation Center, and did not propose 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 attempted to balance the desire to build a new payment reform initiative while mitigating the potential challenges to existing shared savings models and programs. We sought 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 assigned 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 initiated an AMI, CABG or SHFFT model.

We 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 established the proposal to exclude from the EPMs beneficiaries who are assigned to an ACO in the Next Generation ACO Model or Comprehensive ESRD Care Initiative at § 512.230(f). We established the proposal to attribute savings achieved during an EPM episode to the EPM participant, and include EPM reconciliation payments for other ACO-assigned beneficiaries as ACO expenditures at § 512.305 and § 512.307. We sought comment on our proposals to account for beneficiary overlap with shared savings models and programs.

The following is a summary of the comments received and our responses.

Comment: We received numerous comments in response to our proposed policies for handling overlap between ACOs and EPMs.

A number of commenters expressed concern that ACOs should not be competing with bundled payment models and that CMS needs a sustainable overlap policy that would allow both models to thrive. Related to this, many commenters expressed concern over the difficulty of understanding the different model policies, and the need for a rigorous analysis of how different programs interact and impact participating providers as well as patients. A few commenters believed more information on the effect of overlapping value based models was necessary before moving forward with additional models.

A commenter wrote to support the current overlap policy and recommended that EPM participants be allowed to execute arrangements to

share or shift risk to an ACO but recommended against automatically excluding certain categories of beneficiaries assigned to ACOs. Only if the ACO and EPM fail to come to agreement on a distribution arrangement should the proposed rule be implemented. Another commenter wrote that giving priority to ACOs over EPMs could subordinate ''provider led'' models and sought further clarification on how this policy might function with future physician led EPMs. A commenter suggested that in the absence of an agreement, ACOs should be allowed to accept EPM assignment for ACO beneficiaries where an ACO participant served as the ''attending physician'' during the anchor stay. Under this policy a beneficiary would only be excluded from an EPM if they are actively being managed by an attending physician associated with the ACO and the provider managed episode would take precedence over the EPM participant which was an institutional provider.

On the other hand, a significant number of commenters wrote to support the proposed exclusion of beneficiaries assigned to ACOs in either the Next Generation ACO or Comprehensive ESRD Care models. A substantial number of these commenters supported extending the exclusion to beneficiaries assigned to Shared Savings Program Track 3 ACOs. A number of these commenters recommended extending the exclusion even further to include more ACO related exclusions from EPMs and expressed concern that the current approach undermines ACOs. These commenters believed it was important to give preference to population based models versus those focused on more limited episodes. While bundling may give short term savings, it was noted, they do not focus on the total cost of care and have the potential to increase total utilization. In support of this perspective, several commenters recommended the exclusion be extended to include beneficiaries assigned to any ACO unless a collaboration agreement is in place. If there is no collaborative agreement in place between an EPM participant hospital and an ACO that it is not part of, then beneficiaries assigned to that ACO should be excluded from the EPM episodes. A commenter suggested that CMS should allow for ''more flexible, market-based options where parties can mutually agree'' to share the risk of an episode rather than the proposed exclusion. A commenter recommended that CMS allow for prospective alignment for all types of ACOs regardless of the risk sharing arrangement with CMS. The commenter disagreed with our statement that ACOs that didn't share downside risk might be less able to manage risk and expressed the view that EPMs had an even lower risk threshold. Extending the option for prospective alignment to all ACOs with downside risk, they noted, could incentivize ACOs to assume more financial risk. Another suggested excluding beneficiaries based on preliminary prospective assignment with retrospective reconciliation if the EPM participant is not a member of the ACO or does not have a collaboration agreement with the ACO. Other commenters suggested that ACO participant hospitals be totally excluded from EPMs.

Response: We acknowledge the range of perspectives expressed by commenters and appreciate the many specific suggestions for handling these overlaps. We also acknowledge the operational challenge both ACOs and EPMs face and the financial impacts on both when there are overlaps. We believe the level and range of responses reflect the challenge in balancing multiple perspectives as was reflected in the discussion in the proposed rule. The predominance of commenters supported our proposal to exclude from EPMs those beneficiaries assigned to Next Generation ACOs and the downside risk track of Comprehensive ESRD Care models, and a significant number of commenters also supported extending this exclusion to Shared Savings Program Track 3 ACOs which also have beneficiaries prospectively assigned and share downside risk. We believe it is appropriate to test the impact of granting full-risk ACO models the opportunity to ''hold the risk'' associated with the care throughout the performance year, rather than defaulting to the EPM participant; ACOs have stated that they are the appropriate accountable entity for beneficiaries for whom they remain financially responsible, even in the event an assigned beneficiary experiences an episode at an EPM hospital. CMS believes there is significant value in testing an alternative approach which would also not significantly deplete the total number of EPMS. We are less convinced that all beneficiaries assigned to ACOs, regardless of model or track, should be excluded from EPMs and, among other issues, believe that would significantly deplete the volume of EPM episodes. We also remain concerned that excluding all ACO beneficiaries could ultimately exclude patients from EPMs that end up not being assigned to any model. We recognize the broader, more comprehensive perspective of ACOs and encourage the development of collaborative partnership agreements with EPMs. We do not, however, believe it is appropriate for CMS to mandate such agreements or the detailed terms of such agreements, or believe it is practical to tie exclusions to the presence of hospital and ACO specific agreements that may be in place for specific episodes.

In sum, we are convinced that there is merit in extending our proposed beneficiary exclusion from EPMs to include those beneficiaries assigned to Shared Savings Program Track 3 ACOs. We also note that CMS has recently announced that it will re-open applications for new participants in the Next Generation Accountable Care Organization (ACO) model for the 2018 performance year. Therefore we are finalizing our proposal with one modification: The exclusion of ACO beneficiaries assigned to Shared Savings Program Track 3 ACOs from the EPMs.

Comment: A few commenters stated that, while bundled payments may provide savings to Medicare in the short term, the EPMs do not sufficiently address volume or total cost of care. Commenters suggested that because ACOs focus on total cost of care and population health, while episode and bundled payments focus on specific disease states, issues such as the utilization or volume of services and selection or type of services such as preventative services could be better managed by ACOs. These commenters believed that the EPMs actually threaten the long term success of ACOs and that further, the EPMs could potentially increase overall Medicare costs.

Response: We appreciate these commenters' concerns. The goals of the EPMs are to test methods to improve the quality of care furnished to beneficiaries and reduce spending during episodes in specific geographic areas. While we understand that overlaps between ACOs and EPMs exist, we believe the policies for handling overlap, which we are finalizing with slight modification in this final rule (that is Shared Savings Program Track 3 ACOs will be excluded from the EPMs), adequately and appropriately address and account for overlap with other Innovation Center Models.

With respect to commenters' assertions that ACOs can better manage patient care and/or lower costs of health care, we believe we must also continue to assess the extent to which ACOs contribute to lowering costs and improving care, as research around this

issue continues to evolve.[88] [89] We will continue rigorous, independent evaluations that examine each particular payment model and how overlapping models affect Medicare beneficiaries so as to determine the need to require participation in these episode models to enhance learning around the best approaches to improving quality while containing costs. We will also continue to monitor the impact of testing alternative payment approaches and consider volume effects as part of that process.

We refer readers to section III.G. of this final rule for discussion of monitoring and beneficiary protections under this model which we believe will address the commenters' concerns about potential increases to overall Medicare spending. We also refer readers to section IV of this final rule where we discuss the evaluation of the EPMs, including consideration of the impact of the EPMs on the total number of episodes, total cost of care and potential beneficiary risk selection.

Comment: Many commenters expressed concern about the challenge of having accurate and timely information on patient attribution with multiple models. They believed it was unrealistic to expect hospital staff and others to be able to accurately identify patients in excluded ACO models and questioned how EPM participants and their partners would be able verify a patient's status. This was a particular concern with patients who may travel out of their home area to receive care, either to referral centers or due to living out of the area for part of the year.

Response: We appreciate the operational challenges that EPM participants and their collaborating partners face in an environment where there are many, potentially overlapping, models in place. CMS is doing what we can to reduce operational barriers where we can practically and effectively do so. To this end we are in the process of developing a web portal where EPM participants can, at the point of care, look up and identify beneficiaries prospectively assigned to ACOs who will be excluded from EPMs. This system is currently in testing, and is expected to be operational when EPMs are implemented in July 2017. CMS will provide more specific information as it is rolled out.

Comment: A commenter stated that they are concerned with our inability to fully model the estimated impact of the EPMs on beneficiaries who are also aligned or attributed to a Medicare Shared Savings Program participant or an ACO model initiated by the CMS Innovation Center. The commenter stated that CMS should delay implementation of EPMs until this issue can be evaluated. Further, they believe CMS should release the data necessary to study this issue.

Response: We understand the commenter's desire to understand the full effect of EPMs in relation to other CMS initiatives. As discussed in the proposed rule (81 FR 50989 through 51002), the high uncertainty associated with concurrent EPM and ACO and/or Shared Savings Program attribution is a limitation in our modeling of the impacts of the interaction between these models and programs. We do not believe that delaying EPMs would enable prospective modeling of the potential interaction. We refer readers to section III.D.6.c. of this final rule for a discussion of our approach to accounting for beneficiaries who are simultaneously receiving care under the EPMs and other alternative payment models such as BPCI or CJR. We refer readers to section III.G. for a discussion of the Monitoring and Beneficiary Protections which will be implemented in the EPMs. We will monitor the impact of the EPMs on other CMS initiatives such as ACOs to ensure quality of care in these programs is not being adversely impacted by the EPMs. As discussed in section III.G. of this final rule, we plan to publish data as part of the EPM evaluations to promote transparency and an understanding of the EPM effects, including impacts on other models and programs such as ACOs.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, with modification, to exclude from eligibility for EPMs not only beneficiaries assigned to Next Generation ACOs and Comprehensive ESRD Care Initiative models but also beneficiaries prospectively assigned to Shared Savings Program Track 3 ACOs. However, for the reasons previously specified in this section, we do not believe it is appropriate to change the proposed policy, as implemented in the CJR model, for handling overlaps between EPMs and other ACOs (ACOs whose beneficiaries are not excluded from the EPMs) to attribute savings achieved during an EPM episode to the EPM participant, and to include EPM reconciliation payments for ACO-assigned beneficiaries as ACO expenditures. We also note that we will implement an on-line system for verification of attribution to support EPM participants in their ability to identify such exclusions.

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 same time that the beneficiary is in an EPM, but the clinical relationship between the services paid for by the PBPM payments and the EPM will vary. For purposes of the proposed rule, we considered clinically related services paid for 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 the proposed rule. As with CJR, we proposed 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 for by the 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 for 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 the 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 the proposed rule) would not be the only mechanism for exclusion of a

[88] Song Z., Fisher E.S. The ACO experiment in infancy—looking back and looking forward. JAMA. 2016;316(7):705–706.

[89] Schulman K.A., Richman B.D. Reassessing ACOs and health care reform. JAMA. 2016;316(7):707–708.

service from an EPM. All such PBPM model payments that we determine are clinically unrelated would be excluded as discussed in the proposed rule. Finally, all services paid for 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 for by these PBPM payments are most appropriately excluded from the EPMs. Our proposal for the treatment of services paid for 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. As we stated in the proposed rule, we believe that this 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 the proposed rule.

As with CJR, we propose to exclude the PBPM payments for the OCM and Medicare Care Choices Model (MCCM) from the AMI, CABG, and SHFFT episode definitions. These PBPM payments (listed on the CMS Web page at *https://innovation.cms.gov/Files/x/cjr-pbpmexclusions.xlsx*) would be excluded from EPM reconciliation calculations. 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 the proposed rule. We believe the care coordination and management services paid for 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 proposed that services paid for by PBPM payments under the OCM be excluded from the AMI, CABG, and SHFFT models. Similarly, we proposed to exclude services paid for 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 the proposed rule, but not the services represented by the PBPM payment, 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 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 have proposed 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 proposed to use to update EPM episode definitions that are discussed in section III.C. of the 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 the proposed rule. To allow for public input on our planned application of these standards, we will post our proposed determination about whether the PBPM payment will be included in the episode on the CMS Web site. After our consideration of any public input received, we will make a final determination on the inclusion of the PBPM payment and will then post the final updated overlap list, reflecting any changes made to PBPM payment inclusions, to the CMS Web site.

With the publication of this final rule, we are initiating the sub-regulatory update process described in the preceding paragraphs to review potential additions to the PBPM exclusion lists for the EPMs. We did not consider the 2017 PBPM changes in the EPM proposed rule, because we limited our PBPM proposals to those models that were active when the proposed rule was published in the **Federal Register** on August 2, 2016. Since the proposed rule was published, other PBPM models have become active, such as the Million Hearts® Cardiovascular Disease (CVD) Risk Reduction Model and the Comprehensive Primary Care Plus (CPC+) model. These would be examples of PBPMs we will review for calendar year 2017 under the sub-regulatory update process we are establishing in this final rule. The potential modifications to the PBPM exclusion list for each EPM are posted on the CMS Web site at *https://innovation.cms.gov/initiatives/epm*. We request that public input on the potential modifications be sent to *epm@cms.hhs.gov* through 11:59 p.m. Eastern Standard Time on January 27, 2017.

After receiving and reviewing public input on potential revised exclusions, we will post the final revised PBPM exclusion lists by February 24, 2017, and will also specify via web post when the revisions will take effect and to which episodes they will apply.

The payment reconciliation process is described in section III.D.5. of the 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 the proposed rule, for beneficiaries who are also in EPM episodes.

We established the proposal for accounting for non-ACO services and payments in the EPM reconciliation process at § 512.210. We sought comment on this proposal.

The following is a summary of the comments received and our responses.

We did not receive any specific comments relating to how we have proposed to handle PBPM payments from non-ACO models in the EPM reconciliation process

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, 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 for by the 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. We will post our list of PBPM payments which we propose to exclude from EPM episode spending calculations on the CMS Web site at *https://innovation.cms.gov/initiatives/epm* model exclusion and request that public input on the potential PBPM exclusions be sent to *epm@cms.hhs.gov* through 11:59 p.m. Eastern Standard Time on January 27th, 2017. After receiving and reviewing public input on potential PBPM exclusions, we will post the final PBPM exclusions by February 24th, 2017 including providing information about when the PBPM exclusions will take effect.

7. Limits or Adjustments to EPM Participants' Financial Responsibility

a. Overview

We recognized 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. That is, 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 participant's own historical EPM-episode utilization in the early years of the EPMs. We also noted 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 proposed to begin to phase in responsibility for repaying Medicare for excess EPM-episode payments, we proposed several specific policies as follows (81 FR 50872).

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 the proposed rule regarding our proposed pricing adjustment for high payment EPM episodes (81 FR 50846), 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 participant's EPM episodes generally had high payments. As an extreme example, if a participants 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 participant's overall repayment responsibility for actual EPM-episode payments under the EPMs, (hereafter called a ''stop-loss limit''), we proposed 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 (81 FR 50872 through 50873). Specifically, we proposed 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, 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 would gradually phase 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). As described in section III.D.5. of the proposed rule, when calculating the NPRA for performance year 2, we would ensure the NPRA attributable to episodes ending during performance year 2 (NDR) was not less than zero and that NPRA attributable to episodes ending during performance year 2 (DR) did 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 conducting the subsequent reconciliation calculation to reassess actual EPM-episode payments for performance year 2 (which would 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 was 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 was 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 was not exceeded as a single stop-loss limit would apply in each year. For example, as described in section III.D.5. of the proposed rule, when calculating the NPRA for performance year 3,, we would ensure the NPRA did not exceed the stop-loss limit of 10 percent of the sum of quality-adjusted target prices. Similarly when conducting the subsequent

reconciliation calculation to reassess actual EPM-episode payments for performance year 3 (which would 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 was not exceeded.

Note that, as described in sections III.D.5.b. and III.D.6.b.(2) of the proposed rule (81 FR 50865 through 50867 and 50869 through 50871), 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 would be added to the NPRA and subsequent reconciliation calculation to create the repayment amount or reconciliation payment. We believed that these limits would both offer EPM participants reasonable protections while maintaining incentives to improve care quality and efficiency. We noted 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 participants' overall payment responsibility under the models was included in § 512.305(c)(2)(iii)(A). We sought comment on our proposal to limit hospitals' overall payment responsibility.

The following is a summary of the comments received and our responses.

Comment: Commenters offered a variety of perspectives on the proposal to limit hospitals' payment responsibility under the models. A number of commenters requested that CMS include additional protection to participants by delaying the phase-in period under which the limits would increase, or reducing the limits across-the-board or for certain hospital types, for example, participants treating a large percentage of complex cases or vulnerable populations. One commenter recommended that the limits remain at a statistically equivalent level of case complexity provided that the participants are improving with respect to their performance measures.

Another commenter recommended that in lieu of a blanket stop loss protection, CMS should instead make outlier payments for high-cost cases as they believed it would provide a better safety net to the small percentage of extremely high-cost episodes. One commenter recommended that hospitals with fewer than 20 episodes not be required to participate and if they did, their stop-loss threshold should be increased. Another commenter suggested that CMS include additional stop-loss protections for participants that provide services to complex patients and patients with co-morbidities. The commenter also seemed to suggest that the additional stop-loss protections be offered where beneficiaries receive hospice services during an episode.

Response: We appreciate the comments we received either in support of our proposal or to modify the proposal. While we are not persuaded by comments to reduce the stop-loss limits or modify our proposed mechanism for offering participant hospitals protections against significant financial loss, we are delaying the phase-in period under which the stop-loss limits would increase to conform with our policy to delay when EPM participants would be required to accept downside risk under the EPMs as described in section III.D.2.c. of this final. Thus, under our final policy, except for those EPM participants with additional stop-loss protections as discussed in section III.D.7.c.(1) of this final rule, the limits on a EPM participant's repayment responsibility as displayed in Table 19 are—

- For performance year 2, 5 percent for EPM participants that voluntarily elect downside risk for that year; and
- For performance years 3, 4 and 5, 5 percent, 10 percent, and 20 percent respectively.

TABLE 19—PROPOSED AND FINAL STOP-LOSS LIMITS BY PY

PY1	PY2	PY3 (percent)	PY4 (percent)	PY5 (percent)
Proposed Stop-Loss Limits				
n/a as no downside risk in PY1	n/a during non–downside risk period and 5% during downside risk period.	10	20	20
Final Stop–Loss Limits				
Downside Risk for All Participants– DR effective for episodes ending on or after 1/1/2019 (anchor discharges occurring on or after 10/4/2018)				
n/a as no downside risk in PY1 and PY2 without election of voluntary downside risk for PY2		5	10	20
Voluntary Downside Risk—DR effective for episodes ending on or after 1/1/2018 (anchor discharges occurring on or after 10/4/2017)				
n/a as no downside risk in PY1	5%	5	10	20

We believe that this policy in conjunction with our policies to delay when hospitals must assume downside risk and cap high cost payments as well as our plans to implement further risk adjustment measures offer sufficient protections to hospitals participating in the model while maintaining incentives that will encourage improvements in care quality and efficiency.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, with modification, to establish limits on participants' overall payment responsibility. Our final policy on participants' overall payment responsibility is included in § 512.305(c)(2)(iii)(A).

(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 would have no repayment responsibility for excess EPM episode spending above the EPM quality-adjusted target price,

and CMS would bear full financial responsibility for Medicare actual EPM-episode payments for an EPM episode that exceeds the EPM quality-adjusted target price; however, we believe our responsibility should have judicious limits. In addition, our proposed rule noted 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 was intended to provide 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. However, for purposes of responsible stewardship of CMS resources and concerns about potentially excessive reductions in utilization under the proposed EPMs that could lead to beneficiary harm, we also believed it would be reasonable and hence proposed to cap an EPM participant's reconciliation payments resulting from actual EPM-episode payments for a given performance year as a percentage of EPM-episode payments.

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 proposed to establish symmetrical stop-gain limits (81 FR 50873). Specifically, we proposed 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 phased-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 would gradually phase up to 20 percent by performance year 4. As was also indicated in the CJR Final Rule, we wanted to ensure that any savings achieved by EPM participants in the early years of the EPM were not due to random variation, and that changes undertaken to improve efficiency included achievement in care quality and not sharp decreases in utilization that could be harmful to beneficiaries (80 FR 73402).

We clarified in our proposed rule that, as with the stop-loss limits, we proposed to determine whether an EPM participant had met the stop-gain limit by assessing the NPRA and subsequent reconciliation for a given performance year, if any. We noted that this approach aligned 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 also noted that we planned 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 the proposed rule for our discussion on monitoring and addressing participants' 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 was included in § 512.305(c)(2)(iii)(B). We sought comment on this proposed cap.

The following is a summary of the comments received and our responses.

Comment: Commenters addressing how reconciliation payments would be capped either opposed the caps or recommended that CMS raise the dollar amount at which payments would be capped. These commenters stated that doing so would make additional resources needed for infrastructure development available or allow greater rewards for savings achieved.

Response: We appreciate the comments we received on our proposal, but disagree with recommendations to eliminate or raise the dollar amount at which payments would be capped. While the proposed models intend to establish financial incentives to better manage and coordinate care throughout the EPM episode in a way that improves both health care quality and efficiency, we believe it is also necessary to establish limits to discourage the chances for excessive reductions in utilization under the proposed EPMs that could lead to beneficiary harm. We believe our proposed cap on reconciliation payments achieves an appropriate balance that both provides incentives for participants to improve care quality and efficiency without also encouraging excessive and inappropriate reductions in utilization.

Also, as previously stated, we believe it is important that stop-gain and stop-loss limits under the models be established in a way that provides proportionately similar protections to CMS and EPM participants for their financial responsibilities under the EPMs as well as to protect the health of beneficiaries. As such, we proposed to establish stop-gain limits under the models that were symmetrical with our stop-loss limits.

As we previously noted in section III.D.7.b.(1), in delaying when EPM participants would be required to accept downside risk under the EPMs as described in section III.D.2.c. of this final rule, our final policy includes conforming adjustments to the limits on EPM participants' overall payment responsibility. These conforming adjustments also necessitate adjustments to the stop-gains limits under the model for consistency with our policy for symmetrical stop-loss and stop-gain limits. Accordingly, the final stop-gain limits are 5 percent in performance years 1, 2, and 3; 10 percent in performance year 4; and 20 percent in performance year 5 for each EPM (see Table 20).

TABLE 20—PROPOSCED AND FINAL STOP-GAIN LIMITS AND FINAL STOP-LOSS LIMITS BY PY

PY1	PY2	PY3 (percent)	PY4 (percent)	PY5 (percent)
Proposed Stop-Gain Limits				
5%	5%	10	20	20
Final Stop-Gain Limits				
5%	5%	5	10	20
Final Stop-Loss Limits: Downside Risk for All Participants*				
n/a as no downside risk	n/a as no downside risk	5	10	20
Final Stop-Loss Limits: Voluntary Downside Risk in PY2*				
n/a as no downside risk	5%	5	10	20

* Limits apply to hospitals other than those eligible for the separate stop-loss limits discussed in section III.D.7.c.(1) of this final rule.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, with modification, 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. Our final policy on the proposed cap, which includes conforming adjustments so that the stop-loss and stop-gain limits are symmetrical, is included in § 512.305(c)(2)(iii)(B).

c. Additional Protections for Certain EPM Participants

(1) 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, we proposed 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 (81 FR 50873 through 50874). Specifically, we proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 health care 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 had similar concerns, which we believed should be addressed by establishing greater protections for these hospitals when they are EPM participants. Accordingly, we proposed 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 was included in § 512.305(c)(2)(iii)(C). We sought comment on our proposed limit on financial loss for these hospitals.

The following is a summary of the comments received and our responses.

Comment: Many commenters supported the proposal to establish separate financial loss limits for certain hospitals. One commenter recommended that CMS provide additional protection to these providers by waiving downside risk for them for the entire duration of the models as well as to retaining the proposed protections to MDHs in the event the MDH status expires during the period of the models. Some commenters requested that CMS extend to participants with a low volume of episodes or to hospitals that serve a large portion of vulnerable populations these same financial loss limits because they likely lacked the infrastructure and support to achieve greater efficiencies or served beneficiaries with more complex and diverse treatment needs. Some commenters provided data in support of their request suggesting that hospitals with fewer episodes had the widest range in gains and losses largest year-to-year variation in episode spending relative to target prices. One commenter suggested that CMS determine eligibility for these separate financial loss limits based on the same thresholds that would be applied for determining whether a participant's EPM-episode benchmark prices would be based only on regional historical EPM-episode payments.

Response: We appreciate and agree with the comments supporting our proposal to establish separate financial loss limits for certain hospitals. We do not agree with the suggestion that we instead waive downside risk entirely for these hospitals. Given their lower tolerance of risk, more limited infrastructure and support to achieve efficiencies, and special status under Medicare to preserve Medicare beneficiaries' access to care from these hospitals, we recognize that certain adjustments to the model are warranted for these hospitals. However, we believe our proposed financial loss limits offer sufficient protection to these hospitals while allowing us to maintain an appropriate balance of incentives to encourage care quality and efficiency improvements as would exist for the other hospitals that would be participating under the models.

Under current law, the MDH program will continue through September 30, 2017, but will expire absent additional legislative authority. As we stated in the CJR Final Rule (80 FR 73406), we understand the concern that with the expiration of MDH status, hospitals will lose their MDH designation and additional Medicare FFS payments provided under the MDH designation. Additionally, under the expiration of MDH status, hospitals would no longer qualify for the protective stop-loss limit tied to that status under the EPM models. We believe it would be inconsistent to apply the additional benefit of protective stop-loss limits to former MDHs when by law, those hospitals are not permitted to retain the other Medicare payment benefits provided to MDHs. We would note, however, that should a participant's MDH payment status expire, some MDHs may apply with their MACs to determine if they qualify as an RRC or SCH and would be able to maintain the protective stop-loss limits.

The requests commenters made to extend separate financial loss limits to hospitals with a low volume of episodes have persuaded us to extend these separate limits under the EPMs under certain specific circumstances. We conducted an analysis of cost variation for episodes under the EPMs and found greater variation in episode-level spending for episodes occurring among low-volume than high-volume hospitals. Under a range of low-volume thresholds, this analysis showed the standard deviation of historical AMI episode spending at low-volume hospitals in selected MSAs was 10 to 32 percent higher than high-volume hospitals in selected AMI model MSAs. Likewise, the standard deviation of historical SHFFT episode spending at low-volume hospitals was 14 to 18 percent above high-volume hospitals in selected AMI model MSAs, and the standard deviation of historical CABG episode spending was 6 to 19 percent higher above high volume hospitals in selected CABG model MSAs.[90] Based on the results of our analysis, we share commenters' concerns that when there is a low volume of episodes under a model, an EPM participant could potentially be held responsible for random variation in spending that occurs under that model. Thus, we have been persuaded to extend the separate financial loss limits that apply to rural hospitals, SCHs, MDHs, and RRCs to EPM participants determined to have a low volume of episodes under an EPM, which we will refer to as ''EPM volume protection hospitals.''

In contrast to rural hospitals, SCHs, MDHs, and RRCs, however, we will apply the separate loss limits to EPM volume protection hospitals at the model level as we will apply loss limits to most other hospitals under the EPMs rather than at the hospital level as is the case for these specific types of hospitals eligible for separate loss limits. Accordingly, this means we could

[90] Episodes for AMI, SHFFT, and CABG beneficiaries initiated by all U.S. IPPS hospitals in MSAs selected for EPMs and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that began in CYs 2012–2014.

extend the separate loss limits to an EPM volume protection hospital for one or more EPMs but not necessarily all of the EPMs, depending on whether their historical EPM episode volume exceeded the threshold number for the specific model.

An EPM participant will qualify as an EPM volume protection hospital if their volume of historical EPM episodes that started in calendar years 2013 through 2015 is at or below the 10th percentile of the number of hospital-specific historical EPM episodes for hospitals located in the MSAs eligible for selection into that specific EPM. For purposes of determining the 10th percentile threshold, we will use historical episodes for the same historical periods used to determine an EPM participant's benchmark and quality-adjusted target prices for performance year 1 based on hospitals with one or more historical episodes under that model in the applicable MSAs. This would include hospitals such as rural hospitals, MDHs, SCHs, and RRCs. While we considered both higher and lower thresholds, we believe the 10th percentile achieves the most appropriate balance with respect to focusing our policy on those hospitals that would uniquely have a low volume of episodes under an EPM. Though our analysis of episode volume from 2012–2014, suggests that around 10 percent of hospitals with any episodes would be subject to these additional protections, we expect that only around 1 percent or less of episode volume would be subject to the additional protections.

We also note that a participant could potentially be eligible for the separate loss limits based on their being either an EPM volume protection hospital or meeting the criteria for being one of the other eligible hospital types such as a rural hospital, MDH, SCH, or RRCs. We wish to clarify that in these cases we would extend the separate loss limits based on the criteria for the latter hospitals as their separate loss limits would apply at the hospital rather than the model level. Also, we would note that the stop-loss protections would not be additive whereby a participant benefitted from the stop-loss protections under both eligibility criteria.

For each EPM, we will post the applicable historical EPM episode number threshold used to determine whether EPM participants are EPM volume protection hospitals and a list of the CCNs of EPM participants that are classified as EPM volume protection hospitals to the CMS Web site before the beginning of performance year 1. We will also indicate to each EPM participant whether it is classified as an EPM volume protection hospital at the same time that we prospectively communicate quality-adjusted target prices to EPM participants, as described in section III.D.4.a. of this final rule.

While the threshold for each EPM will be set for all five performance years so that EPM participants can know before the beginning of the first EPM performance year their hospital status for the five years of the EPM, we make technical revisions to the list of EPM volume protection hospitals to account for changes in business practices, like mergers, acquisitions, or the opening of new hospitals. For example if an EPM participant that was an EPM volume protection hospital merged with another EPM participant and the merged entity continued to use the CCN of the EPM volume protection hospital, we would consider the historical episode volume at both EPM participants to determine whether the merged entity would continue to be an EPM volume protection hospital.

We are not adopting the suggestion to determine an EPM participant's eligibility for the separate protections using the same thresholds that are applied for determining whether their EPM-episode benchmark prices would be based only on regional historical EPM-episode payments. While these thresholds are appropriate for purposes of ensuring reliable estimates when establishing prices under the models, the measure would not be an effective metric for distinguishing hospitals with a low volume of episodes from other hospitals. Rather, it would result in too high a share of hospitals qualifying for the separate protections and thus would be too crude a metric for distinguishing hospitals with a low volume of episodes.

While we appreciate the comment suggesting that we extend the separate stop-loss limits to hospitals treating a large portion of vulnerable patients, we are not adopting this suggestion at this time. As discussed in the following section of this final rule, however, we requested comments on issues specific to hospitals serving a high percentage of potentially vulnerable populations and their opportunities to advance the goals of the EPMs. As we discuss in that section, while we will not be incorporating the suggestions we received in this rule, we will share the comments and suggestions we received with the Assistant Secretary for Planning and Evaluation for their consideration as well as consider their potential applicability, where appropriate, in future rulemaking.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, with modification, to establish separate financial loss protections for certain hospitals. Once again, we would note that in delaying when EPM participants would be required to accept downside risk under the EPMs as is described in section III.D.2.c. of this final rule, our final policy includes conforming adjustments to the separate financial loss limits on participants' overall payment responsibility. We will extend the separate financial loss protections to EPM participants determined to have a low volume of episodes within a model. Thus, under our final policy, the separate financial loss limits for rural hospitals, SCHs, MDHs, RRCs, and EPM volume protection hospitals as displayed in Table 21 are—

- For performance year 2, 3 percent for EPM participants that voluntarily elect downside risk for that year; and
- For performance years 3, 4 and 5, 3 percent, 5 percent, and 5 percent respectively.

TABLE 21—PROPOSED AND FINAL SEPARATE STOP-LOSS LIMITS BY PY

PY1	PY2	PY3 (percent)	PY4 (percent)	PY5 (percent)
Proposed Separate Stop-Loss Limits Rural Hospitals, SCHs, MDHs, and RRCs				
n/a as no downside risk in PY1	n/a during non-downside risk period and 3% during downside risk period.	5	5	5

TABLE 21—PROPOSED AND FINAL SEPARATE STOP-LOSS LIMITS BY PY—Continued

PY1	PY2	PY3 (percent)	PY4 (percent)	PY5 (percent)
Final Separate Stop-Loss Limits Rural Hospitals, SCHs, MDHs, RRCs, and EPM Volume Protection Hospitals				
Downside Risk for All Participants—DR effective for episodes ending on or after 1/1/2019 (anchor discharges occurring on or after 10/4/2018)				
n/a as no downside risk in PY1 and PY2 without election of voluntary downside risk for PY2		3	5	5
Voluntary Downside Risk—DR effective for episodes ending on or after 1/1/2018 (anchor discharges occurring on or after 10/4/2017)				
n/a as no downside risk in PY1	3%	3	5	5

Our final policies for the separate financial loss protections in included in § 512.305(c)(2)(iii)(C) and § 512.305(c)(2)(iii)(D).

(2) Considerations for Hospitals Serving a High Percentage of Potentially Vulnerable Populations

In addition to the aforementioned hospitals, our proposed rule noted our recognition that other EPM participants, for which we did 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 proposed 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 proposed. 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.

Our proposed rule also noted that 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. Our proposed rule noted that upon issuance of these studies' reports, we planned to consider their results as we implemented the proposed EPMs. We also planned 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, however, we did not anticipate that the aforementioned factors should materially affect participants' ability to achieve savings. However, as we increasingly began 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 identified the need for adjustments, we could consider proposing additional policies through subsequent rulemaking. Additionally, we planned 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 the proposed rule (81 FR 50914 through 50915) to inform if potential adjustments would be needed in future years of the model.

Protections for EPM participants were discussed in section III.D.7.b.(1) and III.D.7.c.(1) of the proposed rule (81 FR 50872 through 50874). We sought 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 (81 FR 50875). In particular, we sought 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; 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 final 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.

The following is a summary of the comments received and our responses.

Comment: Commenters urged CMS to provide greater financial protections for providers serving a high portion of vulnerable populations, and recommended that CMS apply lower caps on such providers' losses. While these commenters suggested that further study was needed, they recommended that, at a minimum, CMS should extend the 5 percent cap to include all of performance year 3, and reduce the cap in PY4 and PY5 to 10 percent. These commenters also noted that CMS would establish a definition of vulnerable populations, which should account for Medicaid and uninsured populations, and should seek public comment on this definition. For example, one commenter suggested that CMS consider section 1900 of the Social Security Act to identify hospitals serving a high number of vulnerable patients. Another commenter expressed their appreciation for CMS' highlighting of this issue, recommended that adjustments for socio-demographic variables would be logical starting point, and providers that care for vulnerable patients and populations should be treated equally.

Response: We appreciate the comments we received on these issues and agree that further study is needed. While we will not be incorporating suggestions we received in this rule, we will share the comments and suggestions we received with the Assistant Secretary for Planning and Evaluation for their consideration as well as consider their potential applicability, where appropriate, in future rulemaking.

d. Application of Stop-Gain and Stop-Loss Limits

Because participants could be participating in the proposed AMI, CABG, and SHFFT models concurrently with the CJR model, our proposed rule noted that an additional consideration concerns the level at which the stop-loss and stop-gain thresholds would be applied, for example, at the participant's level, as is currently the case for the CJR model, or at some other level, for example, at the model level. We indicated that our intention was to establish appropriate incentives and protections for participants under the proposed EPMs and the CJR model without creating unnecessary administrative complexity. Further, this issue would become 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 (81 FR 50875 through 50876). 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 participant 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 participant'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 participant 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 participant 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 was included in § 512.305(c)(2)(iii)(D). We sought comment on our proposal to establish stop-gain and stop-loss limits at the model level.

The following is a summary of the comments received and our responses.

Comment: Some commenters expressed concerns that a blanket stop-loss policy could offer insufficient protection to participants with a low volume of cases. Thus, one commenter recommended that the stop-loss provision be calculated on an episode-specific basis for each provider as the degree of outcome variability will differ significantly based on the provider's volume and starting price position relative to the region. Another commenter recommended that CMS apply stop-loss limits at the episode level separately for low, medium, and high volume providers rather than at the model or program level so that the level of protection would vary by the number of episodes. In their view, this approach would offer hospitals, particularly those with lower volume, greater protection against exceptionally high costs.

Response: We appreciate the comment generally supporting our proposal as well as the suggestions to modify our proposal. As discussed elsewhere in this rule, in addition to protections we had proposed with respect to capping high-cost cases with respect to our financial calculations (see section III.D.3.d.), we are finalizing policies that would offer to hospitals with a low volume of episodes under a model the same stop-loss protections that would apply to certain other hospitals (see section III.D.7.c.) as well as further adjustments for risk that we anticipate making effective beginning in PY3 (see section III.D.4.a.2). We believe these protections are sufficient and are thus not adopting the recommended modifications to the application of stop-loss protections.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to establish stop-gain and stop-loss limits at the model level. Our final policy for establishing these limits is included in § 512.305(c)(2)(iii)(E).

e. EPM Participant Responsibility for Increased Post-Episode Payments

Our proposed rule noted 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 also stated our belief 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 proposed 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 the proposed rule, (81 FR 50829 through 50843). This proposal is consistent with our processes for BPCI Model 2 and the CJR model (80 FR 73407 through 73408).

We proposed that the post-episode spending calculation for a performance year would occur at the same time we performed the subsequent reconciliation calculation for that same year (81 FR 50876 through 50877). We believe this timeframe would 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 the proposed rule (81 FR 50846). 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 proposed 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 noted that, consistent with CJR, 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. and III.D.7.c.(1) of the proposed rule (81 FR 50872 through 50875). Also, although we believed that cases in which an EPM participant would be responsible for repayment of post-episode spending that exceeds the threshold would be rare, our intention was 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. This policy is consistent with our proposal for the CJR model in section V.D.1. of the proposed rule (81 FR 50951 through 50952).

We also noted that 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 believed that our proposed threshold of 3 standard deviations above the regional average is a high threshold, and we only proposed that an EPM participant would repay Medicare for the amount that exceeds such threshold. We further noted 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 were included in § 512.307(c). We sought comment on our proposals to determine if a participant exceeds this threshold and to repay amounts in excess of the threshold.

The following is a summary of the comments received and our responses.

Comment: One commenter expressed support for the proposal as it could help identify participants that withhold or delay medically necessary care until after an episode ends in order to reduce their actual episode spending. This commenter further suggested that CMS also implement a financial penalty for participants that are found to inappropriately delay beneficiaries' care.

Response: We appreciate the comments in support of our proposal. As noted in section III.F.2. of this final rule, we have finalized various compliance tools for the EPMs that complement existing laws and regulations prohibiting care stinting, provision of substandard care, or denial of medically necessary care. As discussed in section III.F.2., when an EPM participant or its related EPM collaborator, collaboration agent, or downstream collaboration agent engages in these noncompliant behaviors, CMS may take remedial action, including reducing or eliminating the EPM participant's reconciliation payment or reducing or eliminating the EPM participant's CR incentive payment amount. In addition, under circumstances where CMS has required a corrective action plan, the EPM participant owes a repayment amount to CMS, and the EPM participant fails to timely comply with the corrective action plan or is noncompliant with the EPM's requirements, CMS may add 25 percent to a repayment amount on an EPM participant's reconciliation report. We believe these tools and structure for the financial penalty is consistent with the request of the commenter.

Comment: Some commenters viewed the proposal as unnecessary in light of other enforcement mechanisms to address hospitals that are willfully committing potential fraud and abuse or that the proposal effectively extends the episode duration from 90 to 120 days. One commenter stated that for cases where 30-day post-episode spending exceeded a certain threshold, these expenditures were likely necessary for treatment of a patient's clinical needs rather than representing an intentional delay in providing care to Medicare beneficiaries to game the system for greater financial rewards.

Response: We disagree with the view that our proposal is unnecessary in light of other enforcement actions. We believe that our proposal in conjunction with our policies related to monitoring and enforcement actions is an appropriate means to discourage the occurrence of instances where access to high quality care might be impeded, and believe this deterrence is preferable to having to take enforcement actions subsequent to such an instance. We also do not agree with the comment that we are effectively extending episodes or that expenditures beyond our thresholds would typically be necessary for the care of a beneficiary. We also note that in the event that CMS identifies excessive post-episode spending at an EPM participant greater than 3 standard deviations above the regional average 30-day post-episode spending, the EPM participant will only be required to pay back the amount by which post-episode spending for episodes attributed to the EPM participant exceeds 3 standard deviations above the regional average 30-day post-episode spending. We note that this does not hold the EPM participant responsible for all post-episode spending as would be the case with 120 day episodes. Moreover, we believe that this threshold is sufficiently high to account for all clinically necessary care that would occur in the 30 days following an episode. As we noted in the CJR Final Rule (80 FR 73407), we believe that monitoring for 30 day post-episode spending is an appropriate tool to identify inappropriate shifts in car based on our experience with BPCI.

Comment: Some commenters raised concerns that care or services that are excluded from or unrelated to an episode would be included in the calculation of post-episode spending and recommended that we exclude these services from post-episode payment calculations. One commenter requested that CMS identify care situations that are ''unrelated'' to the EPM episode diagnosis with regard to calculating post-episode spending costs.

Response: As we stated in the CJR Final Rule (80 FR 73407), we disagree that we should exclude the same set of services that are excluded from the episode definition in the 30 day post-episode spending calculations because of concerns that the models could lead to shifting of both related and unrelated (those not included in the episode definition) services due to some providers encouraging delays of services for beneficiaries that are not immediately necessary, without discriminating between those services that are in and out of the episode definition. Additionally, our experience with BPCI that similarly includes all costs when monitoring for 30 day post-episode spending has helped to inform our policy for the CJR and the proposed EPMs. Based on our experience with BPCI, we have not found that by including all costs to measure 30 day post-episode spending, that we are inappropriately penalizing hospitals. While we understand commenters' concerns that hospitals could be held responsible for high cost conditions that are not included in the episode definition, our policy aims to strike a balance to hold participating hospitals accountable for inappropriate shifts or delays in care and to provide hospitals with safeguards on financial risk for 30-day post-episode spending. Thus, we have set a high threshold where only hospitals that have a 30-day post-episode spending average that is 3 standard deviations above the regional average would be subject to repay that difference to Medicare, and in the case where the hospital's average 30-day post-episode spending exceeds regional average 30-day post-episode spending, the participant would repay Medicare for the amount that exceeds such threshold.

Comment: Some commenters opposed the proposal to exclude post-episode spending from the stop-loss for the proposed EPM models in part because they viewed the provision overall as unnecessary and because of potential harm to those hospitals that might result.

Response: We have established the stop-loss policy to account for clinical variation or other high expenditures that are not accounted for by the target price methodology, which is not directly comparable to excessive spending that occurs during the 30 days after an episode. We believe that the post-episode spending policy sets a sufficiently high threshold to identify situations with clear increases in post-episode spending due to shifting of services to maximize financial gain under the EPMs, and thus that the stop-loss policy should not apply to any potential amount that an EPM participant owes CMS under the post-episode spending policy.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, 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. Our final policy for this is included at VII.

Collection of Information Requirements

8. Appeals Process

a. Overview

Consistent with the BPCI initiative and CJR model, we proposed to institute appeals processes for the EPMs that would allow EPM participants to appeal matters related to payment, such as CR incentive payments, reconciliation amounts, repayment amounts, determinations associated with quality measures affecting payment (the use of quality measure results in determining the composite quality score, or the application of the composite quality score during reconciliation) as well as non-payment related issues, such as enforcement matters. These matters are discussed respectively throughout section III.D. and III.F. of this final rule.

We sought comment on the proposal to institute appeals processes for the EPMs.

The following is a summary of the comments received and our responses.

Comment: A commenter requested clarification on how CMS will handle an EPM participant's appeal of a potential calculation error when the beneficiary has substance abuse and/or behavioral health claims which cannot be shared with the EPM participant. The commenter expressed concern regarding the balance between privacy restrictions around substance abuse and behavioral health claims and information that is provided to EPM participants in order to verify the calculations. The commenter stated that EPM participants will have to assume CMS has performed all calculations correctly, and as this is not a desirable situation, according to the commenter, the commenter recommended CMS exclude these claims from the episode calculation or provide the information to the EPM participants.

Response: While we appreciate the commenters' position, we believe that the inclusion of these substance use disorder claims in the episode target and actual price calculations is necessary for accurately pricing the episodes.

Our proposal to exclude this information from the claims shared with model participants is consistent with our usual treatment of these data with other similar CMS programs and models where providers must take on risk in managing the care of their beneficiaries, such as the Shared Savings Program, BPCI and the CJR model. We would note that, based on our experience to date, we are unaware of this policy being a significant impediment to the operations of these efforts. We do understand that by not receiving this data, EPM participants are unable to fully verify the accuracy of CMS' calculations. However, as these claims typically represent less than 0.1 percent of episode spending (based on an analysis of 2015/2016 claims data used in current BPCI episodes) we do not believe their exclusion from the data that we provide to participants will produce material differences in the replication of target/actual prices.

Further, Section 1115A of the Act does not authorize the waiver of the requirements under 42 CFR part 2 which govern the release of substance use disorder claims. We note, though, that we may be able to share these claims with participants in the near future based on proposals outlined in the Confidentiality of Substance Use Disorder Patient Records proposed rule published to the **Federal Register** by SAMHSA on February 9, 2016 (81 FR 6987), which updates the 42 CFR part 2 regulations (referred to hereafter as the Part 2 Rule).

These regulations govern the confidentiality of substance use disorder records. Significant changes have occurred within the U.S. health care system that were not envisioned by the current regulations, including new models of integrated care that are built on a foundation of information sharing to support coordination of patient care, the development of an electronic infrastructure for managing and exchanging patient information, and a new focus on performance measurement within the health care system. In the proposed rule, SAMHSA states that it strives to facilitate information exchange within new health care models while addressing the legitimate privacy concerns of patients seeking treatment for a substance use disorder.

In section 2.53 of the proposed rule, SAMHSA also proposes to permit the disclosure of Part 2 data necessary to a regulated ACO or similar CMS-regulated organization (including a CMS-regulated Qualified Entity (QE)) for a Medicare, Medicaid, Children's Health Insurance Program (CHIP), or related audit or evaluation, under certain conditions. As such, should this SAMHSA proposal become final, EPM participants would be considered CMS-regulated Qualified Entities and would be able to receive this data pursuant to this audit and evaluation exception.

CMS will continue to consider the feasibility of making de-identified aggregate substance use disorder data available in a way that is both meaningful to EPM participants and in compliance with the Part 2 Rule. This issue is discussed in further detail in the data sharing section.

Comment: Commenters expressed concern regarding the data files and reconciliation reports received from the contractors administering our programs based on their experiences thus far with BPCI and CJR. Commenters stated the monthly data feeds from CMS regularly omit data elements that are used by the contractor to identify and reconcile episodes to target prices. Specifically, commenters stated that the master beneficiary files contained errors in the DOD and MSCD 1–12 fields. These fields either contained inaccurate or missing information. Commenters stated without these data elements, it is impossible to replicate the reconciliation results calculated by CMS. Participants are left to assume the contractor's calculations are accurate. Commenters stated that the ability to replicate the reconciliation results helps maintain a transparent and open relationship among the EPM participants, CMS, and CMS' contractor. Commenters also recommended CMS provide a mechanism for EPM participants to challenge and correct payment results that are not accurate. Commenters request the ability to provide evidence contradicting errors. Commenters stated currently there is no process or data system in place for this function. Commenters stated that the lack of a feedback loop will be an increasingly critical barrier to participation as the current system has been known to make errors.

Response: We thank commenters for their feedback. We understand commenters' concern regarding missing data elements but we note that some of these elements are deliberately excluded in compliance with the constraints of 42 CFR part 2 and we are currently unable to provide such data. However, the comment response discussed previously outlines the potential changes that may be forthcoming regarding the data sharing constraints in 42 CFR part 2. Regarding the master beneficiary files that contained errors in the DOD and MSCD 1–12 fields, CMS will work with their contractors to insure that the data provided is accurate. We appreciate the feedback regarding these operational concerns and we will work with the EPM payment contractor to establish a tracking and feedback process for participants to ask questions of CMS regarding payment calculations and potential incorrect amounts and be provided more detailed information regarding their reconciliation report and calculation error reports for the EPM models.

Comment: A commenter recommended that CMS change the time period to recoup monies owed to CMS from EPM participants from 30 days to 60 days from the issuance of the Reconciliation Report.

Response: We thank the commenter for the comment. However, because the operational processes used in payment/recoupment actions are part of a standard system that operates across multiple models, including BPCI and CJR, as well as standard FFS operational timelines, we are unable to accommodate a system change and the recoupment time frame will be finalized at 30 days.

Final Decision: After consideration of the public comments received, we are finalizing the proposal without modification.

b. Notice of Calculation Error (First Level Appeal)

We proposed 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 use of quality measure results in determining the composite quality score, or the application of the composite quality score during reconciliation; and the successful reporting of the voluntary PRO THA/TKA data. 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 proposed 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 use of quality measure results in determining the composite quality score, or the application of the composite quality score during reconciliation; and the successful reporting of the voluntary PRO THA/TKA data. Given that EPM participants bear the financial risk in the EPM model, we proposed that only EPM participants might use the dispute resolution process described in this section.

In summary, we proposed 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 calculation 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 sought comment on the proposed notice of calculation error requirements.

The following is a summary of the comments received and our responses.

Comment: Commenters recommended development of a fair and transparent process for providers to appeal reconciliation report information. Commenters stated EPM participants must be given adequate notice that their reconciliation reports are available, and must be provided with sufficient time to review their data. Commenters stated that, in many cases, the reconciliation reports may need to be reviewed by multiple providers at multiple locations, including both EPM participants and post-acute care providers. Commenters recommended that in order for EPM participants to access, review, and contest data in 45 days, they would be required to ignore the demands of patient care and competing priorities providers face on a daily basis. Commenters recommended extending the appeals process to no less than 90 days. A commenter suggested the appeal process be extended to 90 days for at least the first 2 performance years. Another commenter recommend that the 45 days for hospitals to provide written notice of error should not begin until it is mutually agreed upon by the contractor and stated hospital that a complete report, which includes all data elements used by the contractor to identify and reconcile episodes to target prices, has been received.

Commenters also disagreed that a reconciliation would be considered final if a notice is not provided in the time window. Commenters stated that they understood that there must be a timeframe to finalize these payments and that a disputed amount cannot be brought forth for an indefinite amount of time. However, commenters also stated that it is important for EPM participants to have an opportunity to submit a notice for substantial errors over a longer period of time. Commenters suggested that for submitted participant-caused errors that are greater than 20 percent of the payment amount, a 180-day window should be allowed. Due to the size of the potential error, commenters stated that EPM participants may require additional time to gather the necessary information and conduct the appropriate analysis to provide to CMS stating the rationale for their request. Commenters stated that many EPM participants will be new to the EPMs and this recommendation is an important safeguard for potential ''large ticket'' errors. Commenters concurred with CMS' proposal to provide a response within 30 days of receiving a request, including CMS reserving the right to an extension of that 30 days if CMS provides this notice to participants in writing.

Response: We appreciate these comments and are sympathetic to the requests from commenters for more time to submit a notice of calculation error.

However, we are also conscious of the need to distribute funds to providers with positive NPRAs in a timely fashion and the payment/reconciliation disbursement/recoupment system is designed such that no funds can be released until notices of calculation errors are received by CMS. In balancing these needs, consistent with our rationale in the CJR model, we believe that 45 days is sufficient time for EPM participants to review reconciliation reports, and if they choose, to submit notices of calculation error. We believe that 45 days is the appropriate timeframe to allow for this process, as it allows for a reasonable time to review reconciliation reports and does not seriously delay payment of reconciliation payments. Specifically, CMS currently uses the following established operational procedures for appeals in both BPCI and CJR that we are finalizing in section III.D.8. of this final rule.

The procedures for processing and issuing reconciliation payments and repayments require that we submit the payment files for EPM participants to the payment systems in batches. CMS uses this batch processing method for several reasons. It is administratively more efficient to continue to use MACs to issue payments to all providers and suppliers that furnish services to beneficiaries during an EPM, so as not to disrupt the timing of FFS payments that providers and suppliers normally receive. For reconciliation payments and repayments, CMS has developed and implemented a process for handling these payments, which is already in use for other CMS models. This current process is the result of a substantial number of infrastructure changes to payment and recoupment procedures that were made over a period of several years. As a result, we believe it is appropriate to utilize those processes for the EPMs, given that the challenges associated with establishing these processes, as well as the fact that they were created for other CMS models.

The effect of these processes is that the batches are sent at specified intervals. The first batch is sent after the calculation error timeframe closes. The second batch is sent after CMS has responded to the notices of calculation error of EPM participants and those EPM participants choose to not proceed with the dispute resolution process detailed in section III.D.8.c. of this final rule. The final batch is sent after CMS has adjudicated all of the reconsideration reviews for those participants that selected to utilize the dispute resolution process.

Given these established operating processes, any extension in the timeframe allowed for submission of notices of calculation error delays payment not only to EPM participants that choose to utilize the calculation error and dispute resolution processes, but also those EPM participants that choose not to engage in these processes. Historically, 90 percent of BPCI awardees do not file a notice of calculation error form. As such, we believe the need for extending the deadline for submission of notices of calculation error should be balanced with CMS' goal to issue reconciliation payments and repayments promptly, as an extension for these submissions would delay the processing of reconciliation payments for all participants for a significant period of time. EPM participants have stated these monies will be used for implementing both IT and care redesign. We believe that an extension beyond the 45 days proposed would cause undue burden on non-appealing EPM participants.

We also considered the commenters' requests to extend the time frame for notice of participant-caused errors that are greater than 20 percent of the payment amount to 90 or 180 days, but we rejected these recommendations because we note that the calculation error form represents the first step in a two-step appeals process. Where an EPM participant submits a calculation form and is dissatisfied with CMS' response, the dispute resolution option is available to the EPM participant via a reconsideration review request. Upon receipt of a reconsideration review request, the date of such a review would be scheduled by CMS approximately 115 days from the issue date of the reconciliation report. Thus, we believe that the option for reconsideration review, at a much later date, provides EPM participants with adequate additional time to analyze the data on reconciliation reports, that a 90 or 180 day submission deadline for the calculation error form is unnecessary. Finally, we believe the 45 days appropriately balances the goal of CMS to process reconciliation payments on a timely basis with the needs of EPM participants to have adequate time to review their reconciliation reports and submit notices of calculation error.

Final Decision: After consideration of the public comments received, we are finalizing the proposal to allow 45 days for participants to advise CMS of errors without modification.

c. Dispute Resolution Process (Second Level of Appeal)

We proposed the following dispute resolution process. First, we proposed 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 proposed 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 that we proposed 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 proposed that 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 proposed it would first need to submit a calculation error form. Where the EPM participant does not timely submit a calculation error form, we proposed 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' 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 use of quality measure results in determining the composite quality score, the application of the composite quality score during reconciliation, or the successful reporting of the voluntary PRO THA/TKA data.

• 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, we proposed that the EPM participant need not submit a calculation error form. We proposed 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 a request is timely received, we proposed CMS would process the request as discussed later in this section.

We proposed that the reconsideration review would be an on-the-record review (a review of briefs and evidence only). The CMS reconsideration official would make reasonable efforts to notify the 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 final 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 solicited 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 sought comment on whether we should develop an alternative appeal process. We are also interested in whether there should be appeal rights for reductions or eliminations of NPRA as a result of enforcement actions, as discussed in section III.F. of the proposed rule, and if so, whether the process for such appeals should differ from the processes proposed here.

In summary, we proposed the following requirements in § 512.310(b) for the reconsideration process:

• If the EPM participant is dissatisfied with CMS' 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' response to the EPM participant's notice of calculation error, then CMS' 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 sought comment on the proposed reconsideration process for the EPMs.

The following is a summary of the comments received and our responses.

Comment: Commenters were concerned with the timing proposed in the second level appeal to submit a reconsideration request, arguing 10 calendar days is insufficient. Commenters stated that 10 calendar days is grossly inadequate for providers to analyze and seek any necessary clarification from CMS on the response, to conduct any further necessary analysis and to submit the reconsideration request. Commenters stated that the timeframe should be no less than 60 calendar days. Commenters believed this should provide sufficient time for providers to gather the necessary information and make the request. Commenters also stated that this extension accounts for other timing issues, such as holidays, that do not make 10 calendar days reasonable. Commenters also criticized the proposal regarding timeframes required for CMS responses, arguing these are not firm timeframes and that they are contradictory to those timeframes that CMS is proposing to implement for EPM participants. Commenters stated that while CMS states they will make every reasonable effort to meet these timeframes, there are no proposed consequences to CMS should they not meet them.

Response: We appreciate these comments and are sympathetic to the requests from commenters for more time to resubmit a reconsideration request. However, we believe that a longer timeframe for submission of the reconsideration request is not appropriate for the EPMs. We note the EPM participant must make the request within this timeframe and provide an explanation of the basis of the dispute. CMS will make all reasonable efforts to schedule the review to occur no later than 30 days after the date of receipt of the notification. This rule does not prevent an EPM participant from supplying supplemental documentation after they submit the request to support their basis. As such we believe that 10 days to make the request is sufficient since this deadline requires only that the EPM participant submit the request and an explanation of the basis for the dispute. Upon submitting the request for dispute resolution, the rule allows the EPM participant to submit additional supporting documentation in the interim period prior to the final review by the CMS reconsideration official.

Final Decision: After consideration of the public comments received, we are finalizing the proposal without modification.

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 the proposed rule (81 FR 50878), in instances where a notice of calculation error is not required, for example an EPM participant's termination from the EPM, we proposed 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 proposed 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. This does not apply to the limitations on review in sub-paragraph (e).

In summary, we proposed 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 sought comment on the proposed exception to the notice of calculation error process and notice of termination.

The following is a summary of the comments received and our responses.

Final Decision: CMS did not receive any comments regarding this section. Therefore, we are finalizing the proposal without modification.

e. Limitations on Review

In summary, we proposed 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 the 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 sought comment on the proposed limitations on review.

The following is a summary of the comments received and our responses.

Final Decision: CMS did not receive any comments on this section. Therefore, we are finalizing the proposal without modification.

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 proposed pay-for-performance methodologies similar to the CJR model for the proposed EPMs. Specifically, we proposed 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 7065). 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 did not propose 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 proposed to use the term anchor 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 final 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 final rule.

We recognized 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. As we stated in the proposed rule, 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 final rule for a discussion of potential future EPM episode measures.

2. Selection of 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 the 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 proposed 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 final rule. We proposed 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.

I. We refer to sections III.E.4.a. and d. of this final 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 sought comment on our proposals for AMI model quality measures.

The following is a summary of the comments received and our responses.

Comment: A few commenters supported the selection of these measures as good indicators of quality for AMI patients under the model. Commenters expressed an appreciation for the small size of the proposed measure set, compared to the larger more burdensome set of measures that have been proposed in previous demonstrations and CMS programs.

Response: We appreciate the support expressed for the small, yet comprehensive, set of measures selected for this model. 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 and we believe the small

set of measures we proposed will enable us to achieve this goal.

Comment: Several commenters expressed concern that the 30-Day All cause Risk Standardized Mortality Rate (RSMR) following Acute Myocardial Infarction is not a good indicator of quality for the EPM episode 90 day episode of care. They stated that the quality metrics proposed for AMI are too hospital centric and will not assess quality across the full continuum of care. In contrast, a few other commenters recommended that CMS narrow the window for the AMI episode from 90 days to 30 days, stating that it is known from large randomized trials of therapies for AMI patients that the overwhelming majority of disease related complications and poor outcomes occur within the first 30 days. Additionally, some commenters expressed concern that reporting quality data could discourage the treatment of the most vulnerable and frail AMI patients. Other commentators stated that patients with AMI and serious disability, frailty and concurrent illnesses would not benefit from the model quality measures as these patients may have much higher mortality rates. Commenters also expressed concern that the proposed quality metrics do not offer useful ways to risk adjust for local patterns of care regarding end of life care in hospitals for these frail, high-risk patients. Several commenters expressed concern that the measures that were proposed are misaligned with the cohort for this model. Additionally, commenters were concerned that the quality metrics as proposed may not provide a meaningful measure of the quality of care for those targeted under the model.

Response: We appreciate comments regarding the use of this measure in the model, and the duration of the episodes. While previous studies indicate that most complications occur during the 30-Day post discharge period, under this model we are evaluating the impact of a bundled payment on quality of care for a 90 day episode. For consistency sake across the model, we intend to evaluate the impact of such payment across a full 90 day period to ensure we capture longer term outcomes for patients. The models we proposed define hospitals as the episode initiators and financially accountable entities and while we acknowledge that the measures we proposed are hospital-centric, we believe they are appropriate for these hospital initiated models. We are appreciative of the concern regarding the quality of care for the beneficiaries including the frail, severely ill beneficiaries that may be included in the population on which this model is focused and that is why we proposed a comprehensive set of measures that rely on quality metrics that are readily available for use under the model. 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. We acknowledge that longer measures are needed and will begin investigating the development of measures to assess the quality of care across the full 90 day episode and if feasible, will incorporate such measures into model if deemed appropriate.

Comment: We received a mix of comments for and against the proposed EDAC measure for the AMI model. A few commenters urged CMS to remove the EDAC measures from the AMI model measure set, noting that the proposed EDAC measure was adopted for the FY 2018 hospital IQR program, and is intended to capture ''all-cause acute care utilization'' in the 30 days after discharge for patients with a discharge diagnosis of AMI. Commenters further stated that in contrast to the existing AMI hospital readmission measure in IQR, the AMI EDAC measure includes both emergency department (ED) visits and observation stays, in addition to hospital readmissions. Commenters stated the purpose of the bundled payment is to create a financial incentive that aligns with the care goal of improving the patients' health to the point where a return to the hospital is unnecessary. Measuring EDAC may be important when the financial incentives push toward greater numbers of hospital encounters, as they do in the fee for service system. However, in a bundled payment model, the commenters stated that this measure may not be as meaningful. Commenters urged CMS to alter how we think about what to measure in the bundle, stating that excess days in hospital care should not be the focus. Additionally, commenters were concerned that this measure inappropriately overlaps with the HRRP, thereby creating inconsistent incentives to reduce readmissions. Some stakeholders believe the use of this measure may lead to mixed performance signals between the existing HRRP and EPM model, potentially leading to hospitals doing well in one program and poorly in another. Some of these commenters expressed concern that the EDAC measure lacks NQF endorsement and has not yet been publicly reported on Hospital Compare. Commenters stated the hospital field has limited insight on whether the measure is accurate and reliable and also noted the lack of socio-demographic adjustment in the EDAC measure as a potential problem.

Alternatively, commenters in support of patients' rights endorsed the EDAC measure stating that it will capture all hospital contact including emergency room and observation stays. These commenters supported EDAC as it measures the full experience of a patient's stay which should be a meaningful measure of hospital care quality. Another commenter offering support for the EDAC from a patients' rights point of view stated that mortality and excess days in acute care are undoubtedly outcomes that matter to beneficiaries and their families and should absolutely be measured.

Response: We appreciate stakeholder concerns regarding inclusion of the EDAC measure in the model. Although we received fewer comments supporting the inclusion of this measure in the model, we believe the points made in favor of patients' rights and the need to measure the full hospital experience from the patient point of view are valid and relevant to this model that is designed to improve quality of care for the beneficiaries. We also note that the AMI EDAC measure has been recommended for endorsement without risk adjustment for sociodemographic status (SDS) and it will be publicly reported starting July 2017.

Regarding concerns for measure overlap with HRRP, we conducted additional comparison analysis to determine the degree to which the EDAC and readmission measures provide distinct information about hospitals' performance. In our analysis we compared hospitals' outlier status using results from both sets of measures. The findings demonstrate that more hospitals are characterized as outliers by the EDAC measures compared with the readmission measures. Therefore, the two sets of measures provide different and directionally consistent information about hospitals performance. Very few hospitals are characterized in opposing directions by the two sets of measures, meaning that those few hospitals with poorer performance on the readmission measures tend to also perform poorly on the EDAC measures.

We conclude that, with the inclusion of this measure in the AMI EPM, nearly all hospitals that are currently penalized in the HRRP will also be poor performers on the EDAC measure. However, most poor performers on the

AMI EDAC measure will not be identified as poor performers on the AMI readmissions measure. The total overlap is minimal although there is a risk that some hospitals will be penalized in both the HRRP and AMI EPM programs.

While some commenters suggest that measuring EDAC may only be important when the financial incentives push toward greater numbers of hospital encounters, as they do in the FFS system, we believe tracking return visits to the hospital is a good indicator of the overall quality of care in an episode payment model as well.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modifications, to the AMI measure set as proposed.

c. CABG Model Quality Measures

In order to encourage care collaboration among multiple providers of CABG model beneficiaries, we proposed 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 final rule. We proposed 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 final 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.

II. 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 sought comment on our proposals for CABG model quality measures.

The following is a summary of the comments received and our responses.

Comment: A few commenters support our proposed CABG measures stating that the measures represent a brief, focused and relevant set of quality metrics. They expressed support for the use of the Thirty (30) day mortality measure, stating that this measure appropriately focuses on the key quality metrics that matter in the domain of cardiac care.

Response: We appreciate the support for the model and quality metrics proposed and we also believe that these measures reflect key quality metrics that matter for cardiac care.

Comment: A commenter suggested that CMS should also consider including a quality measure to evaluate blood transfusion rates during and after CABG procedures, stating that unnecessary blood transfusions during and after CABG procedures are costly to patients and to hospitals. Perioperative red blood cell transfusion is the single factor most reliably associated with increased perioperative morbidity events after CABG, such as serious infections, prolonged ventilation support and renal failure.

Response: We thank the commenter for their suggestion. CMS believes the 30 Day All Cause Risk Standardized Mortality rate will capture complications that lead to death related to the CABG procedures performed under the model.

Comment: A group of commenters recommended that the Society of Thoracic Surgeons (STS) consensus based outcomes be included for the CABG measure set. The STS has a robust, risk adjusted National Adult Cardiac Database that tracks measures for CABG Commenters stated that the vast majority of cardiothoracic programs and provides already report to and participate in the Database.

Response: We agree with commenters that the STS measure set is a comprehensive NQF-endorsed composite measure with strong potential to meaningfully improve quality. Although the STS measures were not proposed as a measure initially we intend to amend the measure set for CABG to include a voluntary data submission for various measures (there are 11 distinct measures) within the STS composite measure. Reporting of this measure data will be voluntary and will only help model participants. This measure will count for 10 percent of the score which will be worth 2 points. We have re-weighted the CABG and HCAHPS scores out of a total point basis of 18. We will rank the overall scores out of 18 to set the performance ranges and then we offer 2 points on top of that if participants voluntarily submit data for this measure. The revised scoring and weighting methodology for the CABG model is discussed in detail in the linking quality payment section III E.4.f of this final rule.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, with modification, to incorporate the STS composite measure data submission as a voluntary option (would only help participants) weighted at 10 percent of the composite quality score as discussed in detail in section III E.4.f of this final rule. CMS does not anticipate significant operational difficulties as we plan to work collaboratively with the STS Registry to receive the data files following each data collection period as prescribed by the STS Registry. EPM participants who are not members of the STS Proprietary Registry, but are a HQR participating facility would have access to Secure File Transfer (SFT). Data files can be securely sent via SFT in a transitional submission format available to systems using a spreadsheet-based approach.

d. SHFFT Model Quality Measures

In order to encourage care collaboration among multiple providers of SHFFT model beneficiaries, we proposed 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 final 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 final 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 proposed 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 did 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 proposed that the SHFFT model be tested as discussed in section III.B.4. of the proposed rule (81 FR 50794).

We refer to sections III.E.4.c. and d. of this final 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 sought comment on our proposals for SHFFT model quality measures.

The following is a summary of the comments received and our responses.

Comment: Several commenters expressed concern that using the Hospital–level Risk Standardized Complication Rate (RSCR) measure of elective THA and/or TKA outcomes as an elective measure is an inappropriate proxy of SHFFT quality, as improving quality for the emergency procedures covered under SHFFT has no impact on RSCR. These commenters stated that the program effectively incentivizes only cutting costs without any beneficiary protection related to the quality of care. There is concern that use of this measure may distort incentives toward improving measures unrelated to care with no regard for the actual quality of an emergency SHFFT episode of care.

Response: We do not agree that the measure only incentivizes cost cutting. 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 final rule, we proposed 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 continue to 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 recognize that more robust measures better targeted to the SHFFT population are desirable and will considering future measure development focused specifically on hip and femur fracture patients.

Comment: Several commenters expressed support for the use of Patient Reported Outcome Measures (PROM) in SHFFT, and were supportive of plans to incentivize model participants who report PROMs.

Response: We appreciate the support for collection of PRO data in this model and believe that patient outcome data which will help develop quality PROMs can be helpful in measuring the quality of care rendered under this model.

Comment: A few commenters expressed concern that the model doesn't include functional outcome measures and quality of life measures to assess the quality of life for the patient population. Commenters recommend that we consider performance-measures of function for the population such as the Six-Minute Walk Test. Including functional performance measures will give CMS better data on the functional outcome of this patient population. Commenters expressed concern that while the measures proposed for use in this model mirror those in the CJR model, and considering the SHFFT model will be operating alongside the CJR episodes the SHFFT model composition of mostly non-elective cases precludes that the population between the two models have stark differences. Therefore, simply transferring the data from one EPM to another is not appropriate. Commenters urged CMS to develop measures that more accurately reflect the populations included in the model specifically.

Response: We appreciate the commenter thoughts regarding utilizing quality metrics to accurately measure and account for the patient population served under the SHFFT model specifically, in contrast to those in the concurrent CJR model. We believe that we have proposed a measure set of readily available measures to assess the quality of care across the SHFFT episodes. We will continue to investigate utilizing measures to more accurately reflect the patient population in this model.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to the quality measures proposed in the SHFFT model.

3. 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 the proposed rule (81 FR 50794), which outlines the pricing methodologies for EPM episodes, for each EPM participant we proposed 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 final rule for further discussion of the relationship between an EPM participant's quality performance and improvement and the effective discount factor. As discussed in section III.C.4.a.(5) of this final rule, we are not finalizing our proposed AMI model inpatient-to-inpatient transfer episode initiation and attribution policy so we will not use the terms chained anchor hospitalization and price MS–DRG in the final AMI episode definition and quality discussion. 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 hospitalization. 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 the proposed rule (81 FR 50794). 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 proposed 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 sought 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.

Final Decision: No comments were received on the EPM-specific composite quality score in the pay-for-performance methodologies of the AMI, CABG, and SHFFT models. Therefore, we are finalizing the proposal, without modification.

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 proposed to assign each EPM participant's measure point estimate from the most recent year as discussed in section III.E.5. of this final 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 22.

TABLE 22—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 We have 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 the proposed rule (81 FR 50794).

We sought 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.

No comments were received on this proposal so we are finalizing without modification.

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 proposed 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 proposed 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 proposed 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 proposed 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 proposed to modify the definition of improvement used in the CJR model in two ways (80 FR 73379 through 73380). First, we proposed 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 proposed 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 the proposed rule (81

FR 50794), 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 the proposed rule (81 FR 50794), we proposed 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 sought comment on our proposals to determine quality measure improvement for the AMI, CABG, and SHFFT models.

The following is a summary of the comments received and our responses.

Comment: A few commenters expressed concern that the improvement thresholds are inappropriate, and are not feasible to allow a hospital to earn improvement points. Commenters suggested the CMS consider a scoring methodology similar to the Hospital Value Based Purchasing scoring methodology in this model.

Response: We appreciate the concern regarding measuring improvement under the model. We did not propose to use the HBVP methodology that assigns either improvement or performance points to quality measures. 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. Thus, the EPM methodology, in comparison with HVBP, provides improvement points as a bonus on top of performance points. We believe improvement points should be awarded only when meaningful improvement is achieved and hospitals will be able to receive improvement points when they achieve meaningful improvement performance For example, 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.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification to methodology to determine quality measure improvement for 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 proposed 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 the proposed rule (81 FR 50794). We sought comment on our proposals for determining successful submission of voluntary data for each AMI model performance year.

Final Decision: No comments were received on this proposal. Therefore we are finalizing the proposal, without modification.

(2) Patient-Reported Outcomes and Limited Risk Variable Voluntary Data Following Elective Primary THA/TKA

Like the CJR model, we proposed 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 the proposed rule (81 FR 50794). We sought comment on our proposals for determining successful submission of voluntary data for each SHFFT model performance year.

Final Decision: No comments were received on this proposal. Therefore we are finalizing the proposal without modification.

e. Calculation of the EPM-Specific Composite Quality Score

(1) AMI Model Composite Quality Score

We proposed 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 23.

TABLE 23—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 proposed to assign the highest individual measure weight of 50 percent to the MORT–30–AMI (NQF #0230) measure. We proposed 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 did 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 24. These individual measure scores have been set to reflect the measure weights included in Table 23 so they can ultimately be summed without adjustment in calculating the AMI model composite quality score.

TABLE 24—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
≥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 proposed 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 proposed 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 sought comment on our proposed methodology to calculate the AMI model composite quality score.

The following is a summary of the comments received and our responses.

Comment: A group of commenters believe the 30 Day Mortality measure is weighted too heavily under the proposed model. Several commenters expressed concern that this measure will not accurately measure quality of care across the proposed 90-day episode of care and therefore should not be weighted so heavily.

Response: We appreciate the comments regarding the heavy weighting that was proposed for the 30-Day Mortality measure. Mortality is a very serious outcome for AMI care and is one that model participants should manage to avoid. We have chosen to weight this measure so heavily because there at not many measures that will accurately measure quality for the EPM model. The mortality measure will assess a specific serious outcomes for these episodes, therefore we proposed high weights for this measure in the scoring methodology.

Comment: Several commenters expressed concerned that HCAHPS are inappropriate and misaligned quality metric for this model. Several commenters have stated that this measure is hospital centric and will not address the patient experience of care for the entire episode therefore weighting this measure in the scoring methodology is an inappropriate approach to hold participants accountable for the overall beneficiary satisfaction during an episode. There is a general consensus that these measures are poorly aligned with the proposed cohorts.

Response: We appreciate the concern that the use of HCAHPS may not accurately assess patient satisfaction and quality related to the model specifically. However we have proposed the use of this instrument to access the patient satisfaction under the model as a readily available instrument to assess quality of care for patients. We will include the HCAHPS survey measure instrument until other alternative measures are available.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification to the AMI composite quality scoring methodology.

(2) CABG Model Composite Quality Score

We proposed 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 25.

TABLE 25—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 proposed 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 proposed 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 did 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 26. These individual measure scores have been set to reflect the measure weights included in Table 25 so they can ultimately be summed without adjustment in calculating the CABG model composite quality score.

TABLE 26—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 sought comment on our proposed methodology to calculate the CABG model composite quality score.

The following is a summary of the comments received and our responses.

Comment: A group of commenters believe the 30 Day Mortality measure is weighted too heavily under the proposed model. Several commenters expressed concern that this measure will not accurately measure quality of care across the proposed 90-day episode of care and therefore should not be weighted so heavily. Several commenters expressed concern about the proposed weighting of the MORT–30–CABG at 50 percent pf the composite quality score because the high weight assigned to the (RSMR) 30 day-mortality rate could encourage inappropriate treatment such as total revascularization even when not clinically indicated at the time of the acute event.

Response: We appreciate the comments regarding the heavy weighting that was proposed for the 30-Day Mortality measure. Mortality is a very serious outcome for CABG care and is one that model participants should manage to avoid. We have chosen to weight this measure so heavily because there at not many measures that will accurately measure quality for the EPM model. The mortality measure will assess a specific serious outcomes for these episodes, therefore we proposed

high weights for this measure in the scoring methodology. We do not believe the use of this measure will lead to inappropriate treatment and intend to monitor for such activities under the model. However, we note that we will be making a slight downward adjustment in the weight this measure carries, from 75 percent to 70 percent in response to comments asking us to incorporate the STS composite CABG measure in our CABG model.

Comment: Several commenters expressed that the use of HCAHPS is inappropriate in the model and recommended removal of these measures. These is concern that the HCAHP scores reflect an entire patient population and not just those included in the EPM episodes specifically. There is also concern that HCAHPS fail to address several important aspects of the EPM episode, and instead focus on aspects of care that not are germane to the episode like ''quietness'' of a hospital for example. Commenters believe the use of these measures and weighting of the measures for this model is inappropriate and a misaligned approach to linking quality of care to payment under the model.

Response: We appreciate the concerns regarding HCAHPS and as mentioned in the proposed rule recognizes the misalignment of measures that exists for the patient population and cohort under the model. However, there are limited instruments available to measure patient experience available at this time. We have chosen to rely on these metrics to assess patient satisfaction under the model. The HCAHPS are a reliable set of metrics widely accepted to adequately measure patient experience. However, we note that we will be making a slight downward adjustment in the weight this measure carries, from 25 percent to 20: Percent in response to comments asking us to incorporate the STS composite CABG measure in our CABG model.

Comment: A group of commenters recommended that the STS measure set be included in the CABG measure set as a comprehensive set of measures currently utilized by several providers to access the quality of care for patients.

Response: We appreciate the feedback regarding the inclusion of the STS measures into the CABG model to offer a more comprehensive measure set. As a result the CABG quality composite score will be revised to include these measures be reported as a voluntary measures. Following our standing policy for CJR and for the other models in this final rule, voluntary measures are set to a composite score weight of 10 percent. Since we had previously allocated 100 percent of the composite weight over the two proposed measures, to be responsive to these comments we also need to adjust the proposed weighting for the mortality and HCAHPS measures. The revised weighting for the CABG measures is shown in the following revised tables 27 and 28:

TABLE 27—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)	70	Outcome/80%.
STS Composite CABG voluntary data submission (NQF #0696)	10	
HCAHPS Survey (NQF #0166)	20	Patient Experience/20%.

TABLE 28—INDIVIDUAL SCORING FOR TWO REQUIRED CABG QUALITY MEASURES

Performance percentile	MORT–30–CABG (points)	HCAHPS survey (points)
≥90th	14	4
≥80th and <90th	12.95	3.7
≥70th and <80th	11.90	3.4
≥60th and <70th	10.85	3.1
≥50th and <60th	9.80	2.8
≥40th and <50th	8.75	2.5
≥30th and <40th	7.70	2.2
<30th	0	0

Final Decision: After consideration of the public comments received, we are finalizing the proposal, with modification, to include the STS measures as voluntary measures with the revised weights displayed in Tables 27 and 28.

(3) SHFFT Model Composite Quality Score

We proposed 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 the proposed rule (81 FR 50794). 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 FR 73370 through 73381). We proposed 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 41.

TABLE 29—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 proposed 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 proposed 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 30. These individual measure scores have been set to reflect the measure weights included in Table 29 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 30—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 proposed 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 sought comment on our proposed methodology to calculate the SHFFT model composite quality score.

The following is a summary of the comments received and our responses.

Comment: Several commenters expressed that the use of HCAHPS is inappropriate in the model and recommended removal of these measures. These is concern that the HCAHP scores reflect an entire patient population and not just those included in the EPM episodes specifically. There is also concern that HCAHPS fail to address several important aspects of the EPM episode, and instead focus on aspects of care that not germane to the episode like ''quietness'' of a hospital for example. Commenters believe the use of these measures and weighting of the measures for this model is inappropriate and a misaligned approach to linking quality of care to payment under the model.

Response: We appreciate the concerns regarding HCAHPS and as mentioned in the proposed rule recognizes the misalignment of measures that exists for the patient population and cohort under the model. However, there are limited instruments available to measure patient experience available at this time. We have chosen to rely on these metrics to assess patient satisfaction under the model. The HCAHPS are a reliable set of metrics widely accepted to adequately measure patient experience.

Comment: Several commenters urged CMS to use the CJR composite scoring methodology.

Response: We appreciate the support for utilizing the CJR composite scoring methodology in the SHFFT model as proposed. We believe the SHFFT model composite scoring methodology accurately reflects the quality measures that will be assessed under the model.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification.

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 proposed 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 final 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.

The following is a summary of the comments received and our responses.

Comment: A commenter suggests that CMS heavily skew the point distributions for the models so that the majority of the hospitals fall into the ''good'' category of performance. There is concern that the disparity between excellent and good would be great across the model using the proposed methodology. Commenters believe the bar for achieving ''excellent'' care is set too high and strongly recommended that threshold be lowered to allow for more hospitals to be placed into the ''excellent'' category under the three models. Lowering the ''excellent'' threshold would correctly recognize additional institutions that are achieving high levels of quality of care for their patients.

Response: We disagree with the commenters that the bar for achieving excellent care is set too high. In modeling the score ranges for the different improvement categories, we are assuming that the majority of model participants will score within the 'good' category. We have proposed to award up to 10 percent of the maximum measure points available and believe that the standard for providing excellent quality of care should be high.

Comment: A commenter supports CMS's stated belief that the EPM models should use the pay for performance methodologies that simultaneously reward improvement in patient outcomes and lower health care spending. The commenter supports the proposal to pay on a quality first principle: Only sharing saving with hospitals that achieve quality scores above the 30th percentile and weighting the discount percentage based on quality performance.

Response: We acknowledge and appreciate your support for the payment methodology and quality driven focus of this model. CMS is committed to linking payments to the quality of care delivered across this model.

Comment: A commenter urged CMS to explore a reward for higher quality, and consider paying bonuses to hospitals which improve quality while keeping costs stable. Under the proposed model there is no reward for a hospital that achieves better outcomes for its patients at the same cost. Under the proposed model, quality measurement only comes into play as a punitive measure. If spending is the same but quality is higher, there is no bonus.

Response: The basic design of the EPMs requires savings to Medicare first, before any payment would be made to EPM participants for future savings Thus, the payments to EPM participants are not ''bonus'' Payments to participants may vary based on episode quality. Quality is not used as a ''punitive'' measure but, rather, improved quality allows EPM participants to receive a higher amount of their savings achieved. No payment is made to any EPM participant under the design when there are no measurable savings to the Medicare program. Rewarding hospitals who achieve higher quality at the same cost is not within the scope of this model or the intent.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification.

(2) AMI and CABG Model Pay-for-Performance Methodologies

(a) AMI Model Pay-for-Performance Methodology

We proposed 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 31, 32, and 33 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.[91]

TABLE 31—PERFORMANCE YEAR 1 (ALL PARTICIPANTS) AND PERFORMANCE YEAR 2 (FOR PARTICIPANTS WHO DO NOT ELECT EARLY DOWNSIDE RISK): RELATIONSHIP OF AMI MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

AMI model composite quality score (proposed)	AMI model composite quality score (final)	Eligible for reconciliation payment	Effective discount factor for reconciliation payment (%)	Effective discount factor for repayment amount
<3.6	<3.8	No	3.0	Not applicable.
>=3.6 and <6.9	>=3.8 and <6.3	Yes	3.0	Not applicable.
>=6.9 and <=14.8	>=6.3 and <=15.0	Yes	2.0	Not applicable.
>14.8	>15.0	Yes	1.5	Not applicable.

TABLE 32—PERFORMANCE YEARS 2 (FOR PARTICIPANTS WHO ELECT EARLY DOWNSIDE RISK ONLY), 3 AND 4: RELATIONSHIP OF AMI MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

AMI model composite quality score (propose)	AMI model composite quality score (final)	Eligible for reconciliation payment	Effective discount factor for reconciliation payment (%)	Applicable discount factor for repayment amount * (%)
<3.6	<3.8	No	3.0	2.0
>=3.6 and <6.9	>=3.8 and <6.3	Yes	3.0	2.0
>=6.9 and <=14.8	>=6.3 and <=15.0	Yes	2.0	1.0
>14.8	>15.0	Yes	1.5	0.5

* The applicable discount factor for the repayment amount only applies in performance years 2 (for participants who choose early downside risk) and 3 (for all other participants) when repayment responsibility is being phased-in.

TABLE 33—PERFORMANCE YEAR 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 (proposed)	AMI model composite quality score (final)	Eligible for reconciliation payment	Effective discount factor for reconciliation payment (%)	Applicable discount factor for repayment amount (%)
<3.6	<=3.7	No	3.0	3.0
>=3.6 and <6.9	>3.7 and <= 6.25	Yes	3.0	3.0
>=6.9 and <=14.8	>6.25 and <=15.0	Yes	2.0	2.0
>14.8	>15.0	Yes	1.5	1.5

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 31, 32, and 33.

Under this methodology, we proposed to require AMI model participants to achieve a minimum AMI model

[91] 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.

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.

We proposed that 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.

We proposed that 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, we proposed that 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 final rule will 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 sought comment on our proposal to link quality to payment in the AMI model pay-for-performance methodology.

We did not receive comments which uniquely addressed the proposed AMI model pay-for-performance methodology.

Final Decision: Although we did not receive comments on the proposed AMI model pay-for-performance methodology, adjustments to our proposal are necessary due to the final selection of actual EPM MSAs and our policy for participants who elect early downside risk as discussed in section III.D.2.c. of this final rule. Specifically, in our proposed rule we created composite quality score ranges for the AMI measure based on historical performance of a representative group of hospitals within 98 potentially EPM-eligible MSAs. However, for the final rule we have randomly selected 98 MSAs in which to officially conduct the EPM models. Therefore, the composite quality score ranges associated with each quality performance category we are finalizing in this rule are based on a model of historical performance in the actual 98 MSAs selected for this model. Final AMI model composite quality score ranges, associated quality performance categories and discounts are reflected in tables 31, 32, and 33. After consideration of the public comments received, we are finalizing the proposal, with modification to final composite quality score ranges to reflect selection of MSAs, as discussed here.

(b) CABG Model Pay-for-Performance Methodology

We proposed 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 34, D24, and D25 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.[92]

TABLE 34—PERFORMANCE YEAR 1 (ALL PARTICIPANTS) AND PERFORMANCE YEAR 2 (FOR PARTICIPANTS WHO DO NOT ELECT EARLY DOWNSIDE RISK): RELATIONSHIP OF CABG MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

CABG model composite quality score (proposed)	CABG model composite quality score (final)	Eligible for reconciliation payment	Effective discount factor for reconciliation payment (%)	Effective discount factor for repayment amount
<2.8	<=2.2	No	3.0	Not applicable.
>=2.8 and <4.8	>2.2 and <=3.4	Yes	3.0	Not applicable.
>=4.8 and <=17.5	>3.4 and <=16.2	Yes	2.0	Not applicable.
>17.5	>16.2	Yes	1.5	Not applicable.

TABLE 35—PERFORMANCE YEARS 2 (FOR PARTICIPANTS WHO ELECT EARLY DOWNSIDE RISK ONLY), 3 AND 4: RELATIONSHIP OF CABG MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

CABG model composite quality score (proposed)	CABG model composite quality score (final)	Eligible for reconciliation payment	Effective discount factor for reconciliation payment (%)	Applicable discount factor for repayment amount * (%)
<2.8	<2.5	No	3.0	2.0
>=2.8 and <4.8	>=2.5 and <3.5	Yes	3.0	2.0
>=4.8 and <=17.5	>=3.5 and <=16.2	Yes	2.0	1.0
>17.5	>16.2	Yes	1.5	0.5

* The applicable discount factor for the repayment amount only applies in performance years 2 (for participants who choose early downside risk) and 3 (for all other participants) when repayment responsibility is being phased-in.

TABLE 36—PERFORMANCE YEAR 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 (proposed)	CABG model composite quality score (final)	Eligible for reconciliation payment	Effective discount factor for reconciliation payment (%)	Applicable discount factor for repayment amount (%)
<2.8	<2.5	No	3.0	3.0
>=2.8 and <4.8	>=2.5 and <3.5	Yes	3.0	3.0
>=4.8 and <=17.5	>=3.5 and <=16.2	Yes	2.0	2.0
>17.5	>16.2	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 34, 35, and 36.

Under this methodology, we proposed that 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. We proposed that 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.

[92] 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.

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.

We proposed that 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.

We proposed that 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, we proposed that 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 final rule will 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 sought comment on our proposal to link quality to payment in the CABG model pay-for-performance methodology.

We did not receive comments which uniquely addressed our proposed CABG model pay-for-performance methodology.

Final Decision: Although we did not receive comments on the proposed CABG model pay-for-performance methodology, adjustments to our proposal are necessary due to selection of the EPM MSAs and our policy for participants who elect early downside risk as discussed in section III.D.2.c. of this final rule. Specifically, in our proposed rule we created composite quality score ranges for the CABG measure based on historical performance of a representative group of hospitals within 98 potentially EPM-eligible MSAs. However, for the final rule we have randomly selected 98 MSAs in which to officially conduct the EPM models. Therefore, the composite quality score ranges associated with each quality performance category we are finalizing in this rule are based on a model of historical performance of in the actual 98 MSAs selected for this model. Final CABG model composite quality score ranges, associated quality performance categories and discounts are reflected in tables 34, 35, and 36. After consideration of the public comments received, we are finalizing the proposal, with modification to final composite quality score ranges to reflect selection of MSAs, as discussed here

(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 III.D.2.c. of the proposed rule (81 FR 50794), we proposed 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.[93] However, because we proposed 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

[93] 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.

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 did 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 sought 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.

Final Decision: No comments were received on the proposed pay for performance methodology. Therefore, we are finalizing the proposal, without modification.

(3) SHFFT Model Pay-for-Performance Methodology

We proposed 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 37, 38, 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 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.[94]

We refer to section V.E. of this final 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 37 through 39 are the corrected ranges that also apply to the CJR model.

TABLE 37—PERFORMANCE YEAR 1 (ALL PARTICIPANTS) AND PERFORMANCE YEAR 2 (FOR PARTICIPANTS WHO DO NOT ELECT EARLY DOWNSIDE RISK): RELATIONSHIP OF SHFFT MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

SHFFT model composite quality score (proposed)	SHFFT model composite quality score (final)	Eligible for reconciliation payment	Effective discount factor for reconciliation payment (%)	Effective discount factor for repayment amount
<5.0	<5.0	No	3.0	Not applicable.
>=5.0 and <6.9	>=5.0 and <6.9	Yes	3.0	Not applicable.
>=6.9 and <=15.0	>=6.9 and <=15.0	Yes	2.0	Not applicable.
>15.0	>15.0	Yes	1.5	Not applicable.

TABLE 38—PERFORMANCE YEARS 2 (FOR PARTICIPANTS WHO ELECT EARLY DOWNSIDE RISK ONLY), 3 AND 4: RELATIONSHIP OF SHFFT MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

SHFFT model composite quality score (proposed)	SHFFT model composite quality score (final)	Eligible for reconciliation payment	Effective discount factor for reconciliation payment (%)	Applicable discount factor for repayment amount * (%)
<5.0	<5.0	No	3.0	2.0
>=5.0 and <6.9	>=5.0 and <6.9	Yes	3.0	2.0
>=6.9 and <=15.0	>=6.9 and <=15.0	Yes	2.0	1.0
>15.0	>15.0	Yes	1.5	0.5

* The applicable discount factor for the repayment amount only applies in performance years 2 (for participants who choose early downside risk) and 3 (for all other participants) when repayment responsibility is being phased-in.

[94] 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.

TABLE 39—PERFORMANCE YEAR 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 (proposed)	SHFFT model composite quality score (final)	Eligible for reconciliation payment	Effective discount factor for reconciliation payment (%)	Effective discount factor for repayment amount (%)
<5.0	<5.0	No	3.0	3.0
>=5.0 and <6.9	>=5.0 and <6.9	Yes	3.0	3.0
>=6.9 and <=15.0	>=6.9 and <=15.0	Yes	2.0	2.0
>15.0	>15.0	Yes	1.5	1.5

Under this methodology, we proposed that 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. We proposed that 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 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.

We proposed that 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.

We proposed that 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, we proposed that 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 final rule will 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 sought comment on our proposal to link quality to payment in the SHFFT model pay-for-performance methodology.

We did not receive comments on the proposed SHFFT model pay-for-performance methodology.

Final Decision: We are finalizing without modification our proposal for 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.[95] 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

[95] Agency for Healthcare Research and Quality (AHRQ). Healthcare Cost and Utilization Project (HCUP) *http://hcupnet.ahrq.gov/.*

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 health care system.[96]

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.[97] [98] 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 an 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 is 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 proposed to use Medicare Part A and Part B FFS claims submitted by the 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 proposed 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 final 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 proposed 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 term 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 the proposed rule (81 FR 50794), 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

[96] American Heart Association. Heart Disease and Stroke Statistics—2010 Update. Dallas, Texas: American Heart Association; 2010. c2010, American Heart Association.

[97] 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.

[98] 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.

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 proposed 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 the proposed rule (81 FR 50794), 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 sought 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.

The following is a summary of the comments received and our responses.

Comment: One commenter supported the proposal to use mortality rates as the principal outcome measure for the cardiac EPMs. The commenter agreed that mortality is an extremely serious outcome for these episodes, and it has the added benefit of not requiring adjustment for SES, demographic, or environmental risk factors.

Response: We thank the commenter for their support.

Comment: Several commenters expressed concern about the proposed weighting of the 30-day risk-standardized mortality rate (RSMR) at 50 percent of the composite quality score because the high weight assigned to the risk-standardized 30-day mortality rate could encourage inappropriate treatment such as total revascularization even when not clinically indicated at the time of the acute event. One commenter was also concerned that with this weighting proposal, hospitals with fewer AMI cases would be further disadvantaged since there will be less data used to calculate the hospital's quality score.

Response: To ensure hospitals have enough cases to produce a valid quality score, the AMI mortality measure uses 3 years of claims data to calculate the measure. Hospitals must have at least 25 qualifying index admissions within the 3-year measurement period to calculate and publically report a measure result. We do not believe these measures disadvantage smaller volume hospitals. We have found hospitals with fewer cases tend to have measure results that are close to the national average, hospital rate and are therefore rarely identified as poor performing outliers.

Comment: One commenter recommended excluding cardiogenic shock and sepsis patients because patients with either of these conditions and AMI have a higher mortality rate than those who do not.

Response: In order to account for differences in patient mix among hospitals, the measures adjust for variables (for example, age, comorbid diseases, and indicators of patient frailty) that are clinically relevant and have relationships with the outcome. In the case of the AMI measure, we risk adjust for cardio-respiratory failure or shock. However the measure's risk model does not include a risk variable for sepsis.

Comment: Several commenters requested clarification or expressed concern about attribution of the measure outcome to hospitals when patients are transferred among acute-care hospitals. One commenter suggested that hospitalizations that include transfers among institutions be excluded or that the AMI mortality measure not be used in cases where there was a transfer. Another commenter suggested that the current method within the AMI mortality measure of attributing the outcome to the transferring hospital, rather than the receiving hospital should be changed.

Response: In the AMI mortality measures, for patients transferred from one short-term acute care hospital to another, only the first admission in the transfer chain is eligible for inclusion in the cohort. The subsequent admissions are not included. The measures assign a death that occurs within 30 days to the hospital that initially admitted the patient as an inpatient. For example, if a patient is admitted to Hospital A for AMI and then transfers to Hospital B,

only the Hospital A admission (the index admission) would be included in the cohort, and death within 30 days of the Hospital A admission would be captured in Hospital A's AMI mortality outcome. The rationale for this approach is that the initial admitting hospital makes diagnostic and treatment decisions which exert great influence on a patient's risk of mortality in AMI cases even when patient transfers are warranted, for example, for interventions that cannot be provided at the initial admitting institution, such as cardiac catheterization.

Comment: One commenter expressed concern that having 50 percent of an EPM participant's quality score for AMI and 75 percent of a participant's quality score for CABG based upon 30-day hospital mortality places a heavy reliance on only a few quality measures. Furthermore, the commenter believed that the heavy emphasis on 30-day mortality could disadvantage smaller hospitals with relatively low AMI/CABG admissions, such that a few adverse outcomes could disproportionately impact the hospital's quality score.

Response: To ensure hospitals have enough cases to produce a valid quality score, the AMI mortality measure uses 3 years of claims data to calculate the measure. Hospitals must have at least 25 qualifying index admissions within the 3-year measurement period to calculate and publically report a measure result. We do not believe these measures disadvantage smaller volume hospitals. We have found hospitals with few cases tend to have measure results that are close to the average hospital rate and are therefore rarely identified as poor performing outliers.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, 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.[99] [100]

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.[101] 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.[102] [103] 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 proposed 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 proposed 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.

[99] 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.

[100] 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):459–46

[101] 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.*

[102] 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. 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.

[103] 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.

(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 proposed 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 final rule for a discussion of AMI model participant selection.

(d) Inclusion and Exclusion Criteria

We proposed that an index admission is the hospitalization to which the excess days in acute care 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 term 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 the proposed rule (81 FR 50794), 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 proposed 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 health care 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 proposed 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 final 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 final 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 41.

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 sought 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.

The following is a summary of the comments received and our responses.

Comment: Several commenters stated that certain characteristics of the patient population, such as patient expectations, health literacy, inadequate transportation, lack of caregiver support, and socioeconomic status, contribute to the rate of post-discharge hospitalizations and disadvantage hospitals serving poorer populations.

Response: We appreciate the commenters' concerns that socioeconomic factors influence patient's risk of post-discharge returns to the hospital for acute care. The AMI EDAC measure currently does not include socioeconomic factors in the risk-adjustment model. We routinely monitor the impact of SDS on providers' differential performance on our outcome and payment measure.

The NQF is currently conducting a 2-year trial, in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. This trial entails temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF is expected to issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are encouraged to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model. Several measures developed by CMS have been brought to NQF since the beginning of the trial, including the AMI EDAC measure which was submitted to NQF in January 2016 and is a part of the trial. Under the guidance of NQF, we are making every effort to be proactive in examining SDS factors in quality measures by testing SDS factors in the measures' risk models and making recommendations about whether or not to include these factors in the endorsed measure. We are still awaiting final recommendations from the NQF and intend to continue engaging in the NQF process as we consider the appropriateness of adjusting for SDS factors in our outcome measures. For more detailed information about measures in the NQF SDS trial period, we refer commenters to: *http://www.qualityforum.org/SES_Trial_Period.aspx*. Furthermore, we are awaiting the findings of an ASPE report on SDS factors in risk-adjustment. Therefore, we are not currently changing our risk-adjustment methodology with respect to SDS factors at this time. We will continue to consider such factors in our ongoing measure development and maintenance activities.

Comment: Two commenters opposed the AMI EDAC measure because it measures quality based partly on care provided in settings and facilities other than those of the initial discharging hospital.

Response: We believe these measures reflect the actions of hospitals and the care their patients receive post-discharge. Hospitals providing quality inpatient care, conducting appropriate discharge planning, and working with providers and suppliers on appropriate follow-up care will likely perform well, because the Medicare beneficiaries they serve will have a reduced need for excessive post-discharge services. The risk adjustment methodology used for these measures acknowledge the differences in a given hospital's patient case mix, so that their performance can be compared to a national average. We recognize that the structure of health care markets and practice patterns vary geographically, beyond the variation in patient case mix. However, as previously mentioned, we believe that the aforementioned opportunities for hospitals to exert control over post-discharge services exist, regardless of the degree of integration of a health system. In cases where systems are not well-integrated, there may be an even greater opportunity for redesign of care processes to achieve high performance on these measures. We are collaborating with our postacute care quality programs and we will take the commenters' suggestions that similar measures should be incorporated into those programs under consideration. However, we do not believe that it would be appropriate to delay adoption of this measure and the public reporting of this valuable and actionable payment information until such time as any similar, postacute care measures are implemented.

Comment: Several commenters expressed concern with the outcome of the AMI EDAC measures, questioning whether excess days in acute care provides a signal of quality. One commenter opposed the AMI EDAC measure because high readmission rates could stem from the need to care for chronically ill patients. The commenter stated that hospitals should not be punished for high readmission rates when they are associated with lower mortality rates and good access to inpatient hospital care.

Response: We disagree that excess days in acute care does not provide a signal of quality. Our discussions with patients and the TEP, as well as published literature, indicate that acute care utilization after discharge (that is, return to the ED, observation stay, and readmission), for any reason, is disruptive to patients and caregivers, costly to the health care system, and puts patients at additional risk of hospital-acquired infections and complications. These measures are meant to provide patients with a more complete picture of potential post-discharge acute care use as they make choices for their care. We are confident that for most patients, remaining home or remaining in a non-acute setting rather than returning to the hospital

indicates a better outcome. Although some hospital returns are unavoidable, others may result from poor quality of care, overutilization of care or inadequate transitional care. Transitional care includes effective discharge planning, transfer of information at the time of discharge, patient assessment and education, and coordination-of-care and monitoring in the post-discharge period. When appropriate care transition processes are in place (for example, a patient is discharged to a suitable location, communication occurs between clinicians, medications are correctly reconciled, timely follow-up is arranged), fewer patients return to an acute care setting, either for an ED visit, observation stay, or hospital readmission during the 30 days post-discharge. Numerous studies have found an association between quality of inpatient or transitional care and early (typically 30-day) readmission rates [104] and ED visits [105] or a wide range of conditions including AMI.

With respect to the commenter's concern that some hospitals care for a greater number of chronically ill patients, although the measures cannot capture all reasons for variability among hospitals, the EDAC measures incorporate risk adjustment using claims data to account for patient factors that could account for the observed variability. The measures use claims based risk adjusters that are clinically relevant and have strong relationships with the outcome as has been done in other claims-based outcome measures in the Hospital IQR Program. This approach was supported by the TEP. We understand that hospitals have complex patients with varying comorbidities. Although the cohort may contain patients with different disease severity, and therefore, different levels of risk, the measure accounts for this range of severity and risk because it is risk-adjusted for 65 factors that are clinically relevant and have strong relationships with the outcome of acute care utilization.

With respect to the comment that hospitals not be punished for readmission if they reduce patient mortality, the goal of these measures is not to punish hospitals for appropriate readmissions; it is to help patients and providers understand variation among hospitals in the days that are spent by patients in acute care settings following a discharge for AMI. The measures provide a broader perspective on post-discharge events than the current readmission measures and are intended to incentivize improvements in care transitions from the hospital so that patients are less likely to return to the acute setting.

Comment: One commenter recommended the AMI EDAC measure be removed from the model to create a better balance of provider risk and reward. One commenter noted that costs of a hospital emergency department or observation visit following an index admission is already captured and will impact a hospital's reimbursement in this EPM. The commenter stated that hospitals should not be further penalized by including this measure in the quality component. The commenter also opposed the AMI EDAC measure because it was not included in the list of recommended quality measures in the HCP LAN ''Accelerating and Aligning Clinical Episode Payment Models: Coronary Artery Disease'' draft whitepaper released in May, 2016.

Response: We interpreted this commenter's concern to be that because visits to the emergency department and observation stays are less costly than readmissions, by combining all of these types of visits into a single outcome, providers are not incentivized to use the lower cost settings to deliver care whenever appropriate. We agree that all acute care utilization is not equal in its disruption, cost, or risk to patients. In the AMI EDAC measure, the weight of events (such as observation or ED care) is determined by the intensity of care delivered to patients. Prolonged acute care is more costly and worse from a patient perspective than a brief ED visit. That is why we elected to report the AMI EDAC measure as a count of days: Events lasting longer with more cost and disruption (such as readmissions), therefore, naturally weigh more than brief events (such as ED visits) in the overall day count. This approach is based on the believe that, from a patient perspective, it is the count of total days spent in acute care settings that is most meaningful and representative of the disruption, which is why we combine day counts for each type of event and do not separately report rates of each type of event. This day count is also valuable for hospitals, because a hospital with a high number of ED visits may still be able to achieve a low number of total days in acute care by actively coordinating care from the ED and avoiding re-hospitalizations. Because the EDAC measure had not previously been publically reported at the time of the HCP LAN report in May 2016, they did not consider it for inclusion on the list of potential measures to be used in cardiovascular episode of payment models. However, the AMI and CABG readmission measures were recommended suggesting that the HCP LAN did consider the prevention or reduction of post-discharge acute care use as an important quality metric to include in cardiovascular episode payment models.

Comment: One commenter supported inclusion of the AMI EDAC measure in the AMI EPM bundle and recommended CMS include a measure of excess days in acute care for the CABG and surgical hip and femur fracture treatment EPM bundles.

Response: We thank the commenters for their support and will consider additional measure development as was suggested.

Comment: One commenter stated that the AMI EDAC measure will not be helpful to beneficiaries in navigating their care nor will the measure be actionable for hospitals given that physicians dictate the discharge date.

Response: We disagree that the AMI EDAC measure will not be helpful to beneficiaries. We have developed the AMI EDAC measure to try to provide important patient-centered information to providers. The measure supports existing hospital incentives to further invest in interventions and tools to improve hospital care, better respond to individual patient preferences, better assess patient readiness for discharge, and facilitate transitions to outpatient status. Such interventions and tools will reduce the likelihood of patients having any return to the hospital and make it more likely that patients who do return have less severe illnesses which may require fewer days of care. We disagree that providers do not have the ability to take meaningful actions that would have an impact on patient outcomes as a result of adopting the AMI EDAC

[104] Dean NC, Bateman KA, Donnelly SM, Silver MP, Snow GL, Hale D. Improved clinical outcomes with utilization of a community-acquired pneumonia guideline. Chest. 2006;130(3):794–799.

Coleman EA, Parry C, Chalmers S, et al. 2006. The care transitions intervention: Results of a randomized controlled trial. Arch Intern Med 166:1822–1828.

Coleman EA, Smith JD, Frank JC, Min SJ, Parry C, Kramer AM. Preparing patients and caregivers to participate in care delivered across settings: The Care Transitions Intervention. J Am Geriatr Soc 2004;52(11):1817–25.

Hansen LO, Young RS, Hinami K, et al. Interventions to reduce 30-day rehospitalization: A systematic review. 2011; 155(8):520–8.

Leppin AL, Gionfriddo MR, Kessler M, et al. Preventing 30-day hospital readmissions: A systematic review and meta-analysis of randomized trials. JAMA Internal Med. 2014; 174(7):1095–107.

Hansen LO, Young RS, Hinami K, et al. Interventions to reduce 30-day rehospitalization: A systematic review. 2011; 155(8):520–8.

[105] Mistiaen P, Francke AL, Poot E. Interventions aimed at reducing problems in adult patients discharged from hospital to home: A systematic metareview. BMC Health Serv Res 2007;7:47.

measure. The measure spotlights the excess number of days patients spend in acute care (hospital readmissions, observation stays, and ED visits) per 100 discharges during the first 30 days after discharge from the hospital, relative to the number spent by the same patients discharged from an average hospital. We believe the information provided to hospitals through this measure will help inpatient and outpatient providers better understand the trajectory of care for patients that have been discharged from their facility. Specifically, hospitals will be able to assess whether patients discharged from their facility have readmissions, observation stays, and/or ED visits during the first 30 days after discharge from the hospital.

Because the measure provides more granular information regarding patient discharge outcomes, this will assist hospitals in developing targeted quality improvement activities aimed at improving transitions of care. We believe that the measure will reduce readmissions, observation stays, and/or ED visits by encouraging hospitals to further invest in interventions to improve hospital care by better assessing the readiness of patients for discharge and facilitating quality transitions to outpatient status.

Comment: One commenter requested that CMS not include outpatient care that is beneficial to patients as part of the AMI EDAC measure.

Response: We do not dismiss the importance of hospital-level care in outpatient settings, such as the Emergency Department, and support hospitals using the level of care most appropriate for each particular patient's condition. We agree with the commenter that some returns to the acute care setting are necessary and beneficial to patients. The goal is not to avoid all post-discharge acute care service utilization, but to identify excess use of acute care post-discharge. Acute care utilization after discharge (that is, return to the ED, observation stay, and readmission), for any reason, is disruptive to patients and caregivers, costly to the health care system, and puts patients at additional risk of hospital-acquired infections and complications. Although some factors are outside hospitals' control, when appropriate care transition processes are in place (for example, a patient is discharged to a suitable location, communication occurs between clinicians, medications are correctly reconciled, timely follow-up is arranged), fewer patients return to an acute care setting, whether for an ED visit, observation stay, or hospital readmission during the 30 days post-discharge period. Numerous studies have found an association between quality of inpatient or transitional care and early (typically 30-day) readmission rates and ED visits for a wide range of conditions including AMI.

Comment: Several commenters opposed the inclusion of the AMI EDAC measure because it is not NQF endorsed and wasn't reviewed by the MAP for inclusion in this EPM.

Response: Section 1886(b)(3)(B)(IX)(bb) of the Act provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. While we considered other existing measures related to care transitions and post-discharge acute care utilization that have been endorsed by NQF or other consensus organizations, we were unable to identify any NQF-endorsed (or other consensus organization endorsed) measures that assess the full range of post-discharge acute care use that patients may experience.

Existing process measures capture many important domains of care transitions such as education, medication reconciliation, and follow up, but all require chart review and manual abstraction. Existing outcome measures are focused entirely on readmissions or complications and do not include observation stays or ED visits. We are not aware of any other measures that assess the quality of transitional care by measuring 30-day risk-standardized days in acute care (hospital readmissions, observation stays, and ED visits) following hospitalization for AMI that have been endorsed or adopted by a consensus organization, and we have not found any other feasible and practical measures on this topic. However, we note that this measure has been submitted to NQF for endorsement proceedings and received a recommendation for endorsement from the Admissions and Readmissions Standing Committee as part of the All-Cause Admissions and Readmissions project in January 2016.

Furthermore, the AMI EDAC measure was reviewed by clinical experts and a TEP and was subject to separate public input prior to being proposed for the Hospital IQR Program. This measure was also included on a publicly available document entitled ''List of Measures under Consideration for December 1, 2014'' (available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*) and has been reviewed by the NQF MAP Hospital Workgroup. The measure was conditionally supported pending the examination of SDS factors and NQF review and endorsement of the measure update, as referenced in the MAP 2015 Final Recommendations Spreadsheet (available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*). We will continue to work collaboratively with stakeholders in soliciting input on ways to refine this measure in the future.

Comment: Several commenters opposed the inclusion of the AMI EDAC measure because it is not publicly reported.

Response: CMS understands the commenters concern that the measure has not been publicly reported as of yet. We held a dry run to educate hospitals on the AMI and HF EDAC measures in September 2015 and we reported updated results to hospitals in the IQR Preview Period in April 2016. Hospitals results on the measures will be updated with more recent data and reported to hospitals in Spring 2017 as part of the IQR Preview Period for the public reporting release of the measures in July 2017.

Comment: One commenter opposed inclusion of the AMI EDAC measure because it overlaps with the AMI readmission measure.

Response: In response to the commenter's concern about overlap of the AMI EDAC and the current readmission measure, we interpret the commenter to be referring to the 30-day AMI readmission measure. That measure and the AMI EDAC measure assess different outcomes. Although both measures count readmission, the 30-day AMI readmission measure only informs a hospital if a patient had a readmission, and does not include all postdischarge outcomes that matter to patients, such as having to return to the ED or spending time in the hospital under observation, like the AMI EDAC measure does. The AMI EDAC measure provides patients a more comprehensive and patient-centered perspective on the 30-day postdischarge experience because it includes not only readmissions, but also ED visits and observation stays and captures the numbers of days in these settings.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to include the Excess Days

in Acute Care after Hospitalization for AMI measure in the AMI model.

(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 proposed 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 also proposed 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 final 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 proposed 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 final rule.

We sought 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 proposed 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.

The following is a summary of the comments received and our responses.

Comment: Several commenters had concerns or provided suggestions about the reporting standard for voluntary reporting of EHR data elements. One commenter recommended that CMS require QRDA I file format for every year of data submission, as it is already required for the Inpatient Quality Reporting and Meaningful Use programs. Another commenter recommended that CMS not allow data to be submitted for performance year (PY) 1 in a different file format than the other years to avoid confusion. Several commenters agreed with CMS in being flexible in the voluntary reporting of the clinical data elements by allowing multiple reporting formats. One commenter specifically appreciated the flexible approach, as it created a better balance of provider risk and reward. Another commenter suggested that CMS allow both QRDA and Excel reporting in performance years 2 and 3.

Response: We thank commenters for their suggestion to align standards across our programs. We agree that it is important to align these data collection requirements to reduce burden on

hospitals and improve interoperability. We will take this feedback into consideration as we shape future proposals for hybrid measures. One of the main tenets of the 2015 Edition Health IT Certification Criteria final rule (80 FR 62601) is to facilitate greater interoperability for several clinical health information purposes and enable health information exchange through new and enhanced certification criteria, standards, and implementation specifications. We note that we have worked closely with ONC to enhance testing and validation of certified technology's ability to capture, exchange, and report electronic patient data, such as improved testing and certification through the Cypress CQM testing and certification tool. As another example, we note that ONC proposed a 2015 Edition ''CQM—report'' certification criterion in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24613 through 24614). After consideration of stakeholder input on the standards for representing and reporting CQM data in certified health IT to improve the reliability and consistency of such data reporting, we finalized that hospitals can report using either the 2014 or 2015 edition of CEHRT (80 FR 49708). Furthermore, the 2015 Edition certification criteria related to eCQMs offer increased data portability and user access using the established QRDA standards. Because of the support for testing and certification offered by ONC and their certification tools and programs, the widespread deployment of the QRDA standard and CMS' own recent experience that QRDA can provide superior clinical data for assessing quality and performance, we will finalize our selection of QRDA–I as the primary reporting standard for the EPM Model Rule for program years 1–3. If QRDA–I cannot be available to all participants for year 1, we will make a transitional submission format available to systems using a spreadsheet-based approach that will allow these sites additional time to meet the QRDA-based reporting requirements. We thank commenters for their continued support of improving the electronic reporting process and plan to continue to make improvements as standards evolve.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to use the following reporting mechanisms in performance year 1: QRDA, a simpler mechanism such as a spreadsheet, or both. We proposed using QRDA in AMI model performance years 2 through 5.

(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 proposed 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 IT 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.[106] 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.*

[106] AMI Mortality Hybrid Measure methodology report. *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 proposed defining AMI model performance years as outlined in section III.E.5. of the proposed rule (81 FR 50794). 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 requested 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 final 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 sought 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 41 for summary of performance periods.

The following is a summary of the comments received and our responses.

Comment: Several commenters were supportive of including a voluntary hybrid AMI mortality measure in the AMI episode payment model, but were concerned about the timeline to report clinical data. Commenters remarked that hospitals need to redesign their EHRs to collect and validate this data, and recommended delaying the implementation of this measure until 2018. One commenter recommended that CMS delay the start date of the hybrid AMI mortality measure to PY 2 because the proposed rule indicates that data collection will start on July 1, 2017, likely 6 months after release of the final rule, which is not enough time for vendors to consume the final rule and specifications, as well as develop, package, and release the required updates to clients.

Response: We are aware of the burden to hospitals associated with extraction, validation, and submission of EHR data. However, data submission for EHR data elements used in the Hybrid AMI Mortality Measure is voluntary, with an incentive for hospitals that chose to submit clinical data. Hospitals that are unable to consume the specifications, develop, package, and submit the EHR data elements will not be penalized under this payment program. Hospitals that do not submit data in program year one, will have the opportunity to submit data and receive the incentive in program years two through five.

Comment: One commenter noted that, according to CMS's Conditions of Participation (CoPs), hospitals have thirty days following discharge to complete the medical records with final diagnosis. Since CMS is proposing a submission period for the AMI EHR data 60 days following the end of the measurement period, this would only allow thirty days following final diagnosis to compile, validate, and submit data. The commenter recommended that CMS allow a 120 day submission period after the end of the measurement period.

Response: We will use a 30-day claims maturity period to identify the index admissions for the voluntary reporting of EHR data for the AMI EPM in program year 1. This will allow hospitals 30 days to extract data on the appropriate patients and submit the data to CMS. In program years 2 through 5 CMS will use the customary 90-day claims maturity period to identify the index admissions for the voluntary reporting of EHR data for the AMI EPM. This is the same 90-day claims maturity period currently used in the claims-based AMI 30-day mortality measure. Hospitals will have 60 days to complete EHR data extraction and submission to CMS.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification to define 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.

(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 proposed to use the following criteria to determine if a participant has successfully submitted AMI voluntary data: 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 the proposed rule (81 FR 50794). 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 the proposed rule (81 FR 50794).

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 the proposed rule (81 FR 50794).

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 sought 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 the proposed rule (81 FR 50794). 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 sought 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.

The following is a summary of the comments received and our responses.

Comment: Several commenters agreed with the potential value of hybrid measures, but expressed concern about the ability of hospitals to submit accurate and reliable data. Several commenters urged CMS not to finalize any data submission requirements beyond the first reporting period until hospitals and the agency have gained experience with measure submission. Two commenters specifically recommended the percent of data submitted be gradually increased over time, instead of 50 percent in performance year 1, to 90 percent in performance year 2. One commenter expressed concern that hospitals that did not participate in the Meaningful Use Program that utilized QRDA technology would be disadvantaged by being required to submit clinical data in this format. One commenter noted that while CMS continues to conduct testing of the electronic specifications in a few hospitals, the QRDA format has not demonstrated competency, and should therefore not be included in the AMI episode payment model.

Response: We are sensitive to the potential burden on hospitals of mapping, extracting, and reporting data elements from their EHRs. However, we have tested the accuracy of mapping, extracting, and reporting compiled data from the EHRs of four separate health systems, although we have not tested data reporting in QRDA format. These tests showed that, once instructed on the Measure Authoring Tool output, hospitals are able to submit accurate EHR data on nearly all of their admitted patients. We validated the electronically extracted data by comparing values identified through manual chart review. This suggests that hospitals will be able to extract and submit data on the subset of their patients admitted with AMI. We intend to require the QRDA format beginning in program year two in order to maintain alignment with requirements for electronic clinical quality measures. We will continue to coordinate with ONC to maintain alignment with standards and requirements.

Comment: Several commenters supported the proposal to include a voluntary hybrid AMI mortality measure in the AMI episode payment model.

Response: We thank the commenters for their support.

Comment: One commenter supported the inclusion of clinical data into the risk adjustment model for the Hybrid AMI mortality measure. They suggested hospitals submit additional standard laboratory data, including white blood cell count and albumin levels, to support this measure and the development of other quality measures.

Response: We thank the commenter for their support. We sought to develop a model that included key variables that are clinically relevant, demonstrate a strong statistical association with 30-day mortality, and are feasible for use in a hybrid measure. We developed the following criteria to assess feasibility of candidate variables: 1. Data that are consistently obtained in the target population based on current clinical practice; 2. Data that are captured with a standard definition and recorded in a standard format; 3. Data that are entered in structured fields that are feasibly retrieved from current EHR systems. During measure development the members of the expert working group reviewed the entire list of variables in the National Cardiovascular Data Registry ACTION Registry—Get With The Guidelines database and selected variables that met these criteria. We then tested all candidate variables in multivariate regression models with 30-day mortality as the outcome. CMS did

evaluate white blood cell count as one of the candidate variables. However it was not consistently predictive of mortality in the risk model and therefore was not included in the final measure. Albumin was not considered. We have developed two other hybrid outcome measures which use additional clinical data including the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879), and the Hybrid Hospital 30-day, All-cause, Risk-standardized Mortality Rate (RSMR) Following Acute Ischemic Stroke with Risk Adjustment for Stroke Severity (NQF #2877). For descriptions of these measures we refer readers to the FY 2016 IPPS/LTCH final rule 80 49698, and the FY 2017 IPPS/LTCH final rule 81 57161, respectively.

Comment: Several commenters referred to the hybrid AMI mortality measure as a ''hybrid eCQM''.

Response: We wanted to clarify the hybrid AMI mortality measure is a claims-based measure, and not an electronic clinically quality measure (eCQM). The cohort and outcome for the hybrid AMI mortality measure is derived from claims and not the EHR.

Comment: One commenter recommended that CMS release the final specifications for the hybrid AMI mortality measure as soon as possible following the release of the final EPM rule. The commenter further recommended that CMS align the specifications of the hybrid AMI mortality measure as closely as possible with other electronically submitted CQMs available through the IQR program.

Response: The measure specifications have been published along with this final rule. We refer readers to ''Core Clinical Data Elements and Hybrid Measures'' folder on our Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

We closely aligned our development process for the hybrid AMI mortality measure electronic specifications with the electronic clinical quality measures (eCQM) development process, according to the MMS Blueprint. This process included a stakeholder public comment on the measure specifications, input from experts in the field, Bonnie testing, Mitre review, and VSAC review of the value sets. Additionally, we tested the electronic specifications in several different health systems, which utilized different EHRs. We aligned the electronic specifications with eCQMs in use by IQR and MU programs. Where appropriate, we harmonized the use of the value sets and logic that are currently used in these program measures to ease the implementation of the CCDE. We plan to continue these harmonization efforts with each annual update cycle.

Comment: One commenter requested clarification how the hybrid AMI mortality measure would be validated using EHR and claims data.

Response: The hybrid AMI mortality measures has been fully tested and validated in merged Medicare claims and registry data from the National Cardiovascular Data Registry (NCDR) ACTION Registry-Get With The Guidelines. The measure was endorsed by the NQF in 2014. However, we plan to perform additional testing as a part of measure reevaluation. We have not yet determined when this testing will take place.

Comment: One commenter believed that CMS did not account for a small but important population of patients that arrive at a participating hospital in an unstable, critical condition by not excluding cardiogenic shock. The commenter noted that this population is at a higher risk of mortality, and thus should have separate quality measures that take into account the severity and complexity of their medical conditions.

Response: In order to account for differences in patient mix among hospitals, the measures adjust for variables (for example, age, comorbid diseases, and indicators of patient frailty) that are clinically relevant and have relationships with the outcome. In the case of the AMI measure, we risk adjust for cardio-respiratory failure or shock. However, the measure's risk model does not include a risk variable for sepsis. A diagnosis of sepsis that occurred during the index AMI admission would not be used as a risk variable because we cannot know whether sepsis was present at the time a patient first presented for care or was a consequence of poor care received during the hospitalization. During measure development we did consider including sepsis as a risk variable only if it occurred in the 12 months prior to the index admission. This variable was not consistently found to predict mortality in the measure cohort and, therefore, was not included in the final risk model.

Comment: One commenter was supportive of using clinical data and claims data to create a hybrid measure, but noted combining these data is a laudable endeavor. They noted that determining the measure population using administrative data would increase the reporting burden on hospitals.

Response: We acknowledge that the need to identify patients with a principal discharge diagnosis of AMI will be required to successfully map, extract, and report data for the hybrid AMI mortality measure. However, we believe that the added benefit of including clinical data in the measure's risk model outweighs the additional burden of EHR data extraction and reporting. Many commenters in this and previous public comment periods have expressed support for this approach. Additionally, we note that reporting of the EHR data elements is voluntary and that hospitals will not be penalized if they cannot or choose not to submit these data.

Comment: One commenter requested CMS explore the use of sociodemographic factors in improving the risk adjustment for the hybrid AMI mortality measure.

Response: We appreciate the commenters' concerns that socioeconomic factors influence patient's risk of post-discharge returns to the hospital for acute care. The hybrid AMI mortality measure currently does not include socioeconomic factors in the risk-adjustment model. We routinely monitor the impact of SDS on providers' differential performance on our outcome and payment measure.

The NQF is currently conducting a 2-year trial, in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. This trial entails temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF is expected to issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are encouraged to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model. Several measures developed by CMS have been brought to NQF since the beginning of the trial, including the AMI EDAC measure which was submitted to NQF in January 2016. Under the guidance of NQF, we are making every effort to be proactive in examining SDS factors in quality measures by testing SDS factors in the measures' risk models and making recommendations about whether or not to include these factors in the endorsed measure. We are still awaiting final recommendations from the NQF and intend to continue engaging in the NQF process as we consider the

appropriateness of adjusting for SDS factors in our outcome measures. For more detailed information about measures in the NQF SDS trial period, we refer commenters to: *http://www.qualityforum.org/SES_Trial_Period.aspx*. Furthermore, we are awaiting the findings of an ASPE report on SDS factors in risk-adjustment. Therefore, we are not currently changing our risk-adjustment methodology with respect to SDS factors. We will continue to consider such factors in our ongoing measure development and maintenance activities.

Comment: One commenter requested CMS clarify when they would replace the current publically reported AMI mortality measure (NQF #0230) with the hybrid AMI mortality measure (NQF #2473).

Response: We have not yet determined and timeline for replacing the claims-only AMI mortality measure (NQF #0230) with the hybrid AMI mortality measure (NQF #2473). However, we will make any changes to the measures used in payment programs through the notice of proposed rulemaking. We point out that the hybrid AMI mortality measure, similar to other CMS condition-specific outcome measures, requires a 3-year measurement period in order for a sufficient number of hospitals to meet the threshold of having discharged at least 25 patients with a principal diagnosis of AMI to be included in the measure cohort. Therefore, reporting measure results would require a minimum of 3 years of EHR data collection.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, 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 health care 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, 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 final 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 proposed 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 proposed 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 the proposed rule (81 FR 50794), 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 41.

We sought 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 the proposed rule (81 FR 50794), several of the outcome measures we proposed 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 proposed the use of 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.

The following is a summary of the comments received and our responses.

Comment: One commenter suggested that the CABG mortality measure not be used in the EPM until it had been reviewed by the NQF in the context of the ongoing SDS trial period. The commenter supported the use of the CABG mortality measure if CMS includes SDS factors in the risk-adjustment because mortality is tied to community factors that are typically outside of the direct control of health care providers.

Response: We appreciate the commenters' concerns that socioeconomic factors influence patient's risk of post-discharge returns to the hospital for acute care. The CABG mortality measure currently does not include socioeconomic factors in the risk-adjustment model. We routinely monitor the impact of SDS on providers' differential performance on our outcome and payment measure.

The NQF is currently conducting a 2-year trial, in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. This trial entails temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF is expected to issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are encouraged to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model. Although the CABG mortality measure was not included in the SDS trial period, several measures developed by CMS have been brought to NQF since the beginning of the trial, including several mortality. Under the guidance of NQF, we are making every effort to be proactive in examining SDS factors in quality measures by testing SDS factors in the measures' risk models and making recommendations about whether or not to include these factors in the endorsed measure. We are still awaiting final recommendations from the NQF and intend to continue engaging in the NQF process as we consider the appropriateness of adjusting for SDS factors in our outcome measures. For more detailed information about measures in the NQF SDS trial period, we refer commenters to: *http://www.qualityforum.org/SES_Trial_Period.aspx.* Furthermore, we are awaiting the findings of an ASPE report on SDS factors in risk-adjustment. Therefore, we are not currently changing our risk-adjustment methodology with respect to SDS factors. We will continue to consider such factors in our ongoing measure development and maintenance activities.

Comment: Once commenter expressed agreement with the decision not to include the CABG readmission measure in this EPM stating that incentives are already in place for hospitals to lower excess readmission rates and it would be duplicative to hold hospitals accountable to these measures.

Response: We thank the commenter for their support.

Comment: Several commenters suggested alternative measures be used in the CABG EPM. One commenter suggested that CMS use the CABG Composite Score suggesting that it is more comprehensive because it is based on several outcomes, not solely mortality and is used by most cardiothoracic surgery programs. They also note that there is more variation among hospitals in the Composite Score compared with a mortality measure. Another commenter suggested that CMS use measures developed by the Society of Thoracic Surgeon (STS) for benchmarking instead of the CMS measure.

Response: We agree with commenters that this is a comprehensive NQF-endorsed composite measure with strong potential to meaningfully improve quality. The STS CABG Composite Score measures surgical performance based on a combination of 11 NQF-endorsed process and outcomes measures, grouped into four domains. We are incorporating the use of the CABG Composite Score performance measure (NQF #0696) as a voluntary option weighted at 10 percent. By including this measure in the CABG EPM, we are reducing proposed HCAHPS and mortality weights by 5 percent each for those hospitals choosing to voluntary submit this data. We intend to address the weighting and the use of the actual measure score in the next EPM rulemaking cycle. For more information about the STS Composite Score, we refer readers here: *http://www.sts.org/sts-public-reporting-online/cabg-composite-score.*

Comment: One commenter expressed concern 75 percent of a hospital's quality score for CABG based upon 30-day hospital mortality places a heavy reliance on only this quality measure. This commenter was also concerned that with this weighing propose, hospitals with few CABG cases would be further disadvantaged since there will be less data used to calculate the hospital's quality score.

Response: To ensure hospitals have enough cases to produce a valid quality score, the CABG mortality measure uses 3 years of claims data to calculate the measure. Hospitals must have at least 25 qualifying index admissions within the 3-year measurement period to calculate and publically report a measure result. We do not believe these measures disadvantage smaller volume hospitals. We have found that hospitals with few cases tend to have measure results that are close to the national average hospital rate and are therefore rarely identified as poor performing outliers.

Comment: One commenter disagreed with the proposal to use the CABG mortality measure in the CABG EPM because this measure is used in the Hospital Inpatient Quality Reporting program (''HIQR''). The commenter suggested that the CABG mortality measure would do little to characterize the quality performance beyond what is already reported through existing CMS programs. The commenter suggested that CMS develop a new measure of complications following CABG surgery.

Response: We disagree with the suggestion that including the CABG mortality measure would do little to characterize the quality performance beyond what is already reported through the existing CMS programs. Mortality is a very serious outcome for AMI and CABG care and is one that EPM model participants should manage to avoid under the AMI and CABG models.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, with modification, to incorporate the STS CABG Composite Score measure (NQF

#0696) from the STS Data Registry as a voluntary option weighted at 10 percent. The measures that were proposed, along with these STS CABG measures are highly relevant to the clinical conditions that are the focus of the model. To use other measures would increase administrative burden on participant hospitals which we do not believe would be appropriate for this model. Even though the measures are used in other CMS programs, we do not believe their use in this model leads to inappropriate financial risk because they are relevant measures of patient experience and outcomes.

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.[107] 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 [108] and 1.6 percent in Medicare patients undergoing TKA after 2 years of follow up.[109] Two studies reported 90-day death rates following THA at 0.7 percent [110] and 2.7 percent, respectively.[111] Reported rates for pulmonary embolism following TKA range from 0.5 percent to 0.9 percent.[112] [113] [114] Reported rates for septicemia range from 0.1 percent, during the index admission [115] to 0.3 percent, 90-days following discharge for primary TKA.[116] Rates for bleeding and hematoma following TKA have been reported at 0.94 percent [117] to 1.7 percent.[118] Combined, THA and TKA procedures account for the largest payments for procedures under Medicare.[119] 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 in 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,[120] 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.[121]

(b) Data Sources

Measure results are calculated using Medicare Part A and Part B FFS claims

[107] 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.*

[108] 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.

[109] 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.

[110] 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.

[111] 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.

[112] 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.

[113] 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.

[114] 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.

[115] 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.

[116] 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.

[117] 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.

[118] 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.

[119] 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.

[120] 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 16, 2015, page 78.

[121] 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.

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 proposed 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 final 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 term 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 the proposed rule (81 FR 50794), 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.

++ 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 the proposed rule (81 FR 50794).

(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.[122] 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.

[122] 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.

(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 final 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 44.

We sought 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.

The following is a summary of the comments received and our responses.

Comment: Several commenters opposed the elective THA/TKA complications measure because the measure's cohort does not align with the SHFFT model cohort. Commenters noted that the measure's cohorts do not include the patients in the SHFFT model population. Commenters requested that CMS provide more justification for including the measures in the SHFFT model. Commenters suggested that because the measures exclude hip fracture patients, they would provide limited insight on the quality of care provided to the patients included in the SHFFT model. Commenters raised specific concerns about a lack of testing of the measures in non-elective procedures and the potential for the rates and types of complications to differ between elective and non-elective procedure groups. Commenters noted that patients with hip fractures have higher mortality, complication, and readmission rates and are generally sicker with multiple comorbidities. As a result, patient recovery and rehabilitation pathways may be different for hip fracture as compared to patients who have elective procedures. Additionally, commenters noted that a hospital's volume of hip fracture patients is often much smaller than the volume of elective surgery patients causing concern that the use of the measures will unfairly assess quality at those hospitals with less arthroplasty experience.

Response: While we recognize that none of the proposed measures specifically target the care of SHFFT model beneficiaries, we provided the following rationale in the proposed rule. The proposed 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. These measures exclude patients with hip and pelvic fractures. However, 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. Therefore, while the quality measures do not specifically assess care for hip fracture patients, they will incentivize quality improvements that also improve care for hip fracture patients. In addition, as discussed further in III.E.3.e.(3) of this final 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 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 III.B.4. of this final rule.

Comment: One commenter expressed support for our proposed approach of using the same measures in the CJR and SHFFT models given the lack of measures specific to the hip fracture population.

Response: We thank the commenter for their support.

Comment: Several commenters suggested that we develop measures that are specific to the SHFFT model population.

Response: We thank the commenter for this suggestion and are considering future measure development focused specifically on hip and femur fracture patients.

Comment: One commenter suggested that the measures proposed do not assess what matters most to patients, such as whether patient's or providers' goals were met by the surgery performed.

Response: We have incorporated the THA/TKA patient-reported outcome-based data submission (henceforth referred to as ''THA/TKA voluntary data'') into the SHFFT model. The THA/TKA voluntary data would provide participant hospitals with valuable information on functional outcomes that would assist them in assessing an important patient-centered outcome, engaging other providers and suppliers in care redesign for joint replacement episodes, as well as provide them with the potential for greater financial benefit from improved episode efficiencies.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, 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.

(2) Hospital-Level Performance Measure(s) of Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty

III. (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.[123] [124] [125] 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 proposed to test SHFFT model episodes in mainly the same hospitals as the CJR model as discussed in sectionIII.B.4. of the proposed rule (81 FR 50794). 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.

[123] 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.

[124] 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.

[125] 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.

• 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 proposed 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 the proposed rule (81 FR 50794). 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 proposed 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 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 proposed 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 proposed 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 proposed to request that SHFFT model participants submit either hospital documentation, chart abstraction, or abstraction from the electronic health records. We proposed 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 39, 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 39, 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 proposed 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 proposed the THA/TKA voluntary data will be submitted to and collected by a CMS contractor in a manner and format similar to existing CMS data submission processes. For example, CMS would supply applicable hospitals with a file template and instructions for populating the file template with data and submitting the data; the hospitals will populate the template, log in to a secure portal, and transmit the file to the appropriate CMS contractor; the CMS contractor would also match the submitted data to Medicare administrative claims-based data and calculate successful submission determination for use in assigning the SHFFT composite quality score as described in section III.E.3.e.(3). of this final 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.[126]

(g) Calculating the Risk-Standardized Rate

We note that the approach to reporting this measure(s) has yet to be

[126] Ash AS, Fiengerg SE., Louis TA, Normand ST, Stukel TA, Utts J. STATISTICAL ISSUES IN ASSESSING HOSPITAL PERFORMANCE, Commissioned by the Committee of Presidents of Statistical Societies. Original report submitted to CMS on November 28, 2011, Revised on January 27, 2012. Available at:*http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Statistical-Issues-in-Assessing-Hospital-Performance.pdf.* Accessed on April 15, 2015.

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 proposed defining data reporting performance periods for each performance year of the SHFFT model as outlined in Table 40. 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 the proposed rule (81 FR 50794), 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 40—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.	22 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 sought comment on our proposed measure reporting periods for the performance years of the SHFFT model.

The following is a summary of the comments received and our responses.

Comment: One commenter expressed support for our proposal to assess patient-reported functional status before surgery and again one year after surgery as a mechanism to provide insight into the effectiveness of these procedures.

Response: We thank the commenter for their support.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to the measure reporting periods for the performance years of the SHFFT model. The performance periods will 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.

(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 the proposed rule (81 FR 50794).
- Data elements listed in section III.E.4.c.(2)(ii) of this final 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 the proposed rule (81 FR 50794). Performance periods for which we proposed to have THA/TKA voluntary data submitted are displayed in Table 29 of the proposed rule (81 FR 50794). 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 the proposed rule (81 FR 50794). This description is important as these patients are those in which we sought 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 sought public comment of these requirements to determine successful voluntary submission of THA/TKA data. We also sought 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.

The following is a summary of the comments received and our responses.

Comment: One commenter expressed support of our proposal to incentivize SHFFT model participants who submit PRO data.

Response: We thank the commenter for their support.

Comment: Several commenters expressed concern that the instruments used for the proposed Total Hip Arthroplasty (THA)/Total Knee Arthroplasty (TKA) voluntary patient-reported outcome (PRO) measure had not been validated in hip fracture patients, specifically the Hip disability and Osteoarthritis Outcome Score (HOOS), JR.

Response: The purpose of the voluntary PRO data collection is to collect the data required to develop a future PRO-based performance measure that will assess hospital quality of care for patients undergoing elective primary THA/TKA procedures. Because only patients with elective primary THA/TKA procedures will complete these survey instruments, there is no need to assess their validity in hip fracture patients. Although we plan to develop a PRO-based measure that excludes patients with fracture-related THA/TKA, we believe quality improvement efforts initiated in response to the future 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 THA/TKA procedures, such as fracture-related THA.

Comment: Several commenters suggested that hospitals will not be able collect PRO data on hip fracture patients

prior to the procedure because hip fractures are acute and unanticipated events.

Response: The PRO data will be collected only for patients undergoing elective THA/TKA procedures within hospitals participating in the SHFFT model and not for hip fracture patients.

Comment: One commenter expressed concern that the proposal that hospitals seeking credit for voluntary submission of PRO data need only submit data on 80 percent of eligible elective primary THA/TKA patients could cause hospitals to report data only on those patients who had positive outcomes. The commenter requested that CMS raise the threshold.

Response: We appreciate the commenter's suggestion to increase the successful criterion based upon the concern that lowering the successful criterion (that is, the patient-reported outcome instrument response and risk variable submission rates required for successful participation) may produce biased data that are not generalizable to all patients undergoing elective primary THA/TKA procedures at a given hospital. We refer the commenter to our response to this concern in the CJR model final rule (80 FR 73499–73500).

Comment: One commenter suggested that we consider removing the Oswestry Index from the list of required variables to be submitted with pre-operative PRO data. The commenter suggested that the Oswestry Index is lengthy and burdensome to complete and is not relevant for hip and knee surgery.

Response: We note that a joint statement from multiple surgical specialty societies received during the public comment of the CJR Model Proposed Rule included back pain as a prioritized risk variable for the voluntary PRO and risk variable data collection [cite final rule (80 FR 73496) and Ayers]. The commenter noted that the Oswestry Index requires responses to a lengthy set of questions. To minimize data collection burden, we have included a single question from the Oswestry Index to capture patient-reported back pain: My BACK PAIN at the moment is (none, very mild, moderate, fairly severe, very severe, worst imaginable).[127]

Comment: One commenter suggested that we reduce the number of responses required to satisfy the HOOS and KOOS completion rate.

Response: In response to the commenter's concern regarding the burden of PRO data collection, we have limited the number of PRO survey data elements to a minimum of 16 or 17 questions, depending upon whether the patient is undergoing a THA or TKA procedure, plus the additional risk variable questions, which CMS believes is a reasonable burden for elective procedures intended solely for improving pain and function. In addition, comments received during the public comment of the CJR Model Proposed Rule indicate that high patient-reported outcome data collection rates are feasible. For example, a commenter shared that its institution reported a reliable 85 percent response rate for its PRO data collection (80 FR 73500).

Comment: Several commenters expressed concerns about hospitals' ability to collect post-operative PRO data one year after surgery. One concern was about the difficulty of locating patients due to the possibility of a beneficiary's death, incapacity, a move, or an unwillingness to participate in a survey. One commenter suggested CMS shorten the timeframe for assessing the PROs to 6 months and that CMS provide a file of CJR/SHFFT patients who are deceased at the start of the post-operative data collection period in order to avoid mailing reminders or surveys to the families of deceased beneficiaries. One commenter suggested extending proposed timing of PRO assessment beyond 365 days in case patients do not return to their provider within a year of surgery.

Response: The PRO data will be collected only for patients undergoing elective THA/TKA procedures within hospitals participating in the SHFFT model and not for hip fracture patients. The collection time window of 270 to 365 days for post-operative PRO data was specified in conjunction with our TEP and based on recovery trajectories for primary elective THA/TKA patients. Because experts and stakeholders have identified this window as ideal for capturing PROs, we encourage hospitals to develop strategies to collect data within the time window, such as mailing surveys to patients well before they return for their one-year follow up visit.

Comment: One commenter suggested that PRO performance measures should be used to assess quality of post-acute care services as well as acute care hospitals.

Response: We thank the commenter for their suggestion. We will consider this feedback during ongoing measure evaluation.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, for voluntary submission of THA/TKA data as included in § 512.413(b). We are also finalizing these requirements 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

[127] Fairbank JC, Pynsent PB. The Oswestry, Disability Index. Spine 2000 Nov 15;25(22):2940–52

items report patients' overall rating of the hospital, and whether they would recommend the hospital to family and friends. We proposed to adopt a measure in the 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 proposed 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 proposed 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 proposed 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'' = 33⅓; ''Usually'' = 66⅔; 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'' = 33⅓; ''Probably Yes'' = 66⅔; and ''Definitely Yes'' = 100 (For item 22).
- ''Strongly Disagree'' = 0; ''Disagree'' = 33⅓; ''Agree'' = 66⅔; and ''Strongly Agree'' = 100 (For items 23, 24, and 25).

The 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_Apr2015.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 proposed to be consistent with the HIQR Program, which uses 4 quarters of data for HCAHPS (79 FR 50259). For the EPMs, we proposed 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 the proposed rule (81 FR 50794), 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 sought 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.

The following is a summary of the comments received and our responses.

Comment: Several commenters did not support or were skeptical of the inclusion of HCAHPS because it is an overall measure of all patients receiving hospital services that is not specific to heart attacks, bypass surgery, or joint replacements. Therefore, HCAHPS does not reflect quality for targeted episodes of care. In addition, the measure is too narrow because it only encompasses patient experience during the inpatient hospital stay and does not capture information about patients' experience later in the episode of care. For these reasons, commenters did not believe that the measure captures the correct information, and it will be of limited value to clinicians for quality improvement.

Response: We appreciate the concerns from the commenters about the broad patient population covered by this measure. Although the HCAHPS Survey encompasses a broader range of patients than the model episode definitions, we are not aware of evidence that such patients' experience of care differs markedly from those of the larger group of eligible patients after patient-mix adjustment for service line (surgery) and age have been applied. Having all patients responding to the survey helps to inform hospitals on areas for improvement. From a survey implementation standpoint, it is not feasible to target only Medicare beneficiaries who had a specific surgery, or to calculate the HCAHPS Linear Mean Roll-up score on the basis of particular surgical patients. In addition to complicating the administration of the survey, the number of completed surveys from such a narrow set of patients would be, for many hospitals, too small to support reliable measurement or comparison. The inclusion of the HCAHPS Survey measure (NQF #0166) as currently implemented and the HLMR derived from it in these models will present participating hospitals with a further incentive to improve experience of care for all patients. HCAHPS, which was launched in 2006 and has been continuously administered ever since, is familiar to over 4,000 hospitals. Modifications to the standardized implementation protocols would be disruptive to the other programs that employ HCAHPS data, such as the HIQR Program and Hospital Value-Based Purchasing program. We believe through the HCAHPS Survey measure (NQF #0166), CMS programs continue to highlight the importance of assessing patient experience of care.

Comment: Several commenters recognized patient satisfaction as an important component of quality and supported the use of HCAHPS as a way to measure patient feedback. One commenter appreciated CMS not creating a bar that is too high for the quality measures included in the EPMs.

Response: We thank the commenters for their support.

Comment: Several commenters were concerned about compounding penalties for the CJR participants that are also selected for participation in the SHFFT model. Commenters further noted that the HCAHPS survey is already a significant part of quality measurement through its inclusion in the Hospital Value Based Purchasing Program.

Response: We appreciate the commenters' concerns regarding the inclusion of HCAHPS in multiple CMS programs. However, this measure aligns with our priorities to reduce AMI and CABG mortality and complications while improving patient experience, as well as our priorities to reduce major LEJR surgery complications while improving patient experience for SHFFT model beneficiaries, like those in the CJR model. Through HCAHPS, CMS programs continue to highlight the importance of assessing patient experience of care. Furthermore, this approach allows hospitals to align with other CMS hospital quality programs, including programs that tie payment to performance such as the HVBP Program, and streamlines EPM measures for EPM participants testing more than one EPM.

Comment: Several commenters recommended that CMS reduce the

weight percentage assigned to HCAHPS. One commenter suggested that HCAHPS should only be 15 percent of the overall quality score, whereas another commenter recommended a reduced, phased-in weighting at least for years 1 and 2.

Response: We believe that the proposed weight percentage assigned to HCAHPS is appropriate and a phased-in weighting is not necessary. Hospitals participating in these models have had several years of experience with the HCAHPS survey. Since July 2007, hospitals subject to the IPPS annual payment update provisions have been required to collect and submit HCAHPS data in order to receive their full annual payment update (71 FR 48037). Non-IPPS hospitals, such as CAHs, may voluntarily participate in HCAHPS. The incentive for IPPS hospitals to improve patient experience was further strengthened by the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148), which specifically included HCAHPS performance in the calculation of the value-based incentive payment in the Hospital Value-Based Purchasing program beginning with October 2012 discharges. With respect to the HCAHPS Linear Mean Roll-up score measure that we proposed for the model, hospitals began receiving HCAHPS Summary Star Rating in their December 2014 *Hospital Compare* Preview Report. The HLMR is the basis for the HCAHPS Summary Star Rating; see HCAHPS Star Rating Technical Notes at *http://www.hcahpsonline.org/StarRatings.aspx*. While the HLMR is a relatively new calculation from the existing measures, hospitals have been using the HCAHPS survey for many years and have had time to become familiar with it, with their results, and with their standing relative to other hospitals through information presented on the HCAHPS On-Line Web site such as the HCAHPS Percentiles tables (*http://www.hcahpsonline.org/SummaryAnalyses.aspx*). IPPS hospitals have available their HCAHPS scores' relative rank compared to other hospitals participating in the HVBP program. As such, we believe that hospitals are familiar with their individual and relative performance on the HCAHPS Survey measure (NQF #0166).

Comment: One commenter expressed concern that inclusion of HCAHPS in the EPMs could negatively affect essential hospitals if used as part of the quality composite score used to determine hospital eligibility to receive reconciliation payments. The commenter stated that patients admitted through the ED report lower HCAHPS scores, thus essential hospitals with higher ED volumes might score lower despite the fact that their quality could be the same or better than other hospitals.

Response: We have examined the performance of ''safety net'' hospitals, sometimes referred to as ''essential'' hospitals, on the HCAHPS component of the HVBP program. Although we do not have an official definition or designation of ''safety net'' hospital, we understand that a safety net status typically entails one or more of three criteria: High Medicaid share; high proportion of uncompensated patients; and high county-associated poverty rate. In general, after all HCAHPS adjustments are applied (patient mix and survey mode), we believe that so-called safety net hospitals, as we understand the term, perform similarly to other hospitals. The current adjustment approach that CMS employs is both well-validated and necessary to ensure fair comparisons of HCAHPS scores across hospitals. When these adjustments are applied according to the rules currently in place, the performance of safety net hospitals for the HCAHPS portion of HVBP is typical of hospitals in general.

With respect to HCAHPS scores of patients admitted through hospital emergency departments, CMS is investigating whether participating hospitals could submit a valid and standardized administrative record regarding ED admission. When HCAHPS was developed, such an indicator was available and was employed in HCAHPS patient-mix adjustment, where it had a small, negative effect on HCAHPS scores. However, collection of this measure ceased several years ago due to misgivings about its validity.

Comment: One commenter requested that the Pain Management scores be included in the HCAHPS measure for CJR Performance Year 1. The commenter believed that removing the Pain Management scores diminish the importance of the role pain management plays in the recovery and sustained well-being of patients.

Response: We remain dedicated to improving the quality of care provided to patients, including the appropriate management of pain and communication between patients and their providers regarding pain. We continue to believe that pain control is an appropriate part of routine patient care that hospitals should manage and is an important concern for patients, their families, and their caregivers. Furthermore, we are unaware of any empirical evidence demonstrating that failing to prescribe opioids lowers a hospital's HCAHPS Survey scores. However, we believe the potential confusion about the appropriate use of the Pain Management dimension questions, coupled with the public health concern about the opioid epidemic, warrants removing these questions from Hospital VBP Program scoring calculations until alternative pain management questions are available. In response to possible confusion about the Pain Management measure, we have finalized our proposal to remove this dimension from the Hospital Value-Based Purchasing payment formula beginning in FY 2018. However, CMS will continue publicly report the Pain Management measure on the Hospital Compare Web site because we continue to believe that pain control is an appropriate part of routine patient care that hospitals should manage and is an important concern for patients, their families, and their caregivers.

Comment: One commenter was concerned about the use of HCAHPS for PAC/LTC based practices as there are no current requirements to use skilled nursing facility patient satisfaction surveys. The commenter believed that the measure is not appropriate for PAC-based clinicians because in many situations the information source is not reliable due to the cognitive status of the patients being surveyed.

Response: Patients discharged to nursing homes and SNFs are excluded from HCAHPS survey administration because of the difficulty contacting such patients and consistently surveying them in a timely manner. We are not aware of evidence that patients discharged to a nursing home or SNF have different experience of care than other inpatients in the hospital. Only acute-care hospitals participate in the HCAHPS Survey, not long term care hospitals.

Comment: One commenter recommended that CMS make the HCAHPS Linear Mean Roll-up (HLMR) score publicly available in order to allow hospitals to not only know their HLMR score, but that of other hospitals in order to understand their percentile levels. The commenter further recommended that this data be released automatically and at least quarterly to facilitate hospitals' ability to improve performance and assess financial risk.

Response: We appreciate the concerns from the commenters about the broad patient population covered by this measure. Although the HCAHPS Survey encompasses a broader range of patients than the model episode definitions, we are not aware of evidence that such patients' experience of care differs

markedly from those of the larger group of eligible patients after patient-mix adjustment for service line (surgery) and age have been applied. Having all patients responding to the survey helps to inform hospitals on areas for improvement. From a survey implementation standpoint, it is not feasible to target only Medicare beneficiaries who had a specific surgery, or to calculate the HCAHPS Linear Mean Roll-up score on the basis of particular surgical patients. In addition to complicating the administration of the survey, the number of completed surveys from such a narrow set of patients would be, for many hospitals, too small to support reliable measurement or comparison. The inclusion of the HCAHPS Survey measure (NQF #0166) as currently implemented and the HLMR derived from it in these models will present participating hospitals with a further incentive to improve experience of care for all patients. HCAHPS, which was launched in 2006 and has been continuously administered ever since, is familiar to over 4,000 hospitals. Modifications to the standardized implementation protocols would be disruptive to the other programs that employ HCAHPS data, such as the HIQR Program and Hospital Value-Based Purchasing program. We believe through the HCAHPS Survey measure (NQF #0166), CMS programs continue to highlight the importance of assessing patient experience of care.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, 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 welcomed 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 welcomed 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.

The following is a summary of the comments received and our responses.

Comment: Several commenters recommended implementing quality measures across the care continuum, including post-acute care (PAC) and measures that address providers beyond the hospital that provides the surgery, such as Independence at Home, FQHCs, PCMHs, and ACOs.

Response: We appreciate the commenters for the suggestion to implement quality measures across the care continuum. We recognize that there are some gaps in the current proposed measures relative to other settings in which patients receive care post-hospital discharge during EPM episodes. We will take these recommendations into consideration in our measure development and testing efforts, as well as in our ongoing efforts to identify and propose appropriate measures for the payment models in the future.

Comment: Several commenters recommended the use of registries to report data for new measures. Commenters suggested measures from the Core Quality Measure Collaborative (CQMC) Cardiovascular and Orthopedic core quality measures set, National Cardiovascular Data Registry (NCDR) measures, and the STS CABG Composite Score.

Response: We thank the commenters for their recommendations. We believe that registries may facilitate valuable quality improvement feedback to hospitals. However, we note that many registry measures are proprietary. With that said, we agree with commenters that the STS CABG Composite Score is a comprehensive NQF-endorsed measure with strong potential to meaningfully improve quality. The STS CABG Composite Score measures surgical performance based on a combination of 11 NQF-endorsed process and outcomes measures. We also note that 7 of the 11 NQF-endorsed process and outcomes measures are used for the Physician Quality Reporting Program (PQRS) which promotes alignment of measurement across programs. We are incorporating the STS CABG composite measure (NQF #0696) data submission as a voluntary option weighted at 10 percent. By including this composite measure in the CABG EPM, we are reducing proposed HCAHPS and mortality weights by 5 percent each for those hospitals that voluntarily report the STS measure. We intend to address the weighting and the use of the actual measure score in the next EPM rulemaking cycle. For more information about the STS Composite Score, we refer readers here: *http://www.sts.org/sts-public-reporting-online/cabg-composite-score*.

Comment: Several commenters recommended that CMS explore the opportunity to develop and implement quality of life and patient reported outcome measures (PROMs). Commenters identified PROMIS Global, VR12, SAQ–7, PHQ–2, Rose Dyspnea Score, and International Consortium for Health Outcomes Measurement (ICHOM) recommended measures as candidates for future inclusion in the EPMs. Furthermore, two commenters supported the inclusion of PROMs in the SHFFT model and encouraged CMS to mandate the PROMs for the SHFFT model as soon as possible.

Response: We thank the commenters for their recommendations. We will take these into consideration as candidates for future inclusion in the EPMs and in our measure development and testing efforts.

Comment: One commenter encouraged CMS to include other CAHPS measures, such as CG–CAHPS and S–CAHPS.

Response: We thank the commenter for their recommendations.

Comment: One commenter supported holding hospitals financially responsible for quality and encouraged CMS to maintain the proposed measures.

Response: We thank the commenter for their support.

Comment: Several commenters recommended including functional status measures, such as functional status improvement from admission to discharge, Functional status change for

patients with Hip impairments (NQF #0423), and other NQF-endorsed functional outcome measures in the EPM models.

Response: We thank the commenters for their recommendations. We will take these into consideration as candidates for future inclusion in the EPMs and in our measure development and testing efforts.

Comment: Several commenters recommended that CMS consider 90-day measures and measures for high-impact areas including medication errors, hospital-acquired infections, and hospital-related injuries, such as surgical site infection (SSI) following hip fracture, complications rate following hip fracture, 90-day reoperations rate following hip fracture, percent of patients returning to pre-fracture ambulatory status at 90 days, length of stay following hip fracture, arrival to surgical procedure, and 30-day readmissions following hip fracture.

Response: We appreciate these comments, including the suggestions for priority areas for further measure development. CMS acknowledges that outcomes measures addressing a longer timeframe, such as 90 days, should be pursued. In developing measures that use a longer timeframe, CMS will conduct empirical analyses to ensure that such measures are scientifically robust and to identify appropriate risk-adjustment approaches. CMS will begin initial exploration of the suggested priority areas as well as review condition specific and procedure specific measure concepts. The timeline for this to occur is dependent upon several factors including expert panel review and comment periods, reliability, and validity testing, thus is varied and subject to change. This timeline ranges between 24–36 months, pending no major setbacks or delays outside of CMS control. Once such measures are fully developed, submitted for NQF endorsement and available, CMS will consider the most appropriate time frame to incorporate these measures into the EPM quality payment methodology through future notice and comment rulemaking.

Comment: One commenter supported the use of shared decision-making measures. The commenter believed that patients and their family caregivers should have the opportunity to receive all relevant information, review all options, weigh the benefits and potential drawbacks, and make a decision.

Response: We thank the commenter for their comment and agree that patients, families and caregivers should have the opportunity to receive relevant information, review all options, weigh the benefits and potential drawbacks, to make the best decision. We will take this measure concept into consideration in our ongoing measure development and testing efforts.

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 proposed 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 proposed 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 proposed to allow hospitals to submit the data elements using either QRDA–I or to submit to data elements using a simpler spreadsheet in performance year 1. We proposed to require hospitals to submit data elements using only QRDA–I 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 the proposed rule (81 FR 50794). The use of QRDA for reporting of EHR data is aligned with requirements used by the HIQR Program for electronic clinical quality measures. We sought comment on the proposal to collect EHR data through either QRDA–I or through a simple spreadsheet in performance year 1 and to collect EHR data through only QRDA–I in performance years 2 through 5.

The following is a summary of the comments received and our responses.

Comment: One commenter was concerned that it will be difficult to link episode data from all of the various sources, such as hospitals, skilled nursing facilities, and clinical practices. The NPRM proposes to use a simple spreadsheet in year 1 and QRDA–I files in subsequent years, whereas participants submitting AMI voluntary data will receive hospital-specific reports that detail submission results from the most recent performance period. The commenter believes this scenario requires extra work and puts burden on providers for two different implementation solutions. The commenter requests additional information on how standardized the spreadsheets will be, as well as who will specify the format.

Response: We thank commenters for their suggestion to align standards across our programs. We agree that it is important to align these data collection requirements to reduce burden on hospitals and improve interoperability. We will take this feedback into consideration as we shape future proposals for hybrid measures.

One of the main tenets of the 2015 Edition Health IT Certification Criteria final rule (80 FR 62601) is to facilitate greater interoperability for several clinical health information purposes and enable health information exchange through new and enhanced certification criteria, standards, and implementation specifications. We note that we have worked closely with ONC to enhance testing and validation of certified technology's ability to capture, exchange, and report electronic patient data, such as through improved testing and certification through the Cypress CQM testing and certification tool. As another example, we note that ONC proposed a 2015 Edition ''CQM—report'' certification criterion in the FY 2016 IPPS/LTCH PPS proposed rule that sought stakeholder input on the standards for representing and reporting CQM data in certified health IT to improve the reliability and consistency of such data reporting (80 FR 24613 through 24614). Furthermore, the 2015 Edition criteria related to eCQMs offer increased data portability and user

access using the established QRDA standards. Because of the support for testing and certification offered by ONC and their certification tools and programs, the widespread deployment of the QRDA standard and CMS' own recent experience that QRDA can provide superior clinical data for assessing quality and performance, we will finalize our selection of QRDA–I as the primary reporting standard for the EPM Model Rule for program years 1–3. If QRDA–I cannot be available to all participants for year 1, we will make a transitional submission format available to systems using a spreadsheet-based approach that will allow these sites additional time to meet the QRDA-based reporting requirements. We thank commenters for their continued support of improving the electronic reporting process and plan to continue to make improvements as standards evolve.

Comment: One commenter requested that CMS conduct an analysis of any performance differences resulting from the transition to ICD–10 for the measures used in the EPMs, and for CMS to make these analyses publicly available.

Response: The AMI EDAC, AMI and CABG 30-day mortality measures all have 3-year measurement periods. Because ICD–10 implementation began in October 2015, measure results calculated for program years 1 through 5 of the EMPs will be based on a combination of ICD–9 and ICD–10 coded claims. Therefore, CMS cannot provide hospitals with any meaningful comparison of measure results with ICD–9 claims alone or ICD–10 claims alone. CMS continues to test ICD–10-based measure specifications to ensure ongoing validity of the measures. CMS provides analysis of claims data for each new performance year added to the 3-year period in the measures' Annual Updates and Specifications Reports posted on QualityNet each April during the IPPS notice of proposed rulemaking.

Comment: Several commenters expressed concern regarding the administrative burden imposed by the proposed data submission. One commenter stated that the current submission process is highly manual, as data must be entered for each patient separately into the CMS spreadsheet. The commenter suggested a portal in which data can be uploaded and validated monthly with greater efficiency than the spreadsheet. Another commenter encouraged the use of measurement instruments which can be administered electronically to reduce burden.

Response: We appreciate the commenters' concern, however, as stated in 81 FR 50910, for the Hybrid AMI mortality measure, we proposed to allow to submit the data elements using either QRDA–I or to submit data elements using a simpler spreadsheet in performance year 1. We proposed requiring the hospitals to submit data elements using only QRDA–I in performance years 2 through 5. We disagree that increased burden is placed on providers in that there are options to use either QRDA–I or simpler spreadsheet in performance year 1. The purpose of the option to use a simpler reporting format (spreadsheet) is to allow hospitals to perfect data extraction with the 2017 data and postpone mastery of reporting in the QRDA format to the following year. CMS 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 proposed the same mechanisms used in the HIQR Program to collect HCAHPS Survey measure data also be used in the AMI, CABG, and SHFFT models (79 FR 50259).

Comment: One commenter expressed concern about collecting quality data that may not yield meaningful results. The commenter recommended a delay in collecting and reporting quality data for the EPMs until CJR data can be examined to ascertain its utility and determine whether it provides robust quality information.

Response: We note that we currently have broad experience with pay-for-performance in Medicare programs, including the HRRP, HVBP Program, HAC Reduction Program, and the Shared Savings Program. These pay-for-performance programs have improved the quality of care for Medicare beneficiaries. For example, since the implementation of HRRP in 2012, readmission and complications rates for various medical conditions such as elective THA/TKA have been significantly reduced, thereby resulting in improvements in the quality of care for Medicare beneficiaries undergoing joint replacement procedures. Furthermore, pay-for-performance is a feature of a number of Innovation Center models currently in testing. We refer readers to section III.D.5. of the CJR Final Rule (80 FR 73473) for further discussion of public reporting of pay-for-performance data during performance year 1 of the model.

We have developed and adopted a variety of new quality measures in programs and models since 2011, as well as gained experience with pay-for-reporting and pay-for-performance in a variety of models and programs involving a wide range of health care providers and clinical conditions. Given our extensive experience over the past several years with pay-for-performance approaches, the availability of existing measures that reflect the quality of care for AMI, CABG, and SHFFT episodes, and the breadth of the EPMs, which reaches substantially all IPPS hospitals in the selected MSAs, including those hospitals who otherwise would not participate in a voluntary payment model, we believe that a pay-for performance approach is necessary and appropriate beginning in the model's first performance year. IPPS hospitals have substantial experience over multiple years with CMS programs that include pay-for-performance and we believe, given the proposed quality measures for the EPMs, that AMI, CABG, and SHFFT pay-for-performance in episode payment models is a natural extension to bundled payment of pay-for-performance measures used in current CMS programs. While we acknowledge that pay-for-performance is not the only way for a model to heighten a focus on maintaining or improving the quality of care, we believe that the EPMs, like other Innovation Center models, should target both improved quality and reduced costs. Based on our experience in other programs and models, we believe that pay-for-performance under the EPMs shows great promise in moving participant hospitals toward greater efficiency and higher quality care. In view of successful implementation of pay-for-performance in other CMS hospital programs using similar quality measures that has resulted in significant improvements in the quality of care, we believe IPPS hospitals have sufficient experience to be ready for pay-for-performance under the AMI, CABG, and SHFFT models.

We expect that other features of the model design, including our plans for data sharing, will help participant hospitals committed to care redesign toward these goals achieve success on both quality and cost performance for episodes. We note that the quality measures finalized for the model as discussed in section III.E.2 of this final rule rely upon data that hospitals are already submitting and which are already analyzed by CMS for other programs, so we see no reason to adopt a period of pay-for-reporting for the first performance year of the model or longer. In the proposed rule, we considered a similar policy that would not penalize hospitals with regard to their eligibility for reconciliation

payments for failure to meet the proposed quality measure thresholds in performance year 1. However, we continue to believe that adopting pay-for- reporting and not pay-for-performance in performance year 1 or longer would be inappropriate given that two of the proposed quality measures are administrative claims based measures and impose no additional reporting burden on hospitals, the proposed measures are all established measures in existing CMS quality programs, and a central goal of the EMPs is improving care for Medicare beneficiaries. In this regard, the EPMs are different from some other CMS value-based initiatives where the data for some measures were newly submitted by providers or newly analyzed by CMS early in the initiative. Furthermore, we do not believe that participant hospitals need a year of pay-for-reporting to develop systems for analyzing episode claims under the model, as we expect hospitals to already be focused on improving their performance on these measures. The measures finalized for the EPMs are aligned with the goals of the models, are familiar to hospitals based on their use in other CMS hospital programs, and are aligned with CMS priorities to reduce mortality and complications while improving the patient experience. Because the measures reflect these goals and accurately measure hospitals' level of achievement and improvement on quality outcomes that are important to beneficiaries, we are finalizing our proposal to implement a pay-for-performance approach in the AMI, CABG, and SHFFT models in the first performance year by using quality performance in the episode payment methodology.

Comment: One commenter recommended clarification on the PROM, specifically the Veterans RAND 12 Item Health Survey (VR–12) data submission requirement to accommodate for the handling of missing data elements consistent with proven methods in the scientific literature as it determines if a hospital has successfully met its reporting threshold.

Response: We thank the commenter for their suggestion. One of the generic health-related quality of life assessment survey that hospitals can use is the Veterans RAND 12 Item Health Survey (VR–12). Hospitals who elect to use this survey instrument must report patient responses to all of the questions; that is, all 14 questions from this survey. Twelve questions or items (*i.e.,* question groups 1–7) in the survey are used to calculate two scores, a ''Physical Health Summary Measure (PCS-physical component score)'' and a ''Mental Health Summary Measure (MCS-mental component score).'' Two additional questions are included as anchor questions that CMS will use to gauge the clinical significance of a (physical and/or mental health) change following an intervention. Likewise, hospitals who elect to use the other generic health-related quality of life assessment, the PROMIS-Global, must also report patient responses to all of the questions to be considered for the successful voluntary reporting of the PRO and risk variable data component of the SHFFT model.

Comment: Several commenters believed that measures should be collected at intervals more immediately post-surgery and more routinely afterward throughout the 6 month post-discharge duration. One commenter further noted that a participant hospital's quality performance must be considered in parallel with its financial performance and these components be compared, in tandem, to a pre-EPM baseline.

Response: The measures proposed for the AMI, CABG, and SHFFT models use a 3-year reporting period and are updated annually. The 3-year reporting period ensures that hospitals have a sufficient number of cases for a reliable and valid estimate of their risk-adjusted outcome rate. The measures are not designed for more frequent reporting of results. CMS does assess trends in hospitals' performance on the proposed measures to identify potential unintended consequences in the HIQR program.

Comment: Several commenters were supportive of the proposed approach to reporting and data collection. Commenters stated that it demonstrates CMS' effort to minimize administrative burden on providers when implementing new care models. One commenter appreciated that many of the proposed quality measures are currently being reported for the Inpatient Quality Reporting Program (IQR), thereby reducing additional reporting burden for hospital staff. Another commenter commended CMS for treating and separately bundling services for patients who fall under the SHFFT model rather than including them in CJR.

Response: We thank the commenters for their support.

Comment: Several commenters raised concerns about the proposed timeline for voluntary data submission in the SHFFT model. Specifically commenters were concerned that the data submission timeline did not align with the model performance years. The commenters suggested that the data submission deadline closely align with the start date of the model so CMS can receive relevant data and have time to analyze initial CJR changes to make necessary changes before implementation of SHFFT data collection.

Response: The intent of the proposed timeline for voluntary data submission for the SHFFT model is to reduce confusion by proposing to use the same 3-year rolling time periods for calculating readmissions and complications performance that are used in the hospital IQR program and to align the data collection timeline with the CJR model timeline starting in program year 1. CMS will assess data submitted for the CJR model and will consider any necessary changes in future rulemaking cycles for the CJR and SHFFT models.

Comment: One commenter recommended that CMS allow hospitals to submit using either the QRDA–I or QRDA–III approach for the first performance period to allow maximum flexibility and to assess which approach is most feasible.

Response: For the Hybrid AMI Mortality measure, CMS is seeking to risk adjust individual patients, thus we have specified QRDA–I, which describes patient level data, as the appropriate standard. The QRDA–III standard, which describes aggregate data, would not be appropriate for this purpose. One of the main tenets of the 2015 Edition Health IT Certification Criteria final rule (80 FR 62601) is to facilitate greater interoperability for several clinical health information purposes and enable health information exchange through new and enhanced certification criteria, standards, and implementation specifications. We note that we have worked closely with ONC to enhance testing and validation of certified technology's ability to capture, exchange, and report electronic patient data, such as through improved testing and certification through the Cypress CQM testing and certification tool. As another example, we note that ONC proposed a 2015 Edition ''CQM—report'' certification criterion in the FY 2016 IPPS/LTCH PPS proposed rule that sought stakeholder input on the standards for representing and reporting CQM data in certified health IT to improve the reliability and consistency of such data reporting (80 FR 24613 through 24614). Furthermore, the 2015 Edition criteria related to eCQMs offer increased data portability and user access using the established QRDA standards. Because of the support for testing and certification offered by ONC

and their certification tools and programs, the widespread deployment of the QRDA standard and CMS' own recent experience that QRDA can provide superior clinical data for assessing quality and performance, we will finalize our selection of QRDA–I as the primary reporting standard for the EPM Model Rule for program years 1–3. If QRDA–I cannot be available to all participants for year 1, we will make a transitional submission format available to systems using a spreadsheet-based approach that will allow these sites additional time to meet the QRDA-based reporting requirements.

Comment: Several commenters raised concerns about the proposed timeline for voluntary data submission in the SHFFT model. Specifically commenters were concerned that the data submission timeline did not align with the model performance years. The commenters suggested that the data submission deadline closely align with the start date of the model so CMS can receive relevant data and have time to analyze initial CJR changes to make necessary changes before implementation of SHFFT data collection.

Response: The intent of the proposed timeline for voluntary data submission for the SHFFT model is to reduce confusion by proposing to use the same 3-year rolling time periods for calculating readmissions and complications performance that are used in the hospital IQR program and to align the data collection timeline with the CJR model timeline starting in program year 1. CMS will assess data submitted for the CJR model and will consider any necessary changes in future rulemaking cycles for the CJR and SHFFT models.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to collect EHR data through either QRDA–I or through a simple spreadsheet in performance year 1 and to collect EHR data through only QRDA–I 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 41, 42, 43, 44, and 45.

TABLE 41—SUMMARY OF 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 42—SUMMARY OF QUALITY MEASURE PERFORMANCE PERIODS BY YEAR OF THE CABG MODEL

Measure I	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 43—SUMMARY OF 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 STS CABG Composite Measure data.	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 44—SUMMARY OF 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 45—SUMMARY OF QUALITY MEASURE PERFORMANCE PERIODS BY YEAR FOR REQUIRED MEAURES 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 proposed 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 sought comment on this proposal.

The following is a summary of the comments received and our responses.

Comment: Several commenters supported the proposal to publicly report hospitals' EPM quality performance data on Hospital Compare.

Response: We thank the commenters for their support.

Comment: Several commenters expressed concern that the description of data publicly displayed on Hospital Compare should accurately reflect performance. Rather than placing hospitals with insufficient volume on a quality measure at the 50th percentile in the ''Good'' category, it should be placed in a separate category noting that there was insufficient volume to determine a performance score. One commenter further suggested that hospitals be provided an opportunity to preview and offer corrections to data provided by CMS before reporting on Hospital Compare.

Response: While we understand the concerns of the commenter that we have no actual outcome measure results for certain hospitals, we continue to believe it would be unfair to disadvantage a participant hospital in the pay-for-performance methodology of this model based on insufficient number or no applicable cases alone and, therefore, we will assign these hospitals to the 50th performance percentile, which is the middle of the national measure performance distribution, and assign quality performance points to the participant hospital accordingly based on the performance percentile scale identified in Table 41.

We note that the Hospital Compare Web site is the vehicle that provides public reporting and within this Web site we indicate that this Web site fulfills section 1886(b)(3)(B)(viii)(VII) of the Act, as amended by section 3001(a)(2) of the Affordable Care Act, which requires the Secretary to establish procedures for making information regarding measures submitted available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. Prior to the release of data on Hospital Compare, hospitals are given the opportunity to review data during a 30-day preview period via the QualityNet Secure Portal (*http://www.qualityreportingcenter.com/wpcontent/uploads/2015/07/IQR_FY-2017_Hospital-IQR-Program-ReferenceChecklist_Tool_7.21.2015_FINAL508.pdf).* With respect to the HCAHPS Survey measure (NQF #0166), CMS similarly provides hospitals with their confidential preview reports on a quarterly basis, before the results are publicly reported on Hospital Compare Web site (*http://www.hospitalcompare.hhs.gov/*) (78 FR 50778).

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to display quality measure results on the Hospital Compare Web site (*http://www.hospitalcompare.hhs.gov*). Regarding the voluntary PRO data collection, because we are collecting the data required to develop a future PRO-based performance measure that will assess hospital quality of care for patients undergoing elective primary THA/TKA procedures, we do not plan to publicly report on Hospital Compare. For the STS CABG Composite measure, which is voluntary for year one, we intend to publicly report if operationally feasible. We plan to utilize notice and comment rulemaking if CMS decides to require this measure in the future and will thus discuss plans for public reporting.

F. Compliance Enforcement and Termination of an Episode Payment Model

1. Overview and Background

The following discussion details the enforcement mechanisms we proposed to make available to CMS for the EPM when an EPM participant or certain other individuals or entities fails to comply with the requirements of the model.

Section 510.410 established that CMS will enforce the CJR model requirements against CJR participant hospitals, and will hold each participant hospital responsible for its own and its CJR collaborators' compliance with CJR model requirements. Given that CJR participant hospitals may receive reconciliation payments, and may choose to distribute or share those

payments with their CJR collaborators, CMS believes that enhanced scrutiny and monitoring of CJR participant hospitals was necessary and appropriate. We also noted in the CJR Final Rule (80 FR 73464) 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. Furthermore, § 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 the participant hospital to terminate a sharing arrangement with a CJR collaborator and to prohibit further engagement in the CJR model by that collaborator, and CMS may also increase a participant hospital's repayment. Section 510.410 as well as 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 proposed an enforcement structure for the EPM that will be consistent with the CJR model, as we believe the CJR model and the EPM share many of the same policy characteristics.

2. Compliance Enforcement for the EPMs

We proposed that CMS will have the remedial actions detailed in § 512.460(b)(2) available for use against any EPM participant where the EPM participant or its EPM collaborator, collaboration agent, or downstream collaboration agent is not compliant with the applicable requirements as set forth in § 512.460(b)(1). These compliance tools will support CMS' objectives for the EPM to maintain or improve quality of care, reduce program expenditures, safeguard program integrity, protect against fraud and abuse, and deter noncompliance with EPM requirements. Furthermore, preventing EPM participants from engaging in avoiding high-cost and high-severity patients or from targeting low-cost and low-severity patients will further CMS' goals under the CR incentive payment model to reduce cardiovascular mortality, improve health-related quality of life, and reduce the risk of hospital admission. Additionally, these compliance tools will support CMS' aim under the EPM that beneficiaries receive complete and accurate information, including notices which promote increasing consumer engagement and freedom of choice. Given that EPM participants may choose to enter into sharing arrangements with EPM collaborators, those EPM collaborators may have distribution arrangements with collaboration agents, and those collaboration agents may have downstream distribution arrangements with downstream collaboration agents, we believe that enhanced scrutiny and monitoring of EPM participants and their EPM collaborators, collaboration agents, and downstream collaboration agents is necessary and appropriate in order to mitigate program integrity risks.

Similar to the CJR model, we proposed to hold the EPM participant responsible for its own and its EPM collaborators' compliance with the EPM requirements. Additionally, in the EPM proposed rule we proposed to add EPM participant responsibility for the other individuals and entities with financial arrangements under the EPM. This was based in part on the proposed addition of ACOs and hospitals, including CAHs, as EPM collaborators. Specifically, because we proposed to allow additional entities and individuals to be EPM collaborators, collaboration agents, or downstream collaboration agents, we must have tools to address noncompliance with the requirements of the EPM by these entities and individuals as well. Overall, we concluded in the proposed rule that EPM participants should ensure that any entity or individual with a financial arrangement under the EPM complies with model requirements in order to safeguard program integrity.

We proposed that CMS have authority to take remedial action against an EPM participant if its related EPM collaborator, collaboration agent, or downstream collaboration agent fails to comply with the requirements of the EPM; has signed a sharing arrangement, distribution arrangement, or downstream distribution arrangement that is noncompliant with the requirements of the EPM; takes any action that threatens the health or safety of patients; avoids at-risk beneficiaries; 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 that could lead to the inability to comply with the requirements of the EPM; takes any action that CMS determines for program integrity reasons is not in the best interests of the applicable EPM, or fails to take any action that CMS determines for program integrity reasons should have been taken to further the best interests of the EPM; is subject to action to redress an allegation of fraud or significant misconduct; or is subject to action involving violations of certain laws, rules, or regulations that are relevant to the EPM. Moreover, we proposed that for purposes of this provision, ''failure to comply with the requirements of the EPM'' would specifically include, but not be 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.

Proposed remedial actions included issuing a warning letter to the EPM participant; requiring the EPM participant to develop a corrective action plan; 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; and terminating the EPM participant's participation in the EPM. Where a participant is terminated from the EPM, we proposed that the EPM participant would remain liable to CMS for all negative NPRA generated from episodes of care that occurred prior to termination. In addition, we noted that any information collected by CMS in relation to termination of a participant from the EPM would be shared with our program integrity colleagues at HHS, the Department of Justice, and their respective designees. We noted further that should an EPM participant, or one of its related EPM collaborators, collaboration agents, or downstream collaboration agents, be noncompliant with the requirements of the EPM or engage in unlawful behavior related to participation in the EPM, such information could be used in proceedings unrelated to the administrative enforcement mechanisms in this section. We believe these remedial actions are necessary tools to safeguard program integrity, including protecting against fraud and abuse and deterring noncompliance with EPM requirements.

In summary, we set forth in proposed § 512.460 that EPM participants must comply with all requirements outlined in part 512. We specified that, 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 proposed in § 512.460 that CMS may take remedial actions 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 EPM, 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 of this part;
- 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 EPM, or fails to take any action that CMS determines for program integrity reasons should have been taken to further the best interests of the 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 the EPM.

We proposed 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 participation in the EPM. Where a participant is terminated from an EPM, the EPM participant will remain liable for all negative NPRA generated from EPM episodes that occurred prior to termination.

Furthermore, we proposed that CMS may add 25 percent to a repayment amount on the EPM participant's reconciliation report if all of the following conditions are met:

- 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 were included in proposed § 512.460. We sought comment on our proposals.

The following is a summary of the comments received and our responses.

Comment: Several commenters acknowledged the need for remedial actions proposed by CMS under the EPM to address EPM participant noncompliance with EPM requirements. However, some commenters expressed concern about CMS' proposal that EPM participants would be held responsible for the compliance of their related EPM collaborators, collaboration agents, and downstream collaboration agents. The commenters claimed that such an expansive accountability for the conduct of others would create a large regulatory and legal burden for the EPM participant, especially regarding collaboration agents and downstream collaboration agents with which EPM participants do not have direct contractual relationships. One commenter stated their belief that while EPM participants can and should validate that each EPM collaborator, collaboration agent, and downstream collaboration agent has a compliance program, EPM participants should not be responsible for the compliance of these individuals and entities with the requirements of the EPM. The commenter asserted that the compliance of these parties is essentially out of the EPM participant's control when the individual or entity with a financial arrangement under the EPM is not owned or operated by the EPM participant. The commenter urged CMS to instead hold each EPM collaborator, collaboration agent, and downstream collaboration agent accountable for its own compliance with the requirements of the EPM or, at a minimum, to identify specific elements for which the EPM participant would be responsible for the compliance of its related EPM collaborators, collaboration agents, and downstream collaboration agents.

Response: We appreciate the concerns of some of the commenters regarding the potential burdens on EPM participants associated with accountability for the conduct of other individuals and entities, especially for those individuals and entities that do not have direct contractual relationships with the EPM participant. With regard to the commenter's belief that EPM participants can and should validate that each EPM collaborator, collaboration agent, and downstream collaboration agent has a compliance program, we want to clarify that our proposal for financial arrangements would only require that an EPM collaborator have a compliance program that includes oversight of the sharing arrangement as proposed in § 512.500(b)(4). We did not propose to require that collaboration agents or downstream collaboration agents have a compliance program.

We note that under the EPM, the EPM participant is the sole entity that is financially accountable to CMS. It is only through an EPM participant that the opportunity exists for EPM collaborators, collaboration agents, and downstream collaboration agents to have financial arrangements under the EPM. In addition, because only EPM participants can generate internal cost savings and receive reconciliation payments and then choose to distribute those funds through gainsharing payments to EPM collaborators, we believe a focus on EPM participants is necessary and appropriate. Therefore,

the enforcement authority over the EPM participant is key to successfully implementing these models and ensuring program integrity.

We note that the Shared Savings Program regulations in § 425.210(b) and § 425.218 similarly permit CMS to hold ACOs accountable for not only the noncompliance of their ACO participants and ACO providers/suppliers but also for the noncompliance of any other individuals or entities performing functions or services related to ACO activities. Furthermore, CMS may terminate the participation agreement with an ACO when an ACO, ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities fail to comply with any of the requirements of the Shared Savings Program under the regulations. The scope of the compliance enforcement authority in the Shared Savings Program is similar to our proposal to hold the EPM participant accountable for the noncompliance of its related EPM collaborators, collaboration agents, and downstream distribution agents.

In the EPM proposed rule and in this final rule, we provide our rationale for the EPM requirements that we proposed and are finalizing, which we believe are necessary to advance the goals of the EPM, protect beneficiaries from potential adverse consequences of the EPM, and provide program integrity safeguards for the Medicare program. We believe it is important that EPM participants, EPM collaborators, collaboration agents, and downstream collaboration agents consider these requirements holistically and determine how to best to achieve compliance. Thus, we will not identify only a subset of EPM requirements or the other proposed provisions to identify noncompliance specified in § 512.460(b)(1)(i) through (ix) for which we will hold the EPM participant responsible with respect to its related EPM collaborators, collaboration agents, or downstream collaboration agents.

Finally, we emphasize that entering into sharing arrangements is a choice that EPM participants may make, and EPM participants also have the choice as to whom to select as an EPM collaborator based on selection criteria developed by the EPM participant as specified in § 512.500(a)(3) and finalized in this final rule. In addition, EPM participants have the authority through their contracts with their EPM collaborators to address the conduct of collaboration agents and downstream collaboration agents.

Comment: One commenter asserted that the compliance enforcement provisions that CMS proposed will not protect EPM beneficiaries in a timely manner. The commenter observed that CMS specifically proposed to allow for termination of an EPM participant's participation in the EPM or termination of a sharing arrangement when an EPM participant or its related EPM collaborator, collaboration agents, or downstream collaboration agent discriminates against at-risk Medicare beneficiaries by avoiding caring for them or takes an action that threatens patients' health or safety. However, the commenter expressed concern that CMS did not appear to allow the termination of an EPM participant or termination of a sharing arrangement for an EPM participant or EPM collaborator, respectively, found to have purposefully steered a patient to a particular provider which it knew, or should have known, would fail to provide needed care. The commenter claimed that CMS' proposal also did not address the termination of providers found to have deliberately administered substandard care. The commenter stated that termination or exclusion of poorly performing providers from the EPM is important because participants cannot ultimately control patient choice and where beneficiaries choose to go post-discharge. The commenter urged CMS to expressly allow for remedial action in the case of an EPM participant or an EPM collaborator who repeatedly withholds care as referenced in other parts of the proposed rule, or steers patients to particular providers which it knew, or should have known, would fail to provide needed care.

Response: We appreciate the commenter's concern about protecting beneficiaries under the EPM from the potentially harmful consequences of withholding care, providing substandard care, or steering beneficiaries to particular providers who fail to provide needed care. These are serious concerns, and we believe that our proposal for compliance enforcement under the EPM allows CMS to take remedial action if any of these circumstances are discovered. We proposed in § 512.460(b)(1)(iii) that CMS may take remedial action against any EPM participant when the EPM participant or its related EPM collaborator, collaboration agent, or downstream collaboration agent takes any action that threatens the health or safety of patients. If an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent is found to have taken any action that threatens the health or safety of patients, including but not limited to, withholding care, providing substandard care, or steering beneficiaries to certain providers or suppliers who will fail to provide needed care, the regulations adopted in this final rule allow CMS to take remedial action. Moreover, CMS may take remedial action in response to actions that threaten health and safety that include the types of actions the commenter requested, including issuing a warning letter to the EPM participant; requiring the EPM participant to develop a corrective action plan; reducing or eliminating the EPM participant's reconciliation payment; increasing the EPM participant's repayment amount; 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 participating in sharing arrangements with the EPM collaborator; or terminating the EPM participant's participation in the EPM.

Comment: One commenter requested that CMS address how a patient's clinical outcome may be considered when determining noncompliance with the requirements of the EPM. The commenter stated there could be scenarios where health care that may not be in the best interest of an EPM participant's cost performance under the EPM may be clinically in the best interest of the patient.

Response: We appreciate the commenter's concern that compliance enforcement take into account what is clinically in the best interest of the patient. We note that the types of noncompliance we identified in our proposal in § 512.460(b)(1)(i) included failing to provide medically appropriate services or systematically engaging in the over- or under-delivery of appropriate care or failing to allow beneficiary choice of medically necessary options, including non-surgical options. Each case of noncompliance determined based on the provisions in § 512.460(b)(1) will be considered on a case-by-case basis, and CMS will weigh both the financial interests of the Medicare program and the clinical needs of beneficiaries when determining the appropriate remedial action.

Comment: One commenter encouraged CMS to clarify the proposal in § 512.460(b)(1)(vii) that CMS may take remedial action if an EPM participant or its related EPM collaborator, collaboration agent, or downstream collaboration agent ''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 reasons of program integrity should have been taken to further the best interests of the EPM.'' The commenter requested that in the final rule, CMS provide examples of actions that are not clear violations of existing fraud and abuse statutes that would fall into this category of noncompliance.

Response: The proposed provision in § 512.460(b)(1)(vii) where the commenter requested that CMS provide examples would allow CMS the flexibility to take remedial action where the EPM participant or its related EPM collaborator, collaboration agent, or downstream collaboration agent takes any action that CMS determines is not in the best interests of the EPM, or fails to take any action that CMS determines for program integrity reasons should have been taken to further the best interests of the EPM. This provision is purposefully structured to include noncompliance that is not a clear violation of existing fraud and abuse statutes. For example, an EPM participant could fail to respond to a request from CMS for records to enable the investigation into concerns about the potential selection of EPM collaborators based on the volume and value of referrals. In this scenario, CMS could determine that the EPM participant was noncompliant based on this proposed provision because the EPM participant failed to provide access to records so that the potential program integrity concerns could be assessed. Thus, CMS could take remedial action in this example by issuing a warning letter to the EPM participant regarding the need to supply the requested records. In another example, if an audit of claims for physicians' services furnished to EPM beneficiaries by a collaboration agent found a high error rate in payment due to incorrect coding, CMS could determine for program integrity reasons that the coding errors of the collaboration agent are not in the best interests of the EPM. CMS could then take remedial action by requiring the EPM participant to develop a corrective action plan to address the coding errors.

Comment: One commenter expressed concern about the proposal in § 512.460(b)(1)(ix) that CMS may take remedial action when the EPM participant or its related EPM collaborator, collaboration agent, or downstream collaboration 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 EPM. The commenter stated specifically that violations ''of any other applicable Medicare laws, rules, or regulations that are relevant to EPM'' is overly broad so that CMS should apply a reasonable knowledge standard to the EPM participant's awareness of a collaborator's involvement in such matters.

Response: We appreciate the commenter's interest in the standard that CMS will apply for purposes of the proposed provision in § 512.460(b)(1)(ix) in identifying circumstances when an EPM participant or its related EPM collaborator, collaboration agent, or downstream collaboration agent is subject to action for violations of the specified laws, or any other applicable Medicare laws, rules, or regulations that are relevant to the EPM. However, we disagree with the commenter's suggestion that CMS apply a reasonable knowledge standard to the EPM participant's awareness of a collaborator's involvement in such matters. We believe the information regarding whether an individual or entity is ''subject to action'' should be readily available to the EPM participant. EPM participants can also include provisions in their contracts to require that they be notified when such circumstances exist. Accordingly, we believe it is reasonable to expect that the EPM participant will be aware of all such circumstances when its related EPM collaborator, collaboration agent, or downstream collaboration agent is specifically 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 EPM. Therefore, we believe that use of a bright-line standard is more appropriate to determine compliance with this provision, regardless of what specific individual or entity is subject to action for a violation.

Comment: One commenter recommended that CMS strengthen the accountability for EPM participants that are found to withhold or delay care by imposing a separate financial penalty that is independent of repayment responsibility. The commenter reasoned that an EPM participant that has already had to repay CMS the maximum percentage permitted under the EPM, that is, met the stop-loss limit, will have little incentive to refrain from other potentially harmful cost-cutting strategies unless the EPM participant could be subject to a separate financial penalty that is not subject to the EPM stop-loss limit.

Response: Given the proposed compliance tools for the EPM, as well as the existing laws and regulations that prohibit care stinting, provision of substandard care, or denial of medically necessary care, we believe that it is unnecessary to implement a process for a separate financial penalty outside of the compliance tools that we proposed. When an EPM participant or its related EPM collaborator, collaboration agent, or downstream collaboration agent engages in these noncompliant behaviors, CMS may take remedial action, including reducing or eliminating the EPM participant's reconciliation payment or reducing or eliminating the EPM participant's CR incentive payment amount. In addition, under circumstances where CMS has required a corrective action plan, the EPM participant owes a repayment amount to CMS, and the EPM participant fails to timely comply with the corrective action plan or is noncompliant with the EPM's requirements, we proposed that CMS may add 25 percent to a repayment amount on an EPM participant's reconciliation report. We are clarifying in regulation in this final rule that the 25 percent is a penalty.

Moreover, we note that in accordance with the provisions finalized in § 512.305(d) for determination of the reconciliation payment or repayment amount, we first calculate the NPRA for a performance year that is adjusted, if applicable, for the stop-loss or stop-gain percentage that applies. Next, we add in the results from the post-episode spending and ACO overlap calculations, if applicable, for the prior performance year. Finally, we adjust the reconciliation or repayment amount as described in §§ 512.460(b) and (c). Thus, the potential financial penalty of up to 25 percent of the repayment amount on an EPM participant's reconciliation report if certain conditions are met is not subject to the EPM stop-loss limitation. Therefore, the EPM participant has a continuing financial incentive to refrain from other potentially harmful cost-cutting strategies that could lead CMS to apply this financial penalty even if that EPM participant already has to repay CMS the maximum percentage permitted under the stop-loss limitation under the EPM. We believe this structure for the financial penalty is consistent with the request of the commenter.

Final Decision: After consideration of the public comments received, we are finalizing the proposals in § 512.460 for

compliance enforcement, with modification to clarify that the 25 percent that CMS may add to the repayment amount under certain conditions is a penalty. The compliance enforcement provisions for the EPM are:

• 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).

• CMS may take one or more of the remedial actions set forth in this section if an EPM participant or its related EPM collaborator, collaboration agent, or downstream collaboration agent does any of the following:

++ Fails to comply with any requirements of this part or is identified as noncompliant through monitoring by HHS (including CMS and OIG) of the EPM, including but not limited to any of the following:
—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.
—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 of this chapter.
++ Avoids patients on the basis of payer status.
++ Is subject to sanctions or final actions of an accrediting organization or Federal, state, or local government agency that could lead to the inability to comply with the requirements and provisions of this part.
++ Takes any action that CMS determines for program integrity reasons is not in the best interests of the EPM, or fails to take any action that CMS determines for program integrity reasons should have been taken to further the best interests of the 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.
++ 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 EPM.

• Remedial actions 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 participation in the EPM. Where a participant is terminated from an EPM, the EPM participant will remain liable for all negative NPRA generated from EPM episodes that ended prior to termination.

• CMS may add a 25 percent penalty to a repayment amount on the EPM participant's reconciliation report if all of the following conditions are met:

++ 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.

3. Termination of an Episode Payment Model

We set forth in proposed § 512.900 that CMS may terminate any EPM 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.

We did not receive any comments on these proposals.

Final Decision: We are finalizing the proposals in § 512.900 for termination of an EPM, with editorial modifications. CMS may terminate any EPM for reasons including, but not limited to, one of the following:

• CMS no longer has the funds to support the EPM; or

• CMS terminates the EPM 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 proposed to complement the CJR model implemented in 2016, as we believe the proposed EPMs represented additional opportunities to improve beneficiary access, patient outcomes, and overall quality of care across a broader spectrum of clinical conditions. The proposed EPM policies were intended to support making care more easily accessible to beneficiaries when and where they need it, increasing beneficiary engagement and thereby informing beneficiary choices.

In the proposed rule, we stated our belief that the proposed EPMs would improve beneficiary access and outcomes, but we further noted that these same opportunities could be used to try to steer beneficiaries into lower cost services without an appropriate emphasis on maintaining or increasing quality. We refer to section III.E.3 of the proposed rule (81 FR 50881 through 50893) for discussion of the methodology for incorporating quality into the payment structure and the measures utilized for these models, which we believe could help identify and mitigate these possibilities.

2. Beneficiary Choice

As with the CJR model, we proposed that all hospitals (with some limited exceptions) in the selected geographic areas for each EPM would participate in the proposed EPMs. An individual beneficiary will retain full choice of providers as they do currently, but upon agreeing to be admitted to an EPM participant that results in discharge from an MS–DRG that initiates an EPM episode, the beneficiary will not be able to opt out of his or her care being included in an EPM episode under the responsibility of that EPM participant. 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 will 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 in the design of the proposed EPMs. It also is important for beneficiaries to know that they can raise any concerns with their physicians, with the 1–800–MEDICARE helpline, or with their local Quality Improvement Organizations (QIOs).

As with the CJR model and other episode-based payment models, the proposed EPMs will not limit a beneficiary's ability to choose among Medicare providers or the range of services that will be available to them. Beneficiaries will 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 for other Medicare services that are not included in an EPM episode. Although the proposed EPMs will allow EPM participants to enter into sharing arrangements with certain providers, suppliers, and ACOs and allow EPM participants to recommend to beneficiaries preferred providers and suppliers, within the constraints of applicable laws and regulations, EPM participants may not restrict beneficiaries to a list of preferred or recommended providers or suppliers 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 the EPM participant accept such payments, which would be considered to be outside the realm of sharing arrangements. Although the emergent nature of some of the clinical conditions that are the focus of the proposed EPMs may limit beneficiaries' abilities to plan the hospital where they will be treated for these conditions, such constraint should be no different than it will be in the absence of the EPMs. Thus, the proposed EPMs will not create any new restriction of beneficiary freedom to choose providers, including surgeons, hospitals, post-acute care providers, or any other providers or suppliers.

To specifically safeguard beneficiary freedom of choice in decision-making about care following hospital discharge, we proposed 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 stated our expectation that the treating physician, as well as all other treating practitioners, would 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 CoPs. We also specifically note that neither the CoPs nor this proposed transparency requirement preclude EPM participants from recommending preferred providers and suppliers within the constraints created by current laws and regulations, as coordination of care and optimization of care are important factors for successful participation in the EPMs.

We invited comment on these proposals, including additional opportunities to ensure high quality care.

The following is a summary of the comments received and our responses.

Comment: Several commenters requested that beneficiaries be permitted to opt out of the EPMs. One commenter was concerned that a beneficiary may try to ''opt out'' by driving to another hospital that is not an EPM participant, thus restricting the beneficiary's freedom of choice.

Response: In proposing that beneficiaries are not able to opt out of the EPMs, we meant that beneficiaries are not able to opt out of having their care, when furnished in an EPM episode, paid for under the EPM methodology. Once a beneficiary initiates an episode through admission to an EPM participant for a clinical condition that results in discharge from an MS–DRG that begins an EPM episode, their care is automatically included in the EPM and they are unable to opt out of having their care included in an EPM episode. In the geographic region of that EPM participant, the EPM is how Medicare pays for care for the clinical condition that is the focus of that EPM episode. Beneficiaries do have the choice to avoid their care being paid for under the EPM by choosing to be admitted to a hospital that is not an EPM participant, which would require that the hospital be in a different MSA that has not been selected for EPM participation. In some cases, such as elective CABG, a beneficiary may choose to travel to a hospital that is not a CABG model participant for surgery that is planned in advance if the beneficiary does not want his or her care to be paid for under the CABG model. However, in most cases under the proposed EPMs this choice is infeasible because beneficiaries with AMI or hip fracture are often transported to hospitals by emergency medical services that use transport protocols to determine the hospital that will receive the beneficiary. In other cases of AMI, even though beneficiaries may travel themselves to an emergency department, it is likely that the severity of AMI symptoms will lead them to go to the nearest hospital emergency department. Once the treatment plan for the hip fracture or AMI is established in the emergency department, to the extent that plan may include immediate admission for surgery or medical management, it is infeasible and unsafe for the beneficiary to choose to travel to another hospital at that point to avoid their care being included in an EPM.

By not allowing beneficiaries to opt out of having their care paid for under the EPM, this does not mean that their right to choose or decline otherwise covered Medicare items and services is limited. EPM beneficiaries retain their right to choose or decline items and services that are covered by Medicare. The EPMs are testing changes to how Medicare pays for care but, like Medicare payment systems, they neither define nor limit coverage, nor limit beneficiary choices to any specific covered services. In both the EPMs and other Medicare payment methodologies, providers are expected to not treat Medicare beneficiaries differently from other patients based on differences in Medicare payment. Moreover, the beneficiary safeguards adopted in this final rule ensure that the EPM payment structure does not disadvantage

Medicare beneficiaries. We note that within traditional FFS Medicare we do not allow beneficiaries to opt out of any Medicare payment systems as payment systems exist to ensure appropriate payment for similar services across beneficiaries and across providers. Furthermore, because beneficiary cost-sharing is unchanged under the EPMs, it does not have a direct financial effect on beneficiaries and, therefore, minimizes any impacts on beneficiary freedom of choice.

We discuss in the next section our requirement for beneficiary notification under the EPMs that must contain an explanation of the model and how it may or may not impact their care; notification that the beneficiary retains freedom of choice to choose providers and services for the EPM episode (where those choices are especially relevant during the 90 days following hospital discharge); 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; a statement that all existing Medicare beneficiary protections continue to be available to the beneficiary, including the ability to report concerns of substandard care to the QIOs and the 1–800–MEDICARE helpline; and a list of the providers and suppliers with whom the EPM participant has a sharing arrangement. We also require that individuals and entities with financial arrangements under the EPMs furnishing care to EPM beneficiaries provide notice to the beneficiary of the EPM's structure and the existence of the financial arrangement. Even if the clinical condition of a beneficiary makes it unrealistic for the beneficiary to make an active choice about whether or not his or her care is included in an EPM episode, we believe the notification policies provide important safeguards to protect beneficiary freedom of choice and access to care throughout EPM episodes which continue for 90 days following discharge from the anchor hospitalization. Notification allows beneficiaries to understand the potential impact of the EPMs on their care and gives them the opportunity to understand the interests of all parties when they are presented with care recommendations that may lead to less costly care under the EPMs.

Comment: Many commenters commended CMS for providing beneficiaries with the ability to choose among Medicare providers and the range of services that would be available to them under the EPM. Some commenters were pleased that EPM participants may not limit beneficiaries upon hospital discharge to receiving services only from preferred or recommended providers. Other commenters believe that changes to beneficiary care patterns under the EPMs may result in beneficiaries not being given true choice to continue to receive care within their home community and advocated for stronger protections to ensure that this choice is available.

Several commenters provided suggestions about strategies CMS could employ to ensure that beneficiary freedom of choice is not being compromised under the EPMs. They encouraged CMS to monitor EPM episode claims data and publish these findings as part of the EPM evaluation to promote transparency and an understanding of the EPM's effects. The commenters supported CMS' proposal to review and audit hospitals if CMS has reason to believe an EPM participant is compromising beneficiary access to care. The commenters also recommended that CMS explore both the retrospective monitoring reviews discussed in the proposal rule, as well as the potential for real-time monitoring to provide more immediate information about EPM beneficiary care.

Response: We appreciate the support of the commenters for our proposal that beneficiaries retain their freedom to choose providers and suppliers, as well services, under the EPMs, in the context of the EPMs that encourage increased care coordination and clinical pathways that may improve the quality and efficiency of EPM episodes. We understand and share the interest of the commenters in ensuring that this freedom of choice is realized in practice in the experience of EPM beneficiaries, when the financial incentives under the EPMs may lead EPM participants and treating providers and suppliers to make specific treatment recommendations to advance the EPM goal of improving the quality and efficiency of care. We believe that our final policies for beneficiary notification, including our requirements for the provision of a list of post-acute care providers as part of discharge planning and for monitoring throughout the EPMs as discussed in sections III.G.3. through 6. of this final rule, provide important safeguards for EPM beneficiary freedom of choice. Monitoring will help us to confirm that EPM beneficiary freedom of choice is not being restricted and to address timely issues of noncompliance by EPM participants or their related EPM collaborators, collaboration agents, or downstream collaboration agents that arise.

Comment: Many commenters provided a variety of perspectives on CMS' proposal to require, as part of discharge planning and referral, EPM participants to inform beneficiaries of all Medicare participating post-acute care providers in an area and identify those post-acute care providers with whom the EPM participant has sharing arrangements, as well as the proposal that EPM participants may recommend preferred provider and suppliers, consistent with applicable statutes and regulations.

The commenters in favor of CMS' proposal reasoned that it was most consistent with maintaining beneficiary choice under the EPMs, in the context of the financial incentives of the EPMs to reduce episode spending. However, even under CMS' proposal, multiple commenters were apprehensive about the potential for patient ''soft steering'' between EPM participants and post-acute care providers to occur due to the incentives for EPM participants to reduce expenditures, which could result in stinting on care or directing beneficiaries to low-cost providers that may provide substandard care. Several commenters were concerned that if an EPM participant reduced the number of preferred providers the EPM participant recommends in response to the financial incentives under the EPMs, patients may be required to travel further for care or be cared for by a provider that is not the best fit for their medical needs. A number of commenters recommended that CMS could mitigate the potential for soft steering by adding additional requirements for the information provided to EPM beneficiaries about post-acute care providers. One commenter urged CMS to institute such additional requirements for those preferred providers that are recommended by an EPM participant, including requiring that any preferred provider furnished enhanced services and/or higher quality services. Another commenter urged CMS to minimize steering by requiring hospitals to inform patients and their families of the post-acute care options available in their geographic area, as well as the pros and cons of selecting a particular post-acute care provider, including the provider's capabilities and limitations.

Other commenters disagreed with elements of CMS' proposed requirements for the information that EPM participants must provide to beneficiaries as part of the discharge planning process. Some commenters objected to CMS' proposal that the EPM participant provide each patient with a ''complete list of all available post-acute care options in the applicable service

area,'' arguing that a complete list may be difficult to keep current because post-acute care providers change often. Other commenters claimed that providing a complete list of post-acute care providers is not useful and will confuse and overwhelm beneficiaries when they receive this list, as well as a list of preferred providers and suppliers. The commenters pointed out that the complete list does not identify the quality of the post-acute care providers. As such, commenters suggested that EPM participants be permitted to provide a preferred list of post-acute care providers only, as long as that list is compiled based upon objective quality metrics which are explained to the beneficiary. Several commenters requested that CMS allow EPM participants to provide a list of post-acute care options based on the patient need.

The commenters who urged CMS to allow EPM participants to provide a preferred list also requested that all Medicare discharge planning requirements be waived since EPM participants are being held financially accountable for costs throughout the episode. The commenters contended that by receiving a targeted list of post-acute care providers to choose from, EPM beneficiaries would be more likely to engage in their follow up care. Alternatively, the commenters recommended that if CMS does not allow EPM participants to provide only a preferred list that EPM participants should be allowed to exclude certain post-acute care providers with poor quality performance from the complete list. They rationalized these suggestions by stating that continuity of care efforts may be hampered between EPM participants and preferred providers if beneficiaries choose to receive post-acute care services from providers on the complete list as opposed to the preferred list, particularly if those post-acute care providers have poor quality performance, yet the EPM participant is still responsible for the cost and quality performance of the EPM episode. The commenters further asserted that in order to align with the goals of the EPM to reduce cost and improve quality of care and care coordination through care redesign efforts, EPM participants should be permitted collaborate with post-acute care providers by selectively targeting those post-acute care providers best able to meet the need for consistency of care and ongoing collaboration and communication with EPM participants regarding the care of EPM beneficiaries.

Other commenters in favor of providing only a preferred list believe this approach would make it easier for physicians to know which beneficiaries are in the EPMs and for which they are accountable. Several commenters urged CMS to allow hospitals, physicians, and post-acute care facilities to organize into provider teams that can better coordinate care for patients and improve adherence to treatment plans throughout the episode. The commenters were concerned about EPM participants that would be held accountable for EPM episode quality and spending if the patient chooses a sub-optimal post-discharge facility and believe that EPM participants should be able to recommend post-acute care providers that they have evaluated and work with to provide higher quality, lower cost care.

Response: Given the wide range of the commenters' views, we believe that our proposed policy on the information about post-acute care providers that must be shared with beneficiaries as part of discharge planning and referral represents a middle position that appropriately balances transparency and beneficiaries' need to be informed of their full range of post-acute care provider options to maintain freedom of choice, with EPM participants' desire to inform beneficiaries of those post-acute care providers that are most efficient and provide the highest quality care.

We believe that requiring the provision of a complete list is most consistent with the CoP on discharge planning in § 482.43 and ensures that beneficiaries have full information about post-acute care providers in the area. To allow EPM participants to provide only a preferred list, even if that list were compiled based on objective criteria, could restrict beneficiary freedom of choice of providers and suppliers under the EPM and would be inconsistent with the discharge planning CoP on that basis. It could also increase the risk of patient ''soft steering'' between EPM participants and post-acute care providers due to the incentives for EPM participants to reduce expenditures, which could result in stinting on care or directing beneficiaries to low-cost providers that may provide substandard care. We did not propose to waive any aspect of the discharge planning CoP and continue to believe the CoP provides important protections for Medicare beneficiaries, including those in an EPM episode, regarding discharge planning, while the proposed EPM requirements are designed to supplement existing discharge planning requirements in the context of the EPMs. We also disagree with the commenters that providing a complete list of post-acute care providers in the area would reduce the likelihood of meaningful beneficiary engagement in follow up care as compared to their engagement if we were to permit EPM participants to provide only a list of preferred providers and suppliers.

Therefore, as we proposed we are requiring EPM participants to provide a complete list of post-acute care providers to EPM beneficiaries as part of discharge planning and referral, and we will not waive Medicare's discharge planning CoP. EPM participants need to make sure the complete list provided to EPM beneficiaries is based on the most current, available information. There are publicly available sources that can be used to maintain and update complete lists of post-acute care providers in the area. Because such complete lists are required to be presented to patients for whom home health care or post-hospital extended care services are indicated and appropriate as determined by the discharge planning evaluation under the discharge planning CoP in the discharge plan for patients who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning under § 482.43, we believe that EPM participants already prepare such lists for many beneficiaries. Therefore, applying this requirement to all EPM beneficiaries with a medical need for a specific level of post-acute care services does not result in any significant additional administrative burden on EPM participants.

While we proposed to require that EPM participants provide each patient with a complete list of all available post-acute care options in the applicable service area consistent with medical need, we did not propose the parameters related to medical need in regulation. We agree with the commenters that the complete list of post-acute care providers presented to EPM beneficiaries should be based on medical need. For example, we do not believe it would be appropriate for an EPM participant to provide a complete list of SNFs to an EPM beneficiary as part of discharge planning and referral if SNF care would not be medically necessary for the beneficiary following hospital discharge. Therefore, we are clarifying in § 512.450(a)(1) that as part the discharge planning and referral, EPM participants must provide a complete list of HHAs, SNFs, IRFs, or LTCHs that are participating in the Medicare program in an area, and that this list must be presented to EPM beneficiaries for whom home health care, SNF, IRF, or LTCH services are medically necessary.

We further note that, while this list must include all post-acute care providers that meet the regulatory requirements and, therefore, may not exclude those post-acute care providers with poor quality performance based on the provisions of the EPM, we also proposed to require that the complete list include beneficiary cost-sharing and quality information (where available and as applicable), although we did not incorporate this in our proposed regulations. We do not believe it would be appropriate for the complete list to require that beneficiary cost-sharing and quality information be included due to the potential burden on EPM participants to prepare this additional information. However, we are confirming that EPM participants may provide beneficiary cost-sharing and quality information about post-acute care providers on the complete list, as long the EPM participant includes cost-sharing and quality information that is comparable for all the post-acute care providers on the complete list. Providing this information on only a subset of post-acute care providers on the complete list could be used to steer beneficiaries to certain post-acute care providers and that would be contrary to the purposes of transparency and beneficiary freedom of choice that are the underlying reasons for providing the complete list.

In response to the commenters who expressed concern that beneficiaries would be confused by the complete list of post-acute care providers, especially if also provided with a preferred list of providers, we believe that discharge planning involves discussions with beneficiaries and caregivers and that those professionals engaged in discharge planning, including the treating physician as well as all other treating practitioners, will continue to identify and discuss all medically appropriate options with the beneficiary to meet the beneficiary's clinically identified needs. In addition, we expect that the EPM participant will discuss the various facilities and providers available to meet the clinically identified needs, taking into account patient and family preferences when they are expressed. We are confident that through these important discussions related to post-discharge planning EPM participants will be available to satisfactorily address any confusion on the part of beneficiaries and caregivers about the list(s) of post-acute care providers that the EPM beneficiary receives.

We proposed that EPM participants could also identify preferred providers and suppliers as part of the discharge planning and referral process, consistent with applicable statutes and regulations. This would allow EPM participants to provide information to EPM beneficiaries about high-quality, efficient providers that an EPM participant would prefer patients choose, on the basis of internal assessments of quality and cost. Because we recognize that there may be many high quality and efficient post-acute care providers and suppliers who do not enter into sharing arrangements with EPM participants, we do not believe that the EPM participant's list of preferred providers and suppliers must include only EPM collaborators, nor do we believe that all EPM collaborators must be considered to be preferred providers and suppliers.

While we understand that some commenters would like us to additionally require that the preferred providers and suppliers recommended by the EPM participant be determined based on specific criteria such as the provision of enhanced services or higher quality care in order to further safeguard against patient steering in discharge planning, we believe that establishing such requirements would be overly prescriptive and is unnecessary. Because EPM participants are responsible for EPM episode cost and quality performance, and the EPM episode includes the period of time during which an EPM beneficiary would be receiving post-acute care services following discharge from the anchor hospitalization, EPM participants have a vested interest in recommending only those post-acute care providers on a preferred list that the EPM participant has reason to believe will provide care that will advance the EPM goals. Therefore, we do not believe it is necessary for to us to set additional requirements for the list of preferred providers and suppliers beyond those already applicable under existing statutes and regulations because to do so would limit the flexibility of EPM participants to identify such preferred providers and suppliers. We recommend that EPM participants be transparent in how preferred providers and suppliers are generally selected, and note that policies that define the relationships between the EPM participant and the physicians and post-acute care providers and suppliers in its region must be consistent with applicable laws and regulations, but we do not believe that the details of hospitals' internal business processes must be disclosed.

Allowing EPM participants to recommend post-acute care providers on the preferred list to EPM beneficiaries, in addition to providing the complete list, meets the need of EPM participants for care redesign that improves the quality and reduces the cost of EPM episodes through collaboration with post-acute care providers that are best able to provide consistency of care and ongoing collaboration and communication with EPM participants regarding the care of EPM beneficiaries, while not restricting beneficiary freedom of choice. We disagree that considerations of ease of physician identification and tracking of EPM beneficiaries should be a consideration in determining the lists of post-acute care providers that are provided to EPM beneficiaries as part of the discharge planning and referral process. EPM participants are accountable for EPM episodes and, therefore, have the primary identification and tracking responsibility for EPM beneficiaries.

We agree with those commenters who believe that hospitals, physicians, and post-acute care facilities that organize into provider teams may better coordinate care for patients and improve adherence to treatment plans throughout the EPM episodes. Our provisions for financial arrangements under the EPMs that are discussed in section III.I. of this final rule facilitate the financial alignment of providers, suppliers, and ACOs in care redesign that advances the goals of the EPMs. By allowing EPM participants to recommend to EPM beneficiaries post-acute care providers on a preferred list, while requiring transparency about the existence of sharing arrangements with post-acute care providers on the list and prohibiting EPM participants from charging fees or accepting payments from any EPM collaborator to be on the list, we expect that EPM participants will be able to capitalize on the care redesign work of such teams, without restricting beneficiary freedom of choice. EPM participants are able to recommend post-acute care providers on a preferred list that is developed in a way that is consistent with applicable statues and regulations and who they have evaluated and work with to provide higher quality, lower cost care, as long as the financial relationships among the parties are disclosed.

Finally, since there is no requirement that the beneficiary receive post-acute care services from a provider on a preferred list, we do not believe the size of the preferred list will influence the distance an EPM beneficiary needs to travel for post-acute care services. The beneficiary may select any provider of post-acute care services for care, and the EPM participant must also provide a complete list of post-acute care

providers in the area so that the beneficiary has complete information to make his or her choice.

Comment: Several commenters requested clarification of ''in the area'' in the context of the requirement that EPM participants must inform beneficiaries of all Medicare participating post-acute care providers in the area as part of discharge planning and referral because the proposed regulation did not define this phrase. The commenters observed that ''in the area'' could have different meanings for different EPM participants and beneficiaries. One commenter noted that for EPM participants that provide tertiary care, it would be unreasonable to require them to provide a complete list of post-acute care providers in the patient's home service area when it is not the same service area as the EPM participant.

Response: As discussed in the proposed rule (81 FR 50915), the proposed requirement for EPM participants to inform beneficiaries of all participating post-acute care providers in an area as part of discharge planning and referral would supplement the discharge planning requirements under the existing CoP. The intention of this EPM requirement is to ensure that beneficiaries are given information about potential post-acute care options in a geographic area that is convenient to the beneficiary after discharge from the hospital. Therefore, for consistency with the complete lists of HHAs or SNFs already required for some patients in the discharge plan under the discharge planning CoP, we are requiring that EPM participants provide a list of HHAs, SNFs, IRFs, or LTCHs that are available to the EPM beneficiary, that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, IRF, or LTCH, in the geographic area requested by the patient. As discussed previously, this list must be presented to EPM beneficiaries for whom home health care, SNF, IRF, or LTCH services are medically necessary. We have added to § 512.2 the definition of area that is the same definition used in the CoP for discharge planning. Area means ''as defined in § 400.200 of this chapter, the geographical area within the boundaries of a State, or a State or other jurisdiction, designated as constituting an area with respect to which a Professional Standards Review Organization or a Utilization and Quality Control Peer Review Organization has been or may be designated.'' We note that we expect the SNF list provided to an EPM beneficiary would also include all rural hospital providers of SNF-level care in swing beds in the geographic area requested by the patient.

In response to the commenter who was concerned that it would be unreasonable to require EPM participants to provide a complete list of post-acute care providers in the patient's home service area when it is not the same service area as the EPM participant, we note that this requirement already exists under the CoP for discharge planning for those Medicare beneficiaries who need a discharge plan and for whom home health care is indicated and appropriate as determined by the discharge planning evaluation. The EPMs simply extend this requirement to all EPM beneficiaries so we believe the provision of such lists is feasible for EPM participants. We emphasize that the EPMs do not restrict Medicare beneficiaries' ability to choose to receive post-acute care services from any Medicare-enrolled provider, regardless of the geographic location of that provider.

Comment: Several commenters encouraged CMS to allow EPM participants to educate beneficiaries on where electronic listings of post-acute care providers can be found, rather than providing EPM participants with hard copy lists. The commenters suggested that beneficiaries could be provided with a notification advising where the complete, electronic list could be located, and that beneficiaries may receive a hard copy upon request.

Other commenters requested that CMS, rather than the EPM participant, provide a list of all Medicare-participating post-acute care providers through the CMS and/or MAC Web sites, as CMS already has this information. The commenters asserted that compiling, updating and providing this information is an administrative burden on EPM participants that could be better handled by CMS.

Response: We appreciate commenters' feedback regarding the form and preparation of the complete list of post-acute care providers that EPM participants must provide to EPM beneficiaries based on medical necessity as part of discharge planning and referral. We believe it is imperative to provide the complete list, as well as a preferred list if applicable, in a written manner as part of discharge planning and referral. Beneficiaries may not have online access at the time of discharge planning, and we believe that the presentation of hard copy lists is key to facilitating productive discharge planning discussions with beneficiaries and caregivers. EPM participants are welcome to post these lists on their Web site to supplement any hard copy list provided as a part of discharge planning and referral.

Finally, we believe that the EPM participant, rather than CMS, is in the best position to provide the complete list of post-acute care providers that is medically necessary for an EPM beneficiary. Because such complete lists are required to be presented to patients for whom home health care or post-hospital extended care services are indicated and appropriate as determined by the discharge planning evaluation under the discharge planning CoP in the discharge plan for patients who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning under § 482.43, we believe that EPM participants already prepare such lists for many beneficiaries. In addition, we expect that the EPM participant will discuss with the EPM beneficiary the various facilities and providers available to meet the clinically identified needs, taking into account patient and family preferences when they are expressed and, therefore, the EPM participant is best-positioned to prepare the complete list and provide it to the EPM beneficiary.

Comment: Several commenters stated their belief that the best approach to avoiding patient steering and promoting patient choice is by educating the beneficiary about the EPMs and the effects on the care they may receive. Some commenters further requested that CMS mandate shared decision-making tools be used during the discharge planning process, such as a patient-decision aid to provide balanced, evidence-based sources of information about treatment options. Several commenters encouraged CMS to adopt more detailed requirements for an all-inclusive discharge planning process that engages a broad team of health professionals in the discharge decision-making process, considers the beneficiary's personal health care goals and preferences in order to provide for better access to care, and does not lose sight of what best meets the needs of the individual patient, while still being cost-effective. One commenter urged CMS to specifically require that discharge planning involve an interdisciplinary team that incorporates expertise in all post-acute care capabilities.

One commenter who believes that discharge planning has historically been focused on getting the patient out of the hospital rather than any extended planning relative to post-hospital care

urged CMS to consider the wider and time-extended responsibility for post-hospital care planning that occurs under an EPM. The commenter requested that CMS require the EPM participant to offer advance care planning discussions as part of care planning that represents the evolution of hospital discharge planning to fit the needs of EPMs.

Other commenters requested that CMS provide a discharge planning notice template to ensure that discharge planning under the EPMs leads to successful transitions. One commenter further recommended that CMS soften the language in the CoP for discharge planning to enable more fruitful conversations between patients and their care teams, and ultimately more effective and efficient transitions of care.

Response: We appreciate the interest of the commenters in successful discharge planning for EPM beneficiaries that results in improved quality and reduced costs for EPM episodes. As discussed previously, we did not propose to waive any aspect of the discharge planning CoP and continue to believe the CoP provides important protections for Medicare beneficiaries, including those included in an EPM episode of care, regarding discharge planning, while the proposed EPM requirements are designed to supplement existing discharge planning requirements in the context of the EPMs. We believe that adopting additional requirements under the EPMs for discharge planning or care planning beyond those that currently exist under all applicable statues and regulations would be overly restrictive for EPM participants without providing additional, necessary beneficiary safeguards and is, therefore, unnecessary. Therefore, we will not require EPM participants to engage in specific additional activities such as advance care planning, use specific strategies such as shared decision-making tools, or involve specified teams of health professionals, beyond any existing requirements under applicable statutes and regulations. For these same reasons, we also decline to adopt the commenters' suggestion that CMS provide a discharge planning template to EPM participants, as we believe such a template would be overly restrictive.

We expect that the accountability of EPM participants for the cost and quality of EPM episodes will lead them to work toward successful discharge planning that results in post-discharge services and beneficiary experiences that advance the EPM goals. As part of care redesign, we expect that EPM participants may make changes to their current discharge planning processes to improve care coordination and informed beneficiary decision-making to the extent these factors are expected to improve the quality and efficiency of EPM episode care and the revised approaches are consistent with all applicable statutes and regulations.

Final Decision: After consideration of the public comments received, we are finalizing the proposals in § 512.450(a) for beneficiary choice under the EPMs, with modification to clarify the complete list of post-acute care providers to be provided to the EPM beneficiary as part of discharge planning and referral. Additionally, we are finalizing the proposal that beneficiaries cannot opt out of having their care included in an EPM episode, without modification. The EPM beneficiary choice policies are the following:

• 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.

++ As part of discharge planning and referral, EPM participants must provide a complete list of HHAs, SNFs, IRFs, or LTCHs that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, IRF, or LTCH, in the geographic area requested by the patient.

—This list must be presented to EPM beneficiaries for whom home health care, SNF, IRF, or LTCH services are medically necessary.

—EPM participants must specify on the list those post-acute care providers on the list with whom they have a sharing arrangement.

—EPM participants may recommend preferred providers and suppliers, consistent with applicable statutes and regulations.

—EPM participants may not limit beneficiary choice to any list of providers or suppliers in any manner other than that permitted under applicable statutes and regulations.

—EPM participants must take into account patient and family preferences when they are expressed.

—EPM participants may not charge any EPM collaborator a fee to be included on any list of preferred providers or suppliers, nor may the EPM participant accept such payments.

3. Beneficiary Notification

As we stated in the EPM proposed rule, we believe that beneficiary notification and engagement is essential because under the proposed EPMs, there will be a change in the way EPM participants are paid, which could affect the type of care or treatments beneficiaries receive. While we believe that existing Medicare provisions are effective in protecting beneficiary freedom of choice and access to appropriate care, we also believe that the additional safeguards implemented with the CJR model will 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 sought 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 the 1–800–MEDICARE helpline.

However, we acknowledged that because of the emergent nature of admissions related to the clinical conditions that are the focus of 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's care will be included in an EPM episode. 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 proposed 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 admission for services included in EPM episodes. When, due to the emergent nature of the admission, it is not feasible to provide such notification in advance of admissions, we proposed 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, or where admissions for covered episodes of care are ordered by physicians who do not have such EPM sharing arrangements, we proposed 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 proposed that each participant of an ACO that has entered into a sharing arrangement with the EPM participant provide to each EPM beneficiary a written notice of the 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 participant with which such ACO has relevant distribution arrangements, to provide the written notification. We proposed the ACO must provide such beneficiary notification no later than the time at which the beneficiary first receives services from such ACO 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 was 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 targeted beneficiaries for whom information is relevant, and increased the likelihood that patients would become engaged and seek to understand the EPMs and their potential impact on their care.

We also proposed that an EPM participant 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 post-acute care option or at the time the beneficiary is discharged, whichever occurs earlier. We proposed that if the hospital knows or should have known that the beneficiary is considering or has decided to receive a non-covered post-acute care service or other non-covered associated service or supply, the hospital must notify the beneficiary that the service would not be covered by Medicare. Moreover, 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 discussed in section III.J.6.a. of the proposed rule (81 FR 50939 through 50041), the hospital must notify the beneficiary that he or she 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.

We proposed that all providers and suppliers that are required to provide notice to beneficiaries of the EPM model (participant and collaborator hospitals, PGPs, physicians, nonphysician 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. The participant 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 upon request. We noted 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 with a list of all beneficiaries that received the notification materials in a specified time period. This requirement will aid CMS in monitoring EPM participant and collaborator compliance with the EPM notification requirements.

We noted that Medicare beneficiaries are accustomed to receiving similar notices of rights and obligations from health care 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 aimed to limit confusion and to provide consistent direction to hospitals which may be participating in both the CJR model and the EPMs. We invited 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.

The following is a summary of the comments received and our responses.

Comment: A number of commenters stressed that education and counseling for patients and caregivers is crucial to patient outcomes. From the perspective of the commenters, when patients and caregivers receive real-time information from providers in language they can understand, patients and caregivers can then take on more active roles and participate more fully in the care patients receive and make more informed decisions. The commenters commended CMS for recognizing the importance of communication between providers, patients, and caregivers in favorably influencing health outcomes. In addition, the commenters agreed that beneficiaries should be adequately educated about applicable Medicare provisions for their care so that they can make informed choices about what care is appropriate for them. Most commenters were pleased that CMS proposed detailed beneficiary notification requirements that would require EPM participants and CJR hospital participants to advise patients and caregivers of care choices and explain how the EPMs or CJR model might impact the care they receive. One commenter suggested that detailed beneficiary notification should only be provided upon beneficiary request.

Other commenters stated that the proposed notification requirements imposed on EPM participants and CJR hospital participants add a significant unnecessary burden with no notable impact on beneficiary care. One

commenter stated that EPM beneficiary notification is unnecessary because providers and suppliers do not provide such notices under the IPPS when a beneficiary is admitted to the hospital. Another commenter stressed that the complexities of patient identification, attribution, and precedence rules make providing the correct notification at the correct time an operational barrier to successful beneficiary notification under the EPM. While several commenters agreed with the idea of promoting transparency for beneficiaries, from their perspective this ideal was outweighed by the administrative burden of beneficiary notification. The commenters stated that the beneficiary notification requirement will require investment in significant heath IT resources to build the necessary tools and reminders in the Electronic Health Record in order to comply with the detailed notification requirement. Several commenters also objected to the proposed requirement that EPM participants furnish to CMS upon request the list of patients who received beneficiary notification and the date the notification was provided on the grounds that it is unduly burdensome. One commenter on the proposal for the CJR model requested that CMS delay the proposed requirement that CJR hospital participants be able to report beneficiaries who received notification until July 1, 2017, noting that it will take time for participants to develop and build information technology programs to retrieve the names of beneficiaries who have received a beneficiary notification, including the date received, for any period of time that CMS may request.

Other commenters urged CMS to be responsible for providing the detailed beneficiary notification to alleviate the administrative burden on EPM participants. Furthermore, because participation in the EPMs is required in the selected geographic regions, some commenters suggested that CMS be responsible for providing the beneficiary notification for this reason as well. The commenters speculated CMS could provide the beneficiary notifications via the annual ''Medicare & You'' handbook that is mailed to all Medicare beneficiaries by adding an insert with the mailing clearly notifying the beneficiary of the Innovation Center models being tested in their MSA and describing how those models may impact beneficiaries who are admitted to a hospital with certain conditions or have certain procedures.

Response: We believe that providing full notification and disclosure of the EPMs or CJR model and the possible implications for beneficiaries' access to care is essential to ensuring that beneficiaries understand the EPMs or CJR model, are protected from potential harm under the EPMs or CJR model, and maintain freedom of choice of providers and suppliers, as well as services, throughout EPM or CJR episodes. We previously finalized detailed beneficiary notification requirements for the CJR model in the CJR Final Rule (80 FR 73516 through 73521). We believe it is essential that this notification be specific to beneficiaries whose care is actually included in the EPMs or CJR model and provided in close proximity (or during) the EPM or CJR episode so it is meaningful to the beneficiary while he or she is receiving recommendations for care during the EPM or CJR episode. In addition, we believe that all beneficiaries whose care is included in an EPM or CJR episode should be provided with detailed information about the model, not just those beneficiaries who request such information. It is not possible for CMS to target notification to the specific Medicare beneficiaries who initiate an EPM or CJR episode; instead, the entity with the best, most timely information on a beneficiary's status is the EPM participant or CJR hospital participant because the beneficiary's EPM or CJR episode initiates at the EPM participant or CJR hospital participant.

Like the CJR model, the EPMs incorporate financial incentives for reducing the cost of care for all related items and services furnished to EPM beneficiaries during the anchor hospitalization and the 90 days post-hospital discharge. This payment methodology creates the potential for the unintended consequences of reduced access to care or care stinting that are not present under the IPPS, which provides a single payment to the hospital for a hospitalization, without regard to payments for Part B services during the inpatient hospitalization or payment for any Part A or Part B items or services furnished after hospital discharge. Thus, while such notification is not required under the IPPS, we believe the EPM detailed beneficiary notification requirement encourages care recommendations that are based on the clinical needs of beneficiaries and not on inappropriate cost savings. Moreover, we note that all existing Medicare beneficiary protections continue to be available to the EPM beneficiary. These include the ability to report concerns of substandard care to the 1–800–MEDICARE helpline and the QIOs, where staff will be trained to assist EPM beneficiaries with any concerns they may have about their care under the EPMs.

While we understand that this detailed notification requirement places some additional burden on EPM participants and CJR hospital participants, we believe the value of the notification in protecting beneficiaries from harm and maintaining beneficiary freedom of choice outweighs this burden, given the potential for beneficiary steering and care stinting that may result from the financial incentives under the EPM or CJR model. Based on their early implementation experience with the CJR model, CJR hospital participants already have significant experience with similar detailed notification requirements to those we proposed for the EPMs and CJR model. We further note that EPM participants have experience with required notification of beneficiary rights and obligations upon hospital admission, and we expect EPM participants will draw upon this experience in operationalizing the beneficiary notification requirement for the EPMs. We encourage EPM participants to notify all beneficiaries under circumstances where it is likely that the beneficiary's care will be included in the EPM, even if the EPM participant may be unable to be certain, in view of the rules around model attribution and precedence or the rapid pace of clinical care, in a timeframe that would otherwise allow timely beneficiary notification that meets the EPM requirements.

In response to those commenters who specifically objected to the proposed requirement that EPM participants provide to CMS upon request the list of beneficiaries who received notification and the date of that notification, this record access and retention requirement is the same as the requirement for other records under the EPMs where those records must be maintained and the Government provided access to enable audit, evaluation, inspection, or investigation as discussed in section III.H. of this final rule. Given the importance of beneficiary notification as a beneficiary safeguard under the EPMs, we must be able to monitor the sufficiency of such notifications. Additionally, regarding the request of one commenter that we delay implementing the proposed requirement that CJR hospital participants be able to provide information on beneficiaries notified upon request by CMS, as discussed in section V.H. of this final rule, the effective date of the full amended beneficiary notification regulations in § 510.405 for the CJR

model is July 1, 2017, which is consistent with the commenter's request for the delayed timing of the effective date of this requirement.

Comment: Several commenters provided their perspectives on CMS' proposal for the contents and timing of the detailed beneficiary notification. The commenters urged CMS to adopt the proposed detailed notification elements, including a detailed explanation of the EPM and how it might be expected to affect the beneficiary's care; notification that the beneficiary retains freedom of choice to choose providers and services; explanation of how patients can access care records and claims data; a statement about all existing Medicare beneficiary protections that continue to be available to the beneficiary; and a list of the providers and suppliers with whom the beneficiary has a sharing arrangement. One commenter suggested that the notification should highlight that participation in an EPM is intended to improve quality and reduce waste, rather than focus on notifying beneficiaries of sharing arrangements. Several commenters stated that while patients should be informed that they are receiving care from a hospital that is required to participate in the EPM, beneficiaries should not be given reason to be unnecessarily worried about the quality of care they will receive.

Some commenters suggested that the beneficiary notification be provided prior to admission for an anchor hospitalization. One commenter stated that notification at the point of admission for LEJR under the CJR model was too late because it would not occur at a time when beneficiaries could process and act on the information. Several commenters on the CJR model proposal for the detailed beneficiary notification recommended that the delivery of the notification to a beneficiary occur before admission to an anchor hospitalization, stating that notification could be provided by the admitting physician regardless of his or her participation in the CJR model as a collaborator or, alternatively, the CJR participant hospital could convey the notification prior to admission once the surgery is scheduled. Another commenter requested that CMS allow the beneficiary notification to be given at any time during a CJR episode, arguing that requiring providers to furnish beneficiary notifications prior to admission for surgery under the CJR model leads to additional administrative burden on providers.

Other commenters were concerned that given the emergent nature of some EPM episodes, notice may not always be able to be provided upon admission since MS–DRGs are not assigned to beneficiaries until the claim is coded and submitted for payment following the beneficiary's discharge from the hospital. One commenter urged CMS to work with the provider community to identify exceptions where delivering a notification is not possible prior to discharge and create an exception to the detailed beneficiary notification requirement in these cases. The commenter provided the example of instances where patients are admitted and then subsequently transferred to another facility for a higher level of care, claiming that in this scenario there may not be time to provide the notification. As a result, the commenter believes that EPM participants may be penalized due to a clinical situation that is beyond their control.

Response: We appreciate the commenters' support for the proposed elements of the detailed beneficiary notification. We do not believe that providing detailed notification to a beneficiary that his or her care is included in an EPM in a format that presents the proposed elements should lead to undue beneficiary concerns about the quality of their care, especially given the beneficiary safeguards that are being adopted for the EPMs. Given the importance of transparency of financial arrangements under the EPMs that have the potential to influence care recommendations for EPM beneficiaries, we disagree with the commenter that providing information on sharing arrangements in the EPM participant's detailed notification to the beneficiary is unnecessary.

We have further considered the timing of the required detailed beneficiary notification in view of the public comments. For the EPMs, we proposed that the EPM participant must provide notification upon admission to the hospital or immediately following the decision to schedule a procedure or provide a service which would result in a patient being discharged under a covered episode. The proposed EPM regulation text specified that 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. We believe this timing is generally appropriate and provides EPM participants and, similarly, CJR hospital participants with necessary flexibility regarding the timing of the detailed notification for beneficiaries with the clinical conditions that are the focus of EPM or CJR episodes. We disagree with the commenter who suggested that beneficiary notification could be provided any time during a CJR episode because it is important that beneficiaries be advised as early as possible in an episode (if not before the episode begins) that their care is included in an EPM or CJR episode, in order to safeguard beneficiary freedom of choice of providers and services and ensure the beneficiary's understanding of how the model might be expected to affect the beneficiary's care.

We believe that the earliest point in time that the detailed beneficiary notification could be provided by the EPM participant or CJR hospital participant is when the admission is scheduled in advance with the EPM participant or CJR hospital participant, consistent with the request of some commenters that the notification be provided prior to hospital admission for the anchor hospitalization. However, under the EPMs many admissions will be unscheduled due to the clinical conditions that are the focus of the models and in those circumstances, beneficiary notification must be provided upon admission or as soon as is reasonably practicable but no later than discharge from the EPM participant accountable for the EPM episode. Similarly, while we believe that the detailed beneficiary notification under the CJR model should be provided by the CJR hospital participant that CMS holds financially responsible for the CJR episode rather than the admitting physician, the earliest point in time that this notification could be provided is when the admission is scheduled in advance with the CJR hospital participant, consistent with the alternative suggested by one commenter as an alternative to admitting physician notification of the model. This timing will allow beneficiaries with scheduled admissions to process and act on the beneficiary notification prior to the beneficiary's admission to the hospital, although this notification timing is not possible for those admissions that are not scheduled in advance with the CJR hospital participant.

We note that in view of our final AMI transfer policy as discussed in section III.C.4.a.(5) of this final rule which cancels the AMI episode initiated at the initial treating hospital when the beneficiary is transferred to another hospital for care, the timing of notification issues raised by the commenter who urged CMS to allow for exceptions should no longer pose a concern. All beneficiaries in the AMI model will be discharged from the acute care hospital responsible for the AMI

episode so we do not believe exceptions to the detailed notification requirement are necessary. We expect that EPM participants will generally be able to identify EPM beneficiaries upon admission given the clinical conditions that are the focus of the EPMs. Moreover, in the case of any uncertainly about the MS–DRG that will ultimately be assigned to the beneficiary's claim, we encourage EPM participants to provide notification to those beneficiaries whose care may be included in the EPM so that the notification requirement is met in the event the beneficiary's care is ultimately included in the EPM.

Given that the EPM participant is required to provide the detailed notification, in our final regulations we are clarifying the requirements for the timing of the notification to be more specific based on whether or not the admission is scheduled in advance with the EPM participant. We note that scheduled admissions are especially relevant to CABG episodes and unscheduled admissions are relevant to AMI, CABG, and SHFFT episodes. If the admission is scheduled in advance, then the EPM participant must provide notice as soon as the admission is scheduled. The notification must be provided upon admission to the EPM participant if the admission that initiates the EPM episode is not scheduled with the EPM participant in advance. We believe this timing is appropriate because hospitals provide other information concerning patient rights and responsibilities upon admission to the hospital. In either case, in circumstances where, due to the patient's condition, it is not 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 EPM participant accountable for the EPM episode.

We are also clarifying in § 512.450(b)(1)(v) that the disclosure of the EPM participant's sharing arrangements as part of the detailed beneficiary notification may be satisfied if the EPM participant provides a web address where beneficiaries may access the list of providers, suppliers, and ACOs with whom the EPM participant has a sharing arrangement. Section 512.500(d)(1)(ii)(A), as we are finalizing it in this final rule, requires the EPM participant to publicly post (and update on at least a quarterly basis) on a Web page on the EPM participant's Web site accurate current and historical lists of all EPM collaborators. We expect that allowing the detailed beneficiary notification to reference the Web site for the list of providers, suppliers, and ACOs with sharing arrangements will reduce the burden on EPM participants to prepare and keep current this element of the notification.

We are finalizing the elements of the detailed beneficiary notification in § 512.450(b)(1), specifically a detailed explanation of the EPM and how it might be expected to affect the beneficiary's care; notification that the beneficiary retains freedom of choice to choose providers and services; 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; a statement that all existing Medicare beneficiary protections continue to be available to the beneficiary, including the ability to report concerns of substandard care to Quality Improvement Organizations or the 1–800–MEDICARE helpline; and a list of the providers, suppliers, and ACOs with whom the EPM participant has a sharing arrangement, which may be fulfilled by the EPM participant including in the detailed notification a web address where beneficiaries may access the list.

Comment: A few commenters expressed support for the proposed requirement that EPM participants and EPM collaborators disclose their financial relationships and interests to patients in the context of the structure of the EPM. Other commenters stated that the multiple beneficiary notices required under CMS' proposal would create an overload for EPM and CJR beneficiaries, result in administrative burden on providers, and be infeasible in some cases unless the EPM participant or CJR participant hospital administers the notice on behalf of physicians. They also questioned the rationale for the differences in the proposed timing for such notices by different collaborators that resulted in a lack of uniformity, ranging from the time the decision to undergo a procedure or service covered under an EPM is made and no later than discharge from the hospital accountable for the episode to when the beneficiary first receives services from a provider or supplier associated with the party with the sharing arrangement. One commenter pointed out that CMS' proposal that a physician who is an EPM collaborator notify the beneficiary of his or her sharing arrangement at the time that the decision to undergo a procedure or service covered under the EPM is made and no later than discharge from the hospital accountable for the episode makes providing timely notice impossible for an EPM collaborator who is a physician who does not furnish a service to the beneficiary until after hospital discharge. The commenter requested clarification about whether such a physician would need to provide notice to the beneficiary of the sharing arrangement and, if so, the timing of such notice. Another commenter asserted that it would be unlikely that certain providers with a sharing arrangement under the CJR model would practically be able to collect administrative documentation from the beneficiary about the notice in the course of clinical care, such as in the case of an independent hospitalist who only sees patients while they are admitted to the CJR participant hospital or an anesthesiologist who is working on improving operating room efficiency.

Several commenters recommended that beneficiary notices should only be provided once by the EPM participant or CJR hospital participant and should provide information on all individuals and entities with sharing arrangements under the EPM or CJR model. The commenters asserted that this approach to notices would make the beneficiary aware of all the individuals and entities with a sharing arrangement with the EPM participant or CJR hospital participant, without overwhelming the patient every time he or she sees a clinician or goes to a facility for care.

One commenter who opposed the collaborator notice requirement requested that CMS provide specific examples of when various EPM collaborators would need to provide notice if the policy is adopted. The commenter described the example of an ACO that has a sharing arrangement with a CABG model participant, and both an independent group of cardiothoracic surgeons and an independent group of primary care physicians are ACO participants who also have sharing arrangements with the same CABG model participant. If the notice requirement is finalized, the commenter requested that CMS clarify the notice requirements for the ACO and both physician groups with respect to a CABG beneficiary who receives included services from physicians in both groups during the CABG episode.

Response: We appreciate the support of the commenters for disclosure to EPM beneficiaries of EPM financial relationships between the EPM participant and other providers, suppliers, and ACOs. We agree that a single notice by the EPM participant to the EPM beneficiary of all individuals and entities with sharing arrangements

under the EPM is important to provide disclosure of these financial arrangements that could potentially influence the recommendations of the EPM beneficiary's treating providers and suppliers and, therefore, we are finalizing this requirement as part of the detailed beneficiary notification discussed previously. However, we believe it is necessary also to provide the EPM beneficiary with such information again at the time and in the context where the beneficiary can best use that information to evaluate the advice he or she is receiving from health care providers and suppliers based on the beneficiary's specific knowledge of any financial interests of those providers and suppliers that could influence their recommendations. By providing additional notice of sharing arrangements specific to the care the beneficiary is receiving from the EPM collaborator and providing this notice in close proximity to when that care is being furnished during the EPM episode, the beneficiary will be better able to assess the recommendations from that individual or entity.

We have further considered the issues raised by the commenters about the potential for multiple notices to beneficiaries and the inconsistency of the proposed notice provisions for different types of EPM or CJR collaborators that would have had different timing during the EPM or CJR episode and might, therefore, have been difficult for EPM or CJR collaborators to comply with or been confusing to providers and suppliers treating EPM or CJR beneficiaries. We proposed different timelines for some of the required EPM notices, ranging from the time the decision to undergo a procedure or service covered under an EPM is made to the time when the beneficiary first receives a service from the entity or its related providers and suppliers that treat beneficiaries. We acknowledge that our timing proposal for collaborating physician, nonphysician practitioner, PGP, and hospital notice of sharing arrangements was a practical impossibility for these types of EPM collaborators if the individual or entity did not furnish a service to the EPM beneficiary prior to discharge from the hospital accountable for the EPM episode. Moreover, while our EPM proposal for ACO notices was intended to refer broadly to ACOs, the specific proposed regulation text regarding the timing appeared to narrow the notice scope to only those ACO providers/suppliers that are PGPs with distribution arrangements, resulting in lack of uniformity for ACO notices. Additionally, while we proposed that physicians, nonphysician practitioners, PGPs, post-acute care providers and suppliers, hospitals, and ACOs with sharing arrangements would be required to provide written notice to EPM beneficiaries of the structure of the EPM and the existence of the individual's or entity's sharing arrangement with the EPM participant, we did not address collaborator notice by providers or suppliers of outpatient therapy services or CAHs that we also proposed be eligible to be EPM collaborators.

We continue to believe that it is an important beneficiary safeguard to provide EPM and CJR beneficiaries with separate, specific notice of each sharing arrangement that has the potential to influence a provider's or supplier's care recommendations, even if that results in the beneficiary receiving multiple notices during an EPM or CJR episode. This rationale is applicable to all EPM and CJR collaborators. We also continue to believe that it is not feasible or necessary to require those individuals and entities with distribution arrangements and downstream distribution arrangements under the EPM or CJR model to provide notice to EPM or CJR beneficiaries. These other arrangements are not entered into directly with the EPM participant or CJR hospital participant and, therefore, they may not have the same potential for affecting clinical decisions. Furthermore, to require an additional notice from each of these parties could greatly increase the number of separate notices to EPM or CJR beneficiaries, potentially resulting in information overload and confusion that do not contribute to improved EPM or CJR beneficiary understanding and greater safeguards.

However, in response to concerns raised by the commenters about the uniformity and feasibility of the EPM collaborator notice requirements we proposed, we also are streamlining the EPM collaborator notice requirements. Specifically, we are adopting requirements for the provision of notice that are more equitable and consistent across all the individuals and entities with sharing arrangements under the EPM, as those individuals and entities are finalized in section III.I. of this final rule, with a notice timeframe that is appropriate and practical for EPM collaborators. We believe our revisions clarify which parties are responsible for providing beneficiary notice of sharing arrangements and when such notice must be provided, and will minimize any confusion among providers and suppliers treating EPM beneficiaries. In our final beneficiary notice requirements discussed later in this section, we distinguish among EPM collaborators that are individual providers or suppliers that furnish items and services directly to EPM beneficiaries, and those EPM collaborators that do not directly furnish items and services to EPM beneficiaries, namely PGPs, nonphysician practitioner group practices (NPPGPs), therapy group practices (TGPs), and ACOs.

First, an EPM participant must require every EPM collaborator that furnishes an item or service to an EPM beneficiary during an EPM episode to provide written notice to the beneficiary of the structure of the EPM and the existence of the individual's or entity's sharing arrangement. The notice must be provided no later than the time at which the beneficiary first receives an item or service from the EPM collaborator during an EPM episode. In circumstances where, due to the patient's condition, it is not feasible to provide notice at such times, the notice must be provided to the beneficiary or his or her representative as soon as is reasonably practicable. The EPM collaborator must be able to generate a list of all beneficiaries who received such a notice, including the date on which the notice was provided to the beneficiary, to CMS upon request. We believe this notice requirement is feasible for all EPM collaborators that furnish items and services to EPM beneficiaries (that is, EPM collaborators other than ACOs, PGPs, NPPGPs, or TGPs) at any point in the EPM episode, including the circumstances raised by the commenter of an independent hospitalist with a sharing arrangement that only sees patients while they are admitted to the model participant or an anesthesiologist who has a sharing arrangement related to improving operating room efficiency. In the case of both of these physicians, the EPM participant must require the physician to provide written notice to the beneficiary of the structure of the EPM and the existence of the physician's sharing arrangement when the beneficiary first receives an item or service from the physician during an EPM episode. If the physician with a sharing arrangement does not provide an item or service to the beneficiary during an EPM episode, no notice is required. However, we point out that ultimately to be eligible to receive a gainsharing payment for an EPM performance year, the physician who is an EPM collaborator must have directly furnished a billable item or service to an EPM beneficiary during an EPM episode that occurred during the performance

year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment according to the requirement in § 512.500(c)(2)(ii).

Second, an EPM participant must require every EPM collaborator that is a PGP, NPPGP, or TGP where a member of the PGP, member of the NPPGP, or member of the TGP furnishes an item or service to an EPM beneficiary during an EPM episode to provide written notice to the beneficiary of the structure of the EPM and the existence of the entity's sharing arrangement. The notice must be provided no later than the time at which the beneficiary first receives an item or service from any member of the PGP, member of the NPPGP, or member of the TGP and the required notice may be provided by that member. The PGP, NPPGP, or TGP must be able to generate a list of all beneficiaries who received such a notice, including the date on which the notice was provided to the beneficiary, to CMS upon request. The required notice for a PGP, NPPGP, or TGP with a sharing arrangement need only be provided once to a beneficiary during an EPM episode. Different members of the same group who furnish items or services to the same beneficiary later in the EPM episode do not need to also provide notice.

Third, an EPM participant must require an EPM collaborator that is an ACO where an ACO participant bills for or ACO provider/supplier furnishes an item or service to an EPM beneficiary during an EPM episode to provide written notice to the beneficiary of the structure of the EPM and the existence of the entity's sharing arrangement. The notice must be provided no later than the time at which the beneficiary first receives an item or service from any ACO participant or ACO provider/supplier and the required notice may be provided by that ACO participant or ACO provider/supplier. The ACO must be able to generate a list of all beneficiaries who received such a notice, including the date on which the notice was provided to the beneficiary, to CMS upon request. The required notice for an ACO with a sharing arrangement need only be provided once to a beneficiary during an EPM episode. Different ACO participants or ACO providers/suppliers that furnish items or services to the same beneficiary later in the EPM episode do not need to also provide notice. We note that in the case of an ACO participant that is a group practice that bills for but does not itself directly furnish the first item or service to an EPM beneficiary from any ACO participant or ACO provider/supplier during an EPM episode, ''the time at which the beneficiary first receives an item or service from any ACO participant'' means the time when the beneficiary first receives an item or service that is billed by the ACO participant and furnished by a group practice member. In these circumstances, the required ACO notice may be provided by that group practice member.

These final notice provisions set forth a consistent framework for beneficiary notice of sharing arrangements that can be applied to all EPM collaborators, with additional details about the notice for those entities that can be EPM collaborators but that do not themselves directly furnish items and services to EPM beneficiaries. While a beneficiary may receive multiple notices of sharing arrangements during one EPM episode, we only require that each individual or entity that is an EPM collaborator provide notice once during the episode, including those circumstances where an EPM beneficiary receives items or services during an EPM episode from more than one member of the PGP, member of the NPPGP, or member of the TGP with a sharing arrangement or more than one ACO participant or ACO provider/supplier in an ACO with a sharing arrangement.

We believe this comprehensive framework clarifies the notice requirements for all EPM collaborators, and that it is feasible for EPM participants to require their EPM collaborators to provide notices that meet the requirements. However, we also appreciate that developing and coordinating the notice processes to fit within the course of clinical care, especially for those collaborators that never themselves directly furnish items and service to EPM beneficiaries, will require effort that is related to the number and complexity of the EPM participant's sharing arrangements, the technological capacity of its collaborators to document and retain notices, the care patterns for EPM beneficiaries for which a particular EPM participant is responsible, and other issues. Nevertheless, as discussed previously, we believe that individual notice of sharing arrangements by each EPM collaborator to EPM beneficiaries is necessary, and we expect that the streamlined structure we are finalizing for these notices minimizes, to the extent possible, any additional burden on EPM participants and their related collaborators.

For purposes of illustration, we will step through the application of these provisions to the commenter's example of an ACO that has a sharing arrangement with a CABG model participant and both an independent group of cardiothoracic surgeons and an independent group of primary care physicians who are ACO participants who also have sharing arrangements with the same participating hospital. We note that this example results in a complex notice pattern that is highly unlikely to occur in practice, because we expect that in general the ACO would contract with the CABG model participant and then enter into distribution arrangements with its ACO participants, in this case the group of cardiothoracic surgeons and the group of primary care physicians, rather than all three entities contracting individually with the CABG model participant. In the example, both physician groups furnish included services to a CABG beneficiary during a CABG episode. We further assume that a member of the cardiothoracic surgery group furnishes a service to a CABG beneficiary during a CABG episode before a member of the primary care physician group. In this scenario, when the cardiothoracic surgeon furnishes the first service to the CABG beneficiary that is billed by the cardiothoracic surgery group, that surgeon is required to provide notice to the CABG beneficiary about the sharing arrangement of the group of cardiothoracic surgeons and the sharing arrangement of the ACO with the CABG model participant. When the primary care physician later in the CABG episode furnishes the first service to the CABG beneficiary that is billed by the primary care physician group, the primary care physician is required to provide notice to the CABG beneficiary about the sharing arrangement of the group of primary care physicians with the CABG model participant. The beneficiary has already been notified about the ACO's sharing arrangement.

Comment: Several commenters urged CMS to allow the required beneficiary notifications and notices by any individual or entity to be permitted on an electronic basis, with proof of receipt by the EPM beneficiary, rather than through a paper process that requires a beneficiary's signature.

Response: We did not propose a written signature requirement in regulation. We agree that electronic health records may be used to maintain documentary evidence of written communications, and we have not specified a specific mechanism by which proof of beneficiary notification must be maintained.

Comment: Several commenters expressed support for CMS' proposal that notification materials be developed

or approved by CMS, because the commenters believe that allowing hospitals and other providers that stand to profit from the EPM to describe the EPM and how it might affect the beneficiary's care is unlikely to result in objective information for consumers. The commenters requested that CMS provide samples of beneficiary notifications to be provided by EPM participants and samples of notices to be provided by post-acute care providers that are EPM collaborators. One commenter pointed out that there are cases where the determination of a procedure, either LEJR or a hip pinning for fracture, is not made until after the surgery is in process, so the commenter urged CMS to consider a combined CJR/SHFFT notice that will incorporate all needed elements and reduce confusion for patients.

Other commenters requested that CMS make available generic sample notifications that could apply to all models in order to reduce confusion for beneficiaries, hospitals, physicians, and the general public. The commenters claimed that a single streamlined beneficiary notification for all models would relieve EPM participants of a large operational burden and ensure that beneficiaries receive appropriate notice related to the care they are receiving, without causing unnecessary confusion. Several commenters stressed that a sample notice will achieve a level of accuracy and consistency that would not occur with individual notice formats and contents devised by each EPM participant.

Response: We appreciate the interest of the commenters in streamlining the beneficiary notification materials that are used for the EPMs, as well as other models, in order to provide greater clarity for beneficiaries, providers and suppliers, and the general public. However, we do not agree that a single general notification could apply to all models, given the elements we are finalizing for the EPM detailed beneficiary notification as discussed previously in this section, which include an explanation of the EPM and how it might be expected to affect the beneficiary's care. While we agree that certain beneficiary notification elements, such as notification that the beneficiary retains freedom of choice to choose providers and services, may be common across many models, other elements differ. Therefore, we cannot provide a single generic beneficiary notification document that applies across all models. Beneficiaries, providers and suppliers, and the general public with an interest in model notifications need to know about the specific model features and how the model might be expected to affect a beneficiary's care.

We also appreciate the commenters' interest in having CMS develop or approve the detailed beneficiary notification about the EPMs in the interest of transparency and accuracy of the information for beneficiaries, for whose benefit the notification is provided. We prepared a detailed beneficiary notification template for the CJR model which is currently used by CJR participant hospitals, and we similarly plan to prepare and make available prior to EPM implementation a detailed beneficiary notification template that EPM participants can use. While we appreciate that a combined notification template for the CJR and SHFFT models could be desirable in some circumstances, for expedience we recommend that if there is uncertainty about the hip fracture surgery that will be performed, the CJR/SHFFT model participant should provide both detailed model notifications to the beneficiary upon unscheduled admission to the hospital that initiates the episode.

We will also consider the possibility of preparing notice templates that may be used for individuals and entities with sharing arrangements under the EPMs that are required to provide notice to EPM beneficiaries. While we are not certain that a single notice is appropriate for all individuals and entities with these arrangements, or even for a single type of provider or supplier (such as a physician or SNF) with a sharing arrangement, we will continue to explore the option of making notice templates available to EPM participants for their related EPM collaborators to use.

Comment: A number of commenters provided recommendations about how CMS should monitor compliance with the beneficiary detailed notification and notice requirements. Some commenters suggested that monitoring could be carried out by a CMS contractor, such as a state survey agency or a QIO. Alternatively, the commenters asserted that a hospital private accrediting body could conduct the monitoring. The commenters recommended that monitoring should include submission of any model notice format and content to the monitoring entity in advance of its use, certification of assurances of compliance by EPM participants and individuals with EPM sharing arrangements, auditing of compliance within the first 30 to 60 days of EPM implementation or implementation of the revised notification requirements in the CJR model, and annual auditing of compliance thereafter. Additionally, several commenters expressed concerned regarding the implications for the EPM participant should an EPM collaborator fail to provide their required notice to a beneficiary.

Response: We agree with the commenters on the importance of monitoring for the sufficiency of beneficiary detailed notifications and notices under the EPMs and CJR model. We appreciate the specific suggestions and will take them into consideration in developing the specific monitoring strategies for these notifications and notices as we refine the plans with the monitoring contractor that is currently engaged with us in monitoring the CJR model and the monitoring contractor that we expect to assist us with monitoring the EPMs.

Beneficiary notifications and notices as finalized in § 512.450(b) are requirements of the EPM and, as such, CMS may take remedial action if an EPM participant or one of its related EPM collaborators, collaboration agents, or downstream collaboration agents is noncompliant with the requirements of the EPM, including on the basis of failure to provide required beneficiary notices. As discussed in section III.F. of this final rule, we require the EPM participant to assume responsibility for compliance of all of these parties to ensure that its activities and those of its related EPM collaborators, collaboration agents, and downstream collaboration agents comply with EPM requirements, and our compliance tools for instances of noncompliance apply to EPM participants. We emphasize that entering into sharing arrangements is a choice that EPM participants may make, and EPM participants also have the choice as to whom to select as an EPM collaborator based on selection criteria developed by the EPM participant

Final Decision: After consideration of the public comments received, we are finalizing the proposals in § 512.450(b) for required beneficiary notifications under the EPMs, with modification to streamline both the detailed beneficiary notification and EPM collaborator notice requirements, as well as to apply the EPM collaborator notice requirements to all individuals and entities with sharing arrangements under the EPMs. We emphasize that all information provided to beneficiaries must be in a form and manner which is accessible to the beneficiary, including those beneficiaries with disabilities and beneficiaries with limited English proficiency, consistent with applicable law and CMS policy. Required beneficiary notifications are—

- Each EPM participant must provide written notification to any Medicare

beneficiary that meets the criteria in § 512.240 of his or her inclusion in the EPM. The notification must be provided upon admission to the EPM participant if the admission that initiates the EPM episode is unscheduled. If the admission is scheduled, then the EPM participant must provide notice when the decision to schedule admission is made. In circumstances where, due to the patient's condition, it is not 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 EPM participant accountable for the EPM episode. The EPM participant 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. The beneficiary notification must contain all of the following:

++ A detailed explanation of the EPM and how it might be expected to affect the beneficiary's care.

++ Notification that the beneficiary retains freedom of choice to choose providers and services.

++ 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.

++ 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 or the 1–800–MEDICARE helpline.

++ A list of the providers, suppliers, and ACOs with whom the EPM participant has a sharing arrangement. This requirement may be fulfilled by the EPM participant including in the detailed notification a web address where beneficiaries may access the list.

• An EPM participant must require every EPM collaborator to provide written notice to applicable EPM beneficiaries of the structure of the EPM and the existence of its sharing arrangement with the EPM participant.

++ Require every EPM collaborator that furnishes an item or service to an EPM beneficiary during an EPM episode to provide written notice to the beneficiary of the structure of the EPM and the existence of the individual's or entity's sharing arrangement. The notice must be provided no later than the time at which the beneficiary first receives an item or service from the EPM collaborator during an EPM episode. In circumstances where, due to the patient's condition, it is not feasible to provide notice at such times, the notice must be provided to the beneficiary or his or her representative as soon as is reasonably practicable. The EPM collaborator must be able to generate a list of all beneficiaries who received such a notice, including the date on which the notice was provided to the beneficiary, to CMS upon request.

++ Require every EPM collaborator that is a PGP, NPPGP, or TGP where a member of the PGP, member of the NPPGP, or member of the TGP furnishes an item or service to an EPM beneficiary during an EPM episode to provide written notice to the beneficiary of the structure of the EPM and the existence of the entity's sharing arrangement under the EPM. The notice must be provided no later than the time at which the beneficiary first receives an item or service from any member of the PGP, member of the NPPGP, or member of the TGP, and the required notice may be provided by that member. In circumstances where, due to the patient's condition, it is not feasible to provide notice at such times, the notice must be provided to the beneficiary or his or her representative as soon as is reasonably practicable. The PGP, NPPGP, or TGP must be able to generate a list of all beneficiaries who received such a notice, including the date on which the notice was provided to the beneficiary, to CMS upon request.

++ Require every EPM collaborator that is an ACO where an ACO participant bills for or ACO provider/supplier furnishes an item or service to an EPM beneficiary during an EPM episode to provide written notice to the beneficiary of the structure of the EPM and the existence of the entity's sharing arrangement under the EPM. The notice must be provided no later than the time at which the beneficiary first receives an item or service from any ACO participant or ACO provider/supplier and the required notice may be provided by that ACO participant or ACO provider/supplier. In circumstances where, due to the patient's condition, it is not feasible to provide notice at such times, the notice must be provided to the beneficiary or his or her representative as soon as is reasonably practicable. The ACO must be able to generate a list of all beneficiaries who received such a notice, including the date on which the notice was provided to the beneficiary, to CMS upon request.

• An EPM participant 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 post-acute care option or at the time the beneficiary is discharged, whichever occurs earlier.

++ 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 post-acute care option or at the time the beneficiary is discharged, whichever occurs earlier.

• If the EPM participant knows or should have known that the beneficiary is considering or has decided to receive a non-covered post-acute care service or other non-covered associated service or supply, the EPM participant must notify the beneficiary that the service would not be covered by Medicare.

• If the EPM participant 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 EPM participant must notify the beneficiary in accordance with paragraph (b)(3)(i) of this section that the beneficiary will be responsible for payment for the services furnished by the SNF during that stay, except those services that would be covered by Medicare Part B during a non-covered inpatient SNF stay.

• Lists of beneficiaries that receive notifications or notices must be retained and access provided to CMS in accordance with § 512.110.

4. Monitoring for Access to Care

Given that an EPM participant could receive a reconciliation payment when the EPM participant reduces average actual EPM-episode spending below the quality-adjusted target price and achieves an acceptable or better level of quality of care, the 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 are not EPM participants. We intend to monitor the EPM participants' episode 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 from the EPM participant's EPM episodes. We proposed to publish these data as part of each EPM's evaluation to promote transparency and an understanding of the EPM's effects. We also proposed 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 EPM participant's catchment area or a clinically unexplained increase or decrease in CABG or rates of other related surgical procedures that do not initiate EPM episodes.

The following is a summary of the comments received and our responses.

Comment: Many commenters emphasized that a beneficiary's access to the full range of treatment options appropriate for a given medical condition is critical for positive health care outcomes to be achieved under the proposed EPMs. The commenters expressed support for CMS' goals for the EPMs to encourage EPM participants and providers and suppliers caring for EPM beneficiaries to improve access to care, manage patients to better outcomes, and achieve improvements in the efficiency of care.

Several commenters expressed concern that the financial incentives under the EPMs will affect both patient selection and access to the most appropriate care for the individual beneficiary, especially because the EPM pricing methodology does not risk adjust EPM episode quality-adjusted target prices for patient demographic and disease characteristics. The commenters claimed that frail, elderly, disabled, sicker, and complex beneficiaries with multiple comorbidities who would be more likely to initiate EPM episodes due to the generally emergent nature of the clinical conditions that are the focus of the EPMs may experience unintended consequences such as problems with access to care, substandard quality of care, and care stinting because these patients commonly require more therapeutic interventions, thereby incurring higher costs, to achieve the best health outcomes. Specifically, the commenters speculated that EPM participants may avoid caring for beneficiaries likely to be complex, high-cost cases by delaying treatment, not admitting patients at all, or transferring patients to nearby facilities or referral centers that are outside of the EPM participant's MSA that was selected for participation in the EPM. A few commenters expressed particular concern that small and rural hospitals that are EPM participants would avoid admitting frail patients in their home communities. Another commenter noted that care coordination for EPM beneficiaries requires prompt attention and early, accurate identification of beneficiaries. The commenter believes that in view of the multiple clinical scenarios and critical nature of the physical condition of most beneficiaries in the proposed EPMs, in many instances the process of identifying patients as being an EPM beneficiary will be a secondary concern to the importance of getting the beneficiary to the proper level of care regardless of inclusion or exclusion in an EPM, which may make patient selection less likely than in episodes in other models.

Many commenters believe the EPMs do not include sufficient safeguards to substantially improve the care experience for the many and growing numbers of Medicare beneficiaries. Some commenters urged CMS to delay testing the models, particularly the CABG model, until the benefits of such models can be proven.

Several commenters encouraged CMS to closely monitor EPM participants' claims data for changes in referral and care patterns to ensure that complex patients are not being excluded from the EPMs and for other changes that may indicate EPM participants are stinting on necessary and appropriate care. Some commenters stressed the particular importance of monitoring for beneficiary access to care because beneficiaries cannot opt out of the EPMs. One commenter recommended that CMS conduct audits, both internally and by an outside party, of a sample of patient medical records to determine whether the services actually received by beneficiaries in the proposed EPMs correspond to existing standards of care—and whether they also include innovative treatments and procedures appropriate for a beneficiary's medical condition.

One commenter provided a detailed crosswalk of potential monitoring measures in the measure domains of beneficiary freedom of choice; access, quality, and cost of care; SHFFT participants' coding for hip and femur fractures and ''upcoding;'' patient shifting; and EPM participants' use of waivers and compliance with other rules. The commenter matched potential monitoring measures in these domains, such as beneficiary complaints in the freedom of choice domain, to the source of information for the measure, which in this example would be complaints registered to the 1–800–MEDICARE helpline and state QIOs. The commenter's list of recommended sources of information for the monitoring measures was extensive and specific, including beneficiary surveys; claims data; patient-reported outcome data; hospital consumer assessment of healthcare providers and systems (hospital CAHPS), home health CAHPS, and clinician and group CAHPS; claims data from EPM participants and EPM collaborators linked to provider of service and Medicare data on provider practice and specialty (MD–PPAS) files; agreements for financial arrangements; site visits, beneficiary engagement incentives documentation; financial records of reconciled payments and repayments; and claims data linked to post-acute care provider data sets.

Another commenter requested clarification about how CMS intends to monitor EPM participants and EPM collaborators for compliance other than through claims review for changes in utilization patterns. The commenter asserted that meaningful claims data required for oversight of the EPMs will not be available for years after the models have been implemented. In addition, the commenter stated that utilization patterns measure only one aspect of compliance.

The commenters urged CMS to strengthen the protections against EPM participants engaging in cherry-picking healthier patients and avoiding sick patients in order to give the appearance of improved EPM cost and quality performance. Several commenters also recommended that beneficiaries in the models should be informed of the hotlines available to convey grievances on care at each level of service during the episode. Some commenters supported CMS' proposal to monitor compliance and to integrate the QIOs into the process as an entity available to handle beneficiary complaints.

Other commenters believe that any discoveries of problems with access to care should be publicly reported, and that EPM participants found to be participating in these practices should not be able to receive reconciliation payments. Another commenter urged CMS to strengthen the accountability of EPM participants by implementing a separate financial penalty for hospitals found to have deliberately withheld medically necessary care or steered a patient toward a health care provider known to be delivering substandard care. The commenter suggested that such a penalty should be sizable enough to act as a disincentive for hospitals and other providers that might consider stinting as potentially profitable.

Response: We appreciate the commenters' support for the goals of the EPM and agree that a beneficiary's access to the full range of treatment options appropriate for a given medical condition should be maintained. We believe that the final design of the EPMs provides sufficient beneficiary protections that there is no need to

delay the EPMs and proceeding with testing beginning on July 1, 2017 as we proposed, coupled with close monitoring and the patient safeguards adopted in this final rule, is the most appropriate way to move quickly to gather new insights into the most effective strategies to improve the quality and reduce the cost of care through episode payment.

We also acknowledge that patient selection and underutilization are both potential issues related to access to care due to the financial incentives of the EPMs. With respect to underutilization, we agree that it is important to monitor changes in utilization patterns and case mix, and to generally monitor whether barriers to patient access develop in MSAs where hospitals are required to participate in the EPMs. We appreciate the extensive potential monitoring measures recommended by one commenter, many of which appear promising and where information will be available to operationalize these measures. We note that the sources of information for monitoring measures extend well beyond claims data to include information on beneficiary experience and outcomes that cannot be obtained through claims data. While there is necessarily some lag in the availability of claims data due to the timing of claims submission and processing, we disagree with the commenter who suggested it would be years after EPM implementation before meaningful claims data for oversight were available. For example, we will be analyzing claims data on an ongoing basis and will be performing the first reconciliation process 9 months after model implementation, for which we expect to have reliable claims data for EPM episodes during the first performance year. We will take the suggestions of monitoring measures provided by the commenters into consideration in developing the specific metrics for monitoring for access to care as we refine the plans with our monitoring and evaluation contractors. We note that further details about these plans are currently unavailable.

We believe that it is appropriate to use our existing oversight authority to monitor the risks of the EPM regarding access to care, just as we monitor the various risks inherent in all payment models and systems, but we do not believe that new controls are necessary in regulation, other than those which we proposed and are finalizing for the EPMs after consideration of the public comments. We do not believe that specific requirements for medical necessity or review against specific standards of care are necessary, beyond those broad requirements which are set by the CoPs. We believe that the existing influences of reputation, care guidelines, QIO review, Joint Commission review, quality metrics, and our EPM monitoring and evaluation activities are sufficient to ensure that beneficiary access to care is not impeded under the EPMs. We further note that the existing antitrust laws help to prevent anti-competitive practices in the maintenance of hospital networks, thereby allowing competition between network providers to promote high quality outcomes.

In response to concerns raised by the commenters about our EPM pricing methodology that the commenters believe heightens the risk of patient selection or hospital financial harm for those hospitals disproportionately caring for complex patients, we are exploring incorporating risk adjustment into the EPM payment methodologies by performance year 3 of the EPMs, as discussed in section III.D.4.b.(2) of this final rule. Risk adjustment could potentially reduce variation in payment stemming from differences in case mix rather than the value of care provided, as well as help minimize the incentive EPM participants may have to avoid complex cases under the EPM. We agree with the commenter that the risk of patient selection under the EPM may be reduced due to the generally emergent nature of the clinical conditions that are the focus of the EPMs, rather than elective surgery such as in the CJR model. However, the potential for patient selection based on our final payment policy for transfers of beneficiaries with AMI from the outpatient or inpatient setting of an initial treating hospital to a transfer hospital as discussed in section III.C.4.a.(5) of this final rule may be increased in comparison with our proposal so we will be monitoring the treatment patterns of beneficiaries with AMI closely throughout the model performance years.

In section III.F. of this final rule, we describe the reasons that an EPM participant or its related EPM collaborator, collaboration agent, or downstream collaboration may be noncompliant under the EPM, which include avoiding potentially high-cost patients or high-severity patients; targeting potentially low-cost or low-severity patients; failing to provide medically necessary services or systematically engaging in the over- or under-delivery of appropriate care; failing to allow beneficiary choice of medically necessary options, including non-surgical options; taking any action that threatens the health or safety of patients; or avoiding at-risk Medicare beneficiaries. We will make a determination of EPM participant noncompliance based on all information available to us, including the information from our monitoring activities regarding access to care, quality of care, and delayed care as discussed in this final rule.

We have several compliance tools available to us for circumstances of noncompliance, including issuing a warning letter to the EPM participant; requiring the EPM participant to develop a corrective action plan; 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 participation in the EPM; and, when certain circumstances are met, adding a 25 percent penalty to a repayment amount on the EPM participant's reconciliation report. We also note that we have the authority to revoke provider enrollment in the Medicare program for cause, such as providing substandard care that places beneficiaries at risk by under-delivering care. This broad range of tools provides us with the flexibility to address noncompliant EPM participant behaviors of varying levels of severity, and provides strong safeguards for beneficiaries and the Medicare program. We note that the compliance tools do not include public reporting of problems with access to care found for specific EPM participants because we do not believe this would be appropriate for EPM enforcement actions. Instead, we may notify our federal program integrity colleagues and, where appropriate, law enforcement, of such behavior, particularly in instances in which HHS (including CMS and OIG) discovered knowing violations or patterns of violations of requirements that directly impacted the safety and health of patients.

Given the enforcement tools delineated in this final rule, as well as the prevalence of existing laws, rules, and regulations prohibiting care stinting, provision of substandard care, or denial of medically necessary care, we believe that it is unnecessary to implement processes for a separate financial penalty specifically for the EPM as requested by one commenter, outside of the compliance tools finalized in section III.F. of this final rule. Where an EPM participant engages

in these behaviors, CMS could consider reducing or eliminating that EPM participant's reconciliation payment or applying a penalty to the repayment amount, as well as notifying our federal program integrity colleagues and, where appropriate, law enforcement, of such behavior.

Finally, as discussed in section III.G.3. of this final rule, we require that detailed beneficiary notification under the EPMs includes advising EPM beneficiaries that all standard Medicare beneficiary protections remain in place. The EPM beneficiary may voice concerns or grievances regarding care, such as to the QIOs or through the 1–800–MEDICARE helpline.

Final Decision: After consideration of the public comments received, we are finalizing the proposals for monitoring beneficiary access to care, without modification.

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 EPMs, and clinical standards can be effective in preventing stinting on medically necessary care in both the inpatient and post-acute care settings during the 90 days in the EPM episode following discharge from the anchor hospitalization. Accordingly, we believe that the potential for the denial of medically necessary care within the EPMs is 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 proposed to perform such auditing activities as we deem appropriate. We also proposed to monitor financial 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. Our proposals were consistent with the policies that have been established for the CJR model.

In the proposed rule, we stated our belief that the 90-day post-hospital discharge episode duration is sufficiently long so as to create financial accountability for the EPM participant and to encourage the provision of high quality care that minimizes the risk of complications and readmissions that typically could occur within such a 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 invited comment on the proposal, including additional opportunities to ensure high quality care.

The following is a summary of the comments received and our responses.

Comment: Several commenters expressed concern that the EPMs could negatively affect a beneficiary's access to and quality of care based on the financial incentives under the EPMs. Some commenters claimed that these incentives may discourage guideline-based care and best practices identified through clinical research. Other commenters speculated that AMI model participants may treat an AMI episode with outpatient observation rather than admit the beneficiary for medical management so as to avoid the episode from being initiated. Similarly, some commenters claimed that beneficiaries with AMI who need a PCI would receive the procedure as an outpatient, also to avoid the initiation of an AMI episode. The commenters were concerned with the potential for such site-of-service shifting to result in lower quality of care for AMI beneficiaries treated medically or with a PCI, especially for those complex beneficiaries that could result in high-cost AMI episodes if admitted for inpatient treatment.

Several commenters identified a potential risk to quality of care that could result from changes in the timing of planned secondary PCIs after AMI due to the financial incentives in the AMI model, where AMI episodes include planned, related care such as readmissions for PCI and outpatient PCI without a payment adjustment, except in the case of a CABG readmission. The commenters speculated that AMI model participants will either perform this secondary PCI during the initial hospital stay, potentially causing harm to patients, or intentionally delaying the procedure until after the episode ends. The commenters recommended that CMS monitor and evaluate whether these shifts in the timing of PCI occur and whether they affect patient outcomes.

One commenter claimed that the performance of SHFFT procedures may not be sustainable in rural hospitals that are SHFFT model participants. The commenter reasoned that rural hospitals in regions selected for SHFFT model participation that have, in the past, provided to their community the service of local joint replacement and hip fracture treatment may no longer be able to sustain this practice given the financial implications of the proposed SHFFT model. Other commenters discussed the unintended consequences of limited access to care throughout the 5-year duration of the EPMs. One commenter presented findings from interviews of SNF staff members at SNFs that experienced shorter lengths-of-stay in markets with heavy Medicare Managed Care penetration who reported having to discharge patients early when the staff members believed those patients were unsafe for release.

One commenter outlined in detail their quality concerns about the transitions at the beginning and end of the EPM episode. The commenter asserted that the required bundling in the EPMs in the selected geographic areas would create a new transition in care, at the end of the 90 days following hospital discharge, for persons for whom care transitions are already problematic. The commenter claimed that the transition into the hospitalization for serious conditions like hip fracture, AMI, and CABG that are the focus of the EPMs is a disruptive event. They recommended that the requirements for the EPMs should attend to this initial transition at least with respect to the quality of care planning and the documentation of the decision to operate. The commenter specifically urged CMS to specify that the merits of the decision to hospitalize and to monitor or operate must be documented, both for fracture patients and for AMI, and that documentation should show that the risks and expected benefits had been discussed thoroughly. In addition, the commenter believes that at the end of the episode, the patient would likely lose whatever care coordination and supplemental benefits that the hospital and its partners were providing under the EPM. They pointed out that this creates another transition, with the associated risks of inadequate information transfer, fear and anxiety in creating and learning another set of care arrangements, and cessation of important services. The commenter reasoned that persons with underlying, serious chronic conditions will be unlikely to be stable and doing well at 90 days following hospital discharge; they will be more likely to be in fragile health and may be continuing to decline. Therefore, the commenter suggested that the EPMs should require attention to these issues by generating quality metrics that track real performance in this transition. The commenter identified this last transition

as an opportunity for CMS to tally utilization and mortality shortly after the EPM episode ends and also to generate and use metrics that directly monitor transition quality.

Response: We agree that the commenters have accurately described possible risks of unintended consequences on care quality as a result of the financial incentives under the EPMs; however, we note that similar risks are inherent in all bundled payment models and systems. We agree that monitoring is necessary in order to further reduce these potential risks. We believe that professionalism, the quality measures proposed for the EPMs, 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-hospital discharge. Additionally, we have consistently found that the traditional authorities available to the Secretary, including antitrust laws, anti-kickback provisions and other existing laws and regulations under the Medicare program, are adequate to provide a counterbalance to the economic incentives that could drive under-delivery of care. Therefore, we believe that we can use our existing oversight authority to monitor the risks of the EPMs, just as we monitor the various risks inherent in all payment models and systems, but we do not believe that new controls are necessary in regulation, other than those which we proposed and are finalizing for the EPMs after consideration of the public comments.

We have a number of established mechanisms by which we will monitor for evidence of the under-delivery of care, and by which we can react to and mitigate any identified problems. We will be monitoring data in the process of calculating quality metrics, and we have several reporting mechanisms, such as the 1–800–MEDICARE helpline. We monitor the quality of hospitals stays and surgical procedures through the QIOs, we routinely review medical records in our claims audits, and we specifically investigate outcomes as part of our evaluations of new payment and service delivery models. All of these processes create opportunities to identify potentially noncompliant providers or suppliers. Providers or suppliers who are investigated and found to be inappropriately denying care, diverting patients, providing unsafe care, or furnishing care in a setting that does not comply with Medicare rules may be sanctioned using our authorities under the Medicare program as well as those adopted for the EPMs, with penalties that may include EPM participant ineligibility for reconciliation payments, revocation from the Medicare program if patients are placed at risk by substandard care, or other applicable administrative actions.

We agree that there are opportunities to employ additional quality metrics in the EPMs, including those around care transitions at the beginning of the EPM episode and the end of the episode. However, we note that obstacles exist not only in defining new measures, but in implementing mechanisms to report and assess those metrics without creating undue administrative burden or technological challenges for providers. Therefore, we are not adopting any additional requirements for these care transitions under the EPMs.

We believe that there are opportunities for rural SHFFT model participants to improve the quality and efficient of care under the SHFFT model that are similar to those for hospitals that are not located in rural areas. Rural SHFFT model participants have the same opportunity as other SHFFT model participants to benefit financially from improvements in the cost and quality performance of SHFFT episodes. In addition, as discussed in section III.D.7.c.(1) of this final rule, we are finalizing more protective limitations on loss for rural hospitals, SCHs, MDHs, and RRCs in recognition of the importance of preserving Medicare beneficiaries' access to care from these hospitals. Therefore, we disagree with the commenter that the financial implications of the SHFFT model are likely to make the provision of surgical hip fracture treatment in rural hospitals unsustainable.

We agree with the commenters that monitoring is essential to protect against practices that may reduce the quality of post-acute care services. We believe that monitoring for this quality is best accomplished at the population level through monitoring for access to the appropriate level and quantity of post-acute care services. We also believe that beneficiary knowledge and engagement; the reliance on the medical direction of the physician; the monitoring of quality metrics; the complaint and oversight opportunities through the 1–800–MEDICARE helpline and the QIOs; and the use of care coordination all cooperate to ensure the quality of individual services delivered to individual beneficiaries, including post-acute care services, is maintained or improved under the EPMs.

We note that we will analyze the care patterns for beneficiaries with AMI who present to AMI model participants for treatment, regardless of whether or not they are admitted to the hospital for treatment, treated as an outpatient, transferred to another hospital for the initial hospitalization, or transferred from an inpatient stay at the AMI model participant to another hospital for an inpatient hospitalization. Because best AMI care practices for hospitals with different cardiac care capacity are not well-defined, we expect that our analyses performed as part of monitoring will help to identify the effects on care quality and costs of different patterns in relation to patient complexity. Not all the beneficiaries we examine through our monitoring analyses will actually be included the AMI model (for example, if the beneficiary is treated for AMI only as an outpatient), but we plan to examine the experiences of all beneficiaries with AMI who present to an AMI model participant for treatment so we can develop the full picture of all care patterns for this emergent, common clinical condition. We will also analyze patterns of planned cardiac care for AMI beneficiaries for consistency with clinical guidelines and to examine the effects of such patterns on beneficiary outcomes.

Comment: Several commenters expressed support for CMS' proposal to continuously monitor financial arrangements between EPM participants and EPM collaborators, as well as auditing of patients' medical records and claims to allow early detection and intervention in the case of quality concerns. However, the commenters requested that the monitoring be conducted through the analysis of already submitted documentation, and not through an additional reporting requirement.

Response: We appreciate the commenters' support for monitoring financial arrangements and patient medical records to allow for early detection of quality concerns, as well as their concerns over the increased administrative burden on EPM participants that could result from these monitoring activities. We note that we do not require routine submission of most information under the EPMs, including documentation on sharing arrangements or EPM beneficiary medical records. However, we proposed in § 512.110 that EPM participants must allow the Government access to all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of several areas, including the entity's compliance with EPM requirements and the quality of services furnished to an EPM beneficiary during EPM episodes. We expect that the

proposed monitoring activities will require records being made available to CMS consistent with the access to records and retention requirements as discussed in section III.H. of this final rule. We further note that CMS may also designate contractors to which these records will be required to be made available. We understand the need to balance our monitoring of financial arrangements and auditing of EPM beneficiaries' medical records and claims as a safeguard for beneficiary quality of care with the administrative burden on EPM participants to make those records available to us, although EPM participants are required retain those records and provide access to them upon request. Therefore, we will be judicious in our request that records be submitted to us to allow for monitoring, keeping in mind the burden on EPM participants of record submission in relation to the value of those records to provide program integrity checks and allow early detection of any quality concerns.

Comment: A few commenters recommended that CMS develop a plan to identify where and when inappropriate reductions in care might occur. While the commenters commended CMS for articulating the potential for such problems to occur under the EPMs, they urged CMS to create a clear and specific monitoring and enforcement plan to ensure beneficiary choice is protected and to ensure that consumers receive the most appropriate care, in the most appropriate setting, at the right time. The commenters suggested that CMS develop training for 1–800–MEDICARE call center employees to identify and flag potential care reductions or inappropriate steering under the EPMs. They also encouraged CMS to ensure that the State Health Insurance Assistance Programs (SHIPs) are appropriately trained and engaged by the time the final EPMs are implemented. Other commenters suggested the CMS adopt an appeals mechanism for beneficiaries who receive poor quality care under the EPMs.

The commenters further recommended that CMS consider establishing an independent Ombudsman program for the purposes of monitoring and assisting beneficiaries in all model tests underway at the Innovation Center, including the proposed EPMs. The commenters reported that Ombudsman programs are being successfully used in the Financial Alignment Initiative for Medicare-Medicaid Enrollees, as well as to monitor the Durable Medical Equipment Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding program authorized by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The commenters stated these independent entities are responsible for monitoring beneficiary access to care, in addition to limiting beneficiary confusion and promoting enhanced understanding. With an increasing number of delivery and payment system models ongoing at the Innovation Center, the commenters believe a dedicated Ombudsman is warranted.

The commenters recommended that beneficiaries be provided information and data about improved outcomes and satisfaction seen to date under payment models. The commenters further believe that general beneficiary education programs regarding medical necessity and beneficiary choice would be advantageous to supporting providers and suppliers furnishing services to EPM beneficiaries. Specifically, one commenter stated that some post-acute care providers are not educated or are continuing to operate with protocols that encourage overuse of certain types of care and result in lower quality health care for Medicare beneficiaries. An example provided by the commenter included service patterns where all patients are treated by the provider for the maximum number of benefit days, regardless of clinical or social need. The commenter explained that in other circumstances than under the EPMs, events that create quality concerns may be a financial benefit to the post-acute care provider, such as when a patient who resides in a SNF falls and fractures his or her hip. The commenter claimed that upon readmission to the SNF, it is likely that the SNF will keep the patient at an acute level of care for 90 days or even longer, regardless of the original functional status of the patient.

Finally, one commenter stated that patients report that some post-acute care providers are engaging in marketing efforts that may not accurately portray beneficiary choice. The commenter asserted that in their direct experience, some post-acute care providers establish mandatory minimum stay requirements that do not align with physician discharge orders and show reluctance to coordinate with the beneficiary's care team during the post-acute stay. In this scenario, the commenter concluded that there would be little an EPM participant could do to influence the pattern of care furnished by such post-acute care providers if an EPM beneficiary is treated by a provider that uses such practices. The commenter requested that CMS support EPM participants in improving the quality and efficiency of EPM episodes by adopting revised payment policies for institutional post-acute care services that are better aligned with medical necessity, including payment for short stays that include more appropriate types of therapy that support improved outcomes and increased quality. The commenter further recommended that CMS engage in marketing monitoring activities in order to support EPM goals.

Response: We thank commenters for their feedback regarding additional mechanisms to monitor the quality of care received by beneficiaries. We will be developing the specific metrics for monitoring for the quality of care as we refine the plans with our monitoring and evaluation contractors so further details are currently unavailable. We appreciate the recommendations of the commenters on metrics for monitoring quality of care as a counter to the financial incentives under the EPMs and will take them into consideration as we finalize our plans for monitoring the effects of the EPMs.

We do not believe that special beneficiary appeal rights are necessary under the EPMs. First, there are numerous processes in place under the EPMs and the Medicare program to protect beneficiary choice. The beneficiary retains all rights to choose the provider or supplier for medically necessary covered services. The beneficiary retains the benefits of the doctor-patient relationship, with additional notification of any sharing arrangement that could create a potential conflict of interest. In addition, the beneficiary must be provided with a notice of non-coverage for continuing services, such as a continued stay in an EPM participant or a SNF, and the beneficiary has access to the existing expedited review process in these cases. The beneficiary may also voice concerns or grievances, such as to the QIO or through the 1–800–MEDICARE helpline. We agree that it would be beneficial to distribute educational materials to ensure that beneficiaries can take advantage of the support available at the 1–800–MEDICARE helpline, SHIP, and the QIOs, and we will consider developing such materials for publication contemporaneously with the start of the EPMs. Additionally, 1–800–MEDICARE helpline staff will be appropriately trained and have access to relevant EPM-specific informational materials that allow them to respond to many potential beneficiary concerns related to the EPMs by the time the EPMs are implemented.

We further note that we intend to establish an Alternative Payment Models Beneficiary Ombudsman within CMS who will complement the Medicare Beneficiary Ombudsman in responding to beneficiary inquiries and concerns arising from care under the models addressed in this final rule, as well as other Innovation Center models, under the existing Medicare processes. These existing Medicare beneficiary inquiry processes include the Quality Improvement Organizations (QIO) and the 1–800–MEDICARE helpline that works with the Medicare Beneficiary Ombudsman and CMS caseworker staff to resolve beneficiary issues. We will ensure that the QIOs, 1–800–MEDICARE helpline, CMS casework staff and the Alternative Payment Models Beneficiary Ombudsman have the information necessary, as well as access to program experts, to the extent consistent with applicable privacy and security laws, to respond to beneficiary issues prior to the implementation of the EPMs on July 1, 2017. The 1–800–MEDICARE helpline staff, QIOs and the Medicare Beneficiary Ombudsman already have information and program expert access for the CJR model, but we will ensure that those same materials are also made available to the Alternative Payment Models Beneficiary Ombudsman and CMS casework staff, to the extent consistent with applicable privacy and security laws.

While we will not revise our payment policies under the Medicare program for EPM participants or other providers or suppliers beyond those discussed in this final rule, we agree with commenters regarding the need to continually improve stakeholder education for models to succeed and we intend to do as much as we can to work to design and deploy a helpful learning and diffusion program. We currently facilitate learning within models by disseminating the lessons learned across models so that participants can benefit from the experiences of other models, and are always looking for better ways to educate and assist participants and their partners in care redesign in knowledge sharing. We continue to believe that these efforts contribute to reducing the administrative burden on the health care delivery system and are responsive to commenters' requests that we address the educational needs of providers and suppliers caring for EPM beneficiaries.

We also note that the usual tools employed by CMS to monitor and prevent overutilization all apply to the services, including post-acute care services, furnished during EPM episodes. These tools include data analysis, the process of tracking patterns of utilization and trends in the delivery of care, and medical review, a clinical audit process by which we verify that services paid by Medicare were reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act. We believe that these tools as employed by the MACs and by the QIOs are sufficient to check for the medical necessity of EPM services, including post-acute care services.

Final Decision: After consideration of the public comments received, we are finalizing the proposals for monitoring quality of care, without modification.

6. Monitoring for Delayed Care

We proposed the EPMs in part to incentivize EPM participants to create efficiencies in the delivery of care during a 90-day post-hospital discharge episode duration following an acute clinical event. Theoretically, the EPMs also could create incentives for EPM participants or their EPM collaborators to delay services until after the 90-day post-discharge period has ended. Consistent with the CJR model, we believe that existing Medicare safeguards and other proposals under the EPMs are sufficient to protect EPM beneficiaries from harm due to delayed care.

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 duration is sufficient to minimize the risk that EPM participants and their collaborators would compromise services furnished in relation to a beneficiary's care. While we recognize that ongoing care for underlying conditions or continued recovery may be required after the EPM episode ends, we believe that EPM participants would be unlikely to postpone key services beyond a 90-day post-discharge period because the consequences of delaying care beyond the episode duration would be contrary to usual standards of care.

However, we also proposed that additional monitoring for delayed care would occur as a function of the proposed EPMs. As with the CJR model, we proposed as part of the EPM payment policies (81 FR 50876 through 50877) that certain post-episode payments occurring in the 30-day window subsequent to the end of the EPM episode would be counted as an adjustment against savings achieved by the EPM participant. We believe that including such a payment adjustment would create an additional deterrent to delaying care beyond the episode duration. In addition, the data collection and calculations used to determine the adjustment would provide a mechanism to check whether providers are inappropriately delaying care. Finally, we noted in the proposed rule that the proposed quality measures would create additional safeguards against delays in medically necessary care under the EPMs, as such measures are used to monitor and influence clinical care at the institutional level, including for other CMS hospital programs.

In the proposed rule, we invited public comment on our proposed methods for monitoring EPM participants' actions and compliance, as well as on other methods to safeguard delivery of high quality, clinically appropriate care.

The following is a summary of the comments received and our responses.

Comment: Several commenters acknowledged that a goal of alternative payment models such as the proposed EPMs is to reduce unnecessary services and their associated costs, resulting in inherent incentives in such models to potentially delay or reduce medically necessary care. The commenters recommended that all alternative payment models should be designed to closely monitor health care received and protect beneficiaries against potential stinting of clinical treatment, delays in care, and case mix shifts. They recommended that CMS continue to offer regular and structured opportunities for stakeholder feedback to ensure that as the number of models increases, CMS continues to protect beneficiary access to care and all clinically appropriate treatment options.

Several commenters expressed concern that AMI model participants would delay costly, medically necessary cardiac care until after the AMI episode ends, a practice that would be inconsistent with clinical guidelines. The commenters identified planned follow-up inpatient or outpatient PCI of lesions identified at the time of the AMI but not responsible for the AMI and readmissions for cardiac surgery, such as cardiac valve replacement or implantable cardioverter defibrillator implantation, as potential instances where cardiac care could be delayed until after the end of an AMI episode. One commenter requested further details regarding how CMS intends to protect beneficiaries from delayed care.

Response: We appreciate the interest of the commenters in ensuring that the EPMs and other alternative payment models are designed to closely monitor care in order to detect and address any

delays in care or other potentially harmful care patterns that could be incentivized by the financial incentives under the models. We agree with the commenters that because the EPM episodes for which an EPM participant is responsible extend 90 days post-discharge from the anchor hospitalization, there is some risk that care could be delayed until after the end of the episode. However, we believe that EPM participants and other providers and suppliers furnishing services to EPM beneficiaries will focus first on clinically appropriate, timely care consistent with evidence-based clinical guidelines. We further note that delaying medically necessary care for more than 90 days following hospital discharge could both be contrary to usual clinical standards of care and potentially lead to complications that could result in utilization of health care services that increases actual EPM-episode spending and endangers the EPM participant's episode cost and quality performance under the EPM. The potential for costly complications serves to counter the theoretical financial benefit that an EPM participant could experience when care is intentionally delayed until after the episode ends.

Moreover, as discussed in section III.E.3 of this final rule, we use quality measures of patient outcomes and patient experience in the pay-for-performance methodologies of the EPMs where the financial opportunity for EPM participants to receive savings for any given level of actual EPM-episode spending increases with higher quality of care. Thus, we believe the use of quality measures in the pay-for-performance methodologies of the EPMs also serves to deter potentially harmful delays in care. Finally, as discussed in section III.D.7.e. of this final rule, EPM participants with post-episode spending in the 30 days following the end of EPM episodes that exceeds a threshold set at 3 standard deviations above average spending in their region for that period of time need to repay Medicare for the amounts in excess of the threshold. This repayment is not subject to the stop-loss limitations under the EPMs, resulting in full risk for EPM participants. Therefore, we believe this policy also discourages delays in medically necessary care until after an EPM episode ends.

We will be developing the specific metrics for monitoring for delayed care as we refine the plans with our monitoring and evaluation contractors so further details are currently unavailable. We note that EPM participants found to engage in delaying medically necessary care would be noncompliant with the EPM under the provisions finalized in § 512.460(b)(1) due to actions that threaten the health or safety of patients. In these circumstances, CMS could utilize one of the compliance tools finalized in §§ 512.460(b)(2) and (b)(3), which include requiring the EPM participant to develop a corrective action plan; reducing or eliminating the EPM participant's reconciliation payment; adding a 25 percent penalty to the repayment amount on the EPM participant's reconciliation report under certain conditions, or terminating the EPM participant's participation in the EPM. We believe that these compliance tools allow us to take timely remedial action for instances of noncompliance by an EPM participant and that the finalization of these tools provides a significant beneficiary safeguard against delayed care.

Final Decision: After consideration of the public comments received, we are finalizing the proposals for monitoring for delayed care, without modification.

H. Access to EPM Records and Record Retention

Consistent with the Shared Savings Program, the BPCI initiative, the CJR model, and other Innovation Center models, we proposed 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 proposed to include them in Subpart B (Episode Payment Model Participants) for the EPM and to move them to Subpart B for the CJR model as discussed in section V.L. of this final 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 proposed 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 proposed 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 proposed additional types of EPM collaborators and types of financial arrangements in section III.I. of this final rule for the EPM, as well as defined EPM activities as those related to promoting accountability for the quality, cost, and overall care for EPM beneficiaries, we proposed 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 proposed 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 proposed 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 final rule.

We have identified six categories of information related to key EPM parameters for which we proposed that the record access and retention requirements would apply. Like the CJR model, we proposed 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 proposed 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 final rule and is different from the current CJR model requirement to the extent that we proposed 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 proposed similar changes to this category of information under the CJR model as discussed in section V.L. of this final rule.

The third category of information for which we proposed 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 proposed and finalize a CR incentive payment in section VI. of this final 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 proposed 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 proposed similar changes to this category of information under the CJR model and discuss further in section V.L. of this final rule

Given the beneficiary notification requirements that we proposed for the EPM in section III.G. of this final rule, we proposed 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 proposed to add this same category of information for the CJR model and discuss this further in section V.L. of this final rule.

Finally, we proposed to establish CEHRT use attestation for EPM participants so that an EPM participant could be in a Track 1 EPM that meets the requirements in the Quality Payment Program final rule with comment period (81 FR 77008) to be an Advanced APM as discussed in section III.A.2 of this final rule. Thus, we proposed 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 proposed to add this same category of information for the CJR model and discuss this further in section V.L. of this final rule.

As we stated in the 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 final 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, as stated in the proposed rule, 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 sought 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 sought 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.

The following is a summary of the comments received and our responses.

Comment: One commenter who stated that the ten year record retention policy we proposed was excessive requested that CMS change the proposed duration of record retention from 10 years to 6 years for the CR incentive payment model, the EPMs and CJR model. The commenter believed that the proposed retention policy is excessive as it extends well beyond the proposed end of the fifth performance year of the EPMs on December 31, 2021 and that a 6-year record retention policy would be more consistent with other CMS programs. Another commenter recommended that CMS also request access to records on gainsharing and other savings-related payments so as to help examine the extent to which savings are equitably being shared by facilities with participating physicians and other healthcare professionals.

Response: While we appreciate the commenter's concerns regarding the ten year retention period, we note that the proposed ten years is more consistent with other models, including the CJR. Furthermore, once an appeal is initiated, such disputes can be lengthy processes and we believe that maintaining this requirement as proposed at ten years, rather than the 6 years suggested by the commenter, would give both the participant and CMS, as well as those completing any audit, evaluation, inspection, or investigation, the resources to prepare and respond to issues that may take several years to surface. CMS will consider requesting access to records of gainsharing payments and other arrangements that will assist in evaluating and measuring the EPM goals of improved EPM episode quality and efficiency. CMS authority under §§ 512.110(a)(1) and (2) allows the Federal Government to sufficiently access records and we believe this will contribute to the ability to enable audits, evaluations, inspections, or investigations to ensure that payments are consistent with model goals and are not abusive.

Final Decision: After consideration of the public comments received, we are finalizing the proposal without modification.

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 proposed 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 would place financial responsibility for the episode on the hospital where the episode begins with a hospitalization and would 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 proposed EPMs have a similar design to the CJR model with the same goals of improving the quality and efficiency of model episodes. We expected that the types of financial arrangements needed to align the financial incentives of CJR participant hospitals 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 believed 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 believed that it was possible to improve on the current regulatory structure for financial relationships that we established for the CJR model in our proposals for the EPM. Our proposals reflected changes from the current CJR model regulations that generally fell 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 the proposed rule (81 FR 50958 through 50968), we proposed changes to the CJR model financial arrangements regulations in Part 510 to parallel those we proposed for the EPM. These proposals would result in the same provisions and requirements for CJR model and EPM financial arrangements when the first performance year of the proposed EPM would begin 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 proposed 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 used this approach because we meant for the proposed requirements to apply to every participant in the EPM regardless of whether the EPM was the AMI, CABG, or SHFFT model.

As discussed in section III.D.2.b. of the proposed rule (81 FR 50844), we proposed 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 was 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 was in the ''acceptable,'' ''good,'' or ''excellent'' quality category. If an EPM episode's actual spending exceeded 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 our approach in the CJR model (80 FR 73412), in the proposed rule for the EPM we discussed our belief that EPM participants might 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 believed that EPM participants might 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 expected that EPM participants would identify key providers and suppliers caring for EPM beneficiaries, as well as ACOs to which EPM beneficiaries were 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 might 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 believed it would be possible that an EPM participant that might receive a reconciliation payment from Medicare or might need to repay Medicare might want to enter into financial arrangements with other providers, suppliers, or ACOs to share risks and rewards under the EPM. We expected 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 might want to enter into financial arrangements to share risks and rewards under the proposed EPM, in the proposed rule we discussed our expectation that EPM participants might choose to engage with organizations that were 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 might play important roles in an EPM participant's plans to implement an EPM based on the experience these organizations might 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 expected 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 expected that all of these relationships would be based solely 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), in the proposed rule we discussed our belief that EPM participants caring for EPM beneficiaries might 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 might 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 improved the quality and efficiency of episodes through care redesign that resulted in EPM beneficiary reductions in hospital readmissions, complications, days in acute care, and mortality, while recovery continued uninterrupted or accelerated.

Comment: Many commenters stressed the need for waivers of existing fraud and abuse laws, given CMS' proposal to allow financial arrangements between EPM participants and other individuals and entities that comply with the requirements of the proposed rule. They stated that such waivers are necessary for aligning the financial incentives of providers and other entities redesigning care and coordinating episode care for EPM beneficiaries to improve episode quality and efficiency. The commenters urged CMS and OIG to use the full scope of their combined authority to waive certain fraud and abuse laws that the commenters believed may inhibit care coordination in order to enable EPM participants to form the financial relationships necessary for success in the models. They claimed that waivers must be issued no later than concurrently with publication of the final rule to allow EPM participants sufficient time to prepare for EPM implementation. One commenter emphasized that the requirement for hospitals to participate in the EPM should not take effect unless and until hospitals have the needed, explicit protections in place and adequate time to form the necessary financial arrangements.

Response: We understand the commenters' interest in the timely publication of fraud and abuse waivers for the EPM and revised waivers for the CJR model. As we stated in the proposed rule (81 FR 50931), any waivers of the fraud and abuse laws for the EPM or revisions to the existing CJR waivers would be issued separately by OIG (as to sections 1128A and 1128B of the Act) and CMS (as to section 1877 of the Act). No waivers of any fraud and abuse authorities are being issued in this final rule.

The substance and timing of any such waivers is outside the scope of this rulemaking. However, the Department is mindful of the significant interest of participants in knowing waiver parameters sufficiently in advance of entering into financial arrangements. The Department's goal is that any waivers meet the legal standard under section 1115A, align closely and appropriately with the final rules, are clear, and limit burden on participants and others to the extent feasible while also protecting the program and patients from fraud and abuse. The Department is considering carefully concerns expressed by commenters about the existing fraud and abuse waivers for the CJR model and will keep those concerns in mind when considering fraud and

abuse waivers for the EPM, as well as any adjustments to the existing CJR waivers. As was done for the CJR model, waivers for the EPM will be promulgated by notice rather than rulemaking, which will expedite issuance. Any fraud and abuse waivers issued in connection with the EPM or revisions to the existing CJR waivers of fraud and abuse laws will be posted on the OIG Web site and at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html.*

Comment: Several commenters asserted that the fraud and abuse laws should be revised to accommodate APMs and other aspects of the modern health care environment. In addition, many commenters offered suggestions regarding how any fraud and abuse waivers should be drafted for the EPM and episode payment models generally. Other commenters advocated for the creation of a new Stark exception that would protect certain financial arrangements in risk-bearing models. One commenter requested that CMS provide a mechanism for EPM participants and CJR participant hospitals to ask questions about fraud and abuse law waivers.

Response: These comments are outside the scope of this rulemaking, but we have forwarded them to appropriate staff within the Department for consideration. We note that the public may contact CMS with questions related to compliance with the EPM and CJR regulations by emailing *epm@cms.hhs.gov* and *cjr@cms.hhs.gov,* respectively.

3. EPM Collaborators

As we explained in the proposed rule, given the financial incentives of episode payment under the EPM, an EPM participant might 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 might be eligible to receive from CMS, or the EPM participant's internal cost savings that resulted from care for beneficiaries during EPM episodes. Likewise, such arrangements would 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 had a role in the EPM participant's episode spending or quality performance. We proposed to use the term ''EPM collaborator'' to refer to these individuals and entities.

Since each proposed EPM's episode duration would be 90 days following discharge from the anchor or chained anchor hospitalization and such episodes would be broadly defined as discussed in section III.C.3.b. of the proposed rule (81 FR 50832 through 50834), many providers and suppliers other than the EPM participant would furnish related services to beneficiaries during EPM episodes. Those providers and suppliers might 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 might be actively involved in coordinating the care of beneficiaries during EPM episodes. The proposed definition of EPM collaborator included each of these categories of individuals and entities as eligible to be an EPM collaborator. The proposed list of types of EPM collaborators was the same list as CJR collaborators, but with the addition of hospitals, CAHs, and ACOs.

We expected that hospitals and CAHs that were not EPM participants might frequently play roles in care delivered to EPM beneficiaries during a chained anchor hospitalization as discussed in section III.C.4.a.(5) of the proposed rule (81 FR 50836 through 50840) or following discharge from an anchor or chained anchor hospitalization that initiated an EPM episode. For example, an AMI model participant without cardiac surgery or interventional cardiology capacity might 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 might, 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 might sometimes be provided at transfer hospitals that initiated EPM episodes as EPM participants, we expected that readmissions during such episodes might sometimes be to other hospitals or CAHs that were not EPM participants near beneficiaries' home communities. Thus, we believed it would be important to allow EPM participants to enter into financial arrangements with other hospitals and CAHs that cared 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 had 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 Final 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, in the proposed rule we noted that we had further considered the potential for accountable care organizations to be EPM collaborators. The proposed EPMs would include beneficiaries with cardiovascular disease as well as beneficiaries with hip fracture who commonly would be 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 proposed to exclude certain accountable care organization-aligned beneficiaries from EPM episodes, we noted that the challenges of attributing savings and changes in the quality of care for beneficiaries simultaneously in EPM and total cost-of-care models or programs, such as accountable care organizations, remained under consideration without full resolution, as discussed further in section III.D.6. of the proposed rule (81 FR 50869 through 50871). 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 would determine which entity provides the resources for coordinating and managing a particular beneficiary's care over time. Finally, we noted 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 EPM. Therefore, we believed it would be 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 proposed EPM would be an episode payment model for Medicare FFS beneficiaries. We note that in section III.D.6. of the proposed rule (81 FR 50869 through 50871), we proposed 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 were important criteria in selection of these models and tracks of models for this proposed exclusion. We also sought comment in that section on extending this exclusion proposal to Track 3 of the Shared Savings Program. Because we proposed to allow financial arrangements under the EPM only with those entities that were involved in the delivery of care to EPM beneficiaries with goals of improving the quality and efficiency of EPM episodes, we did 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 proposed that beneficiaries eligible for Medicare on the basis of ESRD be excluded from the EPM as discussed in section III.C.4.a. of the proposed rule (81 FR 50834), we did 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 noted that the Pioneer ACO model ends in CY 2016, so that model would not overlap with the EPM which was proposed to begin on July 1, 2017.

Thus, we proposed 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 was coordinated and managed in communities, and ensure that entities with appropriate skills and experience were 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 could verify that these ACOs met 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 might 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 limited our proposal of entities that were not providers or suppliers but that were permitted to be EPM collaborators to ACOs alone. We proposed to allow financial arrangements under the EPM only with those entities that were involved in the delivery of care to EPM beneficiaries.

We set forth in proposed § 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 sought comment on the proposed definition of EPM collaborators. In addition to general comment, we were specifically interested in comment on the proposal to include hospitals, CAHs, and ACOs in the definition of EPM collaborators. Furthermore, we sought comment specifically on the accountable care organizations that we proposed to include in the definition of ACO and which accountable care organizations should be included and excluded from the definition of ACOs that might be EPM collaborators to best advance the goals of the EPM and program generally. Finally, we also sought 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.

The following is a summary of the comments received and our responses.

Comment: Several commenters requested clarification about whether certain groups of health care professionals that do not include physicians could be EPM collaborators. The commenters requested that, in addition to PGPs, groups of certified registered nurse anesthetists (CRNAs), advanced practice registered nurses (APRNs), outpatient speech-language pathologists, physical therapists, and other qualified licensed healthcare professionals who are not physicians, be permitted to be EPM collaborators. One commenter explained that these groups are identified by a TIN.

A number of commenters pointed out that while the proposed rule specifically listed PGPs as eligible to be EPM collaborators, CMS' proposal did not separately list groups of physical therapists or other therapists as eligible to be EPM collaborators. One commenter asserted that allowing only

individual therapists to be EPM collaborators and excluding therapy practice groups from entering into sharing arrangements with EPM participants is shortsighted because rehabilitation therapy practices and independent therapists are likely to be significant contributors to SHFFT episodes. The commenters requested that CMS clarify the regulations to explicitly permit groups of therapists to enter into sharing arrangements with EPM participants. One commenter further proposed that once a therapy practice group contracts with a hospital as a collaborator, it should be up to the practice group to ensure that financial exchanges with the participant hospital were attributed to the physical therapists who directly furnished services to EPM beneficiaries.

Response: We appreciate the interest of the commenters in ensuring groups of nonphysician practitioners and groups of therapists have the same opportunities to be EPM collaborators that we proposed for PGPs, as well as their interest in allowing financial exchanges with their members who furnished services to EPM beneficiaries.

Under our proposal, individual nonphysician practitioners are permitted to be EPM collaborators. We also proposed that individual therapists would be permitted to be collaborators to the extent that they fell within the collaborator category for provider or supplier of outpatient therapy services. As collaborators, these individuals would be eligible to receive gainsharing payments from EPM participants. Moreover, our proposal defined a PGP member to include a nonphysician practitioner or therapist who is an owner or employee of a PGP who has reassigned his or her right to receive Medicare payment to the PGP. Accordingly, as PGP members, these nonphysician practitioners and therapists would be eligible for distribution payments and downstream distribution payments from a PGP. We agree with the commenters that because our proposals addressed the role of PGPs as EPM collaborators and collaboration agents without reference to other types of groups, we left some uncertainty about whether groups without a physician owner or employee would be eligible to be EPM collaborators and whether such groups would be permitted to enter into distribution arrangements or downstream distribution arrangements with their members. We also agree with the commenters that our proposal to allow providers and suppliers of outpatient therapy services to be EPM collaborators is potentially unclear, because this term did not separately identify therapists in private practice or groups of therapists in private practice on the list of EPM collaborators, as did our proposal regarding physicians and PGPs. We also appreciate the commenters' uncertainty associated with the fact that we did not address whether a collaborator that was a therapy group practice would be permitted to enter into distribution arrangements or downstream distribution arrangements with their members, as we proposed for PGPs.

We do not believe it would be appropriate to allow a group of licensed health care professionals to be EPM collaborators if that group consists solely of individuals who are not among the categories of individuals we proposed to be EPM collaborators. However, we believe that if a category of individuals is eligible to be EPM collaborators, then Medicare-enrolled groups that include such individuals should also be permitted to be collaborators and that such groups should be permitted to enter into distribution arrangements or downstream distribution arrangements with their members. We clarify these policies through this final rule.

Groups of nonphysician practitioners that do not include a physician are not included in the category of PGPs that we proposed to include on the list of EPM collaborators. However, we believe these groups of nonphysician practitioners should be permitted to be EPM collaborators, just as we proposed to allow both individual physicians and nonphysician practitioners to be EPM collaborators. We also believe these groups of nonphysician practitioners should be treated similarly to PGPs with regarding their ability to engage in distribution arrangements and downstream distribution arrangements with their members, consistent with our treatment of nonphysician practitioners who are PGP members. Therefore, we are adding to the list of entities that are eligible to be EPM collaborators a nonphysician practitioner group practice (NPPGP), defined as ''an entity that is enrolled in Medicare as a group practice, includes at least one owner or employee who is a nonphysician practitioner, does not include a physician owner or employee, and has a valid and active TIN.'' The requirements for sharing arrangements, distribution arrangements, and downstream distribution arrangements for NPPGPs and NPPGP members are discussed in the sections of this final rule that address our policies for these arrangements.

We further believe that our proposal to include a provider or supplier of outpatient therapy services on the list of types of providers and suppliers that can be EPM collaborators should be modified to provide greater clarity about the providers and suppliers of outpatient therapy services that can be EPM collaborators. The Medicare Claims Processing Manual, Chapter 5, Part B Outpatient Rehabilitation and CORF/OPT Services, Section 10 lists the following Medicare-enrolled providers and suppliers that can submit claims for outpatient therapy services: SNF; outpatient hospital; CAH; HHA; outpatient physical therapy provider (OPT), otherwise known as rehabilitation agency; comprehensive outpatient rehabilitation facility (CORF); physician; nonphysician practitioner; and physical or occupational therapist or speech-language pathologist in private practice.[128] We note that the list of EPM collaborators already includes hospitals, SNFs, CAHs, HHAs, physicians, and nonphysician practitioners so their inclusion as collaborators under the proposed definition of provider or supplier of outpatient therapy services is duplicative. Therefore, rather than finalizing our proposed definition of provider of outpatient therapy services which would have included all providers and suppliers of outpatient therapy services, we believe it is clearer to specify individually on the list of EPM collaborators all the types of Medicare-enrolled providers and suppliers that can bill Medicare for outpatient therapy services. Thus, we are defining a new term therapist in private practice as ''a therapist that either: complies with the special provisions for services furnished by physical therapists in private practice in § 410.60(c) of this chapter; or complies with the special provisions for services furnished by occupational therapists in private practice in § 410.59(c) of this chapter; or complies with the special provisions for services furnished by speech-language pathologists in private practice in § 410.62(c) of this chapter.'' We are adding therapist in private practice to the list of EPM collaborators, which ensures that all individual suppliers of outpatient therapy services are on the EPM collaborator list. In addition, we are revising our definition of provider of outpatient therapy services to mean ''an entity that is enrolled in Medicare as a provider of therapy services and furnishes one or

[128] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c05.pdf.*

more of the following: outpatient physical therapy services as defined in § 410.60 of this chapter; outpatient occupational therapy services as defined in § 410.59 of this chapter; outpatient speech-language pathology services as defined in § 410.62 of this chapter.'' Under this revised definition, provider of outpatient therapy services now includes only those entities that enroll in Medicare specifically as a provider of outpatient physical therapy/occupational therapy/speech-language pathology services, and we are revising the list of EPM collaborators to use this defined term in place of ''provider or supplier of outpatient therapy services.'' Finally, we are adding CORFs to the list of EPM collaborators because it is the only other type of provider that can furnish outpatient therapy services that is not included on the EPM collaborator list under our new and revised terms. Thus, with the addition of therapy group practices as discussed specifically later in this section, in total, these changes to the definitions and supplements to the list of EPM collaborators clarify which individuals and entities may be EPM collaborators by separately specifying each type of supplier and provider of outpatient therapy services that is eligible to be an EPM collaborator.

With respect to the specific interest of commenters in therapy practice groups being eligible to be EPM collaborators that can share payments under EPM financial arrangements with their members, we agree with the commenters that such groups should be permitted to be EPM collaborators and to enter into distribution arrangements and downstream distribution arrangements with their members, consistent with our treatment of PGPs and NPPGPs. Thus, we are defining therapy group practice (TGP) as ''an entity that is enrolled in Medicare as a therapy group in private practice, includes at least one owner or employee that is a therapist in private practice, does not include an owner or employee who is a physician or nonphysician practitioner, and has a valid and active TIN'' and adding TGP to the list of EPM collaborators. The requirements for sharing arrangements, distribution arrangements, and downstream distribution arrangements for TGPs and TGP members are discussed in the sections of this final rule that address our policies for these arrangements. We are finalizing, with the modifications discussed, the definition of EPM collaborator in § 512.2 to mean 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) Therapist in private practice.
(8) CORF.
(9) Provider of outpatient therapy services.
(10) PGP.
(11) Hospital.
(12) CAH.
(13) NPPGP.
(14) TGP.

Comment: A number of commenters expressed support for CMS' proposed definition of ''EPM collaborators,'' including the proposed addition of ACOs, hospitals, and CAHs to the types of collaborators that were previously adopted for the CJR model. The commenters claimed that allowing additional health care providers, suppliers, and ACOs to be EPM collaborators would further encourage robust care coordination across EPM episodes. Several commenters asserted that by recognizing the expertise that ACOs may offer EPM participants as EPM collaborators with regard to managing the cost and quality of care that Medicare beneficiaries receive, ACOs will be able to use their substantial expertise and resources to contribute to the EPM's dual goals of limiting spending and increasing quality. One commenter further commended CMS for making the list of EPM collaborators exhaustive and not including third party conveners, who the commenter believes lack a commitment to patients, local providers, or their community.

In contrast, some commenters expressed disappointment that the list of EPM collaborators did not include entities such as pharmaceutical companies; medical device companies; medical technology companies; social services aging networks; and other third parties, such as the types of convening organizations participating in other Innovation Center models. Several commenters believe that were medical device and pharmaceutical manufacturers allowed to be EPM collaborators, those manufacturers may make meaningful contributions to the success of the EPM by ensuring their products are used appropriately; aligning financial and other incentives to improve patient outcomes; demonstrating the value of their products; and reducing costs. Other commenters who favored adding medical technology companies as EPM collaborators asserted that medical technology companies can make a significant, positive impact on care redesign and cost containment as well as provide integrated data analytic infrastructure and services to optimize care and to achieve quality goals. A few commenters suggested that CMS should expand the list of potential EPM collaborators to include non-provider or non-supplier entities that have a track record of providing Medicare providers and suppliers participating in other models with support services such as care redesign, data analytics, and general program support, as well as community-based organizations that are well-equipped and efficient in providing social and supportive services that help beneficiaries stay out of the hospital. Several commenters also encouraged CMS to include all APM entities as EPM collaborators, reasoning that APM entities are similar to ACOs in that they are a legal entity that is separate from its participants.

Additionally, one commenter recommended that Next Generation ACOs be included in the definition of ACOs that are on list on EPM collaborators, so the Next Generation ACO may act on behalf of its providers to enter into financial arrangements with EPM participants for beneficiaries not assigned to the ACO. The commenter explained that not including Next Generation ACOs in the definition of ACOs that CMS proposed could be EPM collaborators will require ACO participants and ACO providers/suppliers of the Next Generation ACO to enter in EPM sharing arrangements on their own without the Next Generation ACO to represent them.

Finally, one commenter shared its perspective that CMS should not restrict the definition of EPM collaborators because such an approach discourages the introduction of new entities and individuals in the healthcare market. The commenter requested that CMS allow market forces to shape the innovation of EPM participants and their community partners in order to determine the financial partnerships that would be most beneficial to achieving the overarching goals of the EPM. The commenter asserted that being too prescriptive regarding the individuals and entities that can and cannot enter into financial arrangements under the EPM would not allow for new organizations to develop in the market that may have the potential to generate substantial cost savings for EPM participants.

Response: We appreciate the support of the commenters for our proposed list of the types of individuals and entities

that can be EPM collaborators, including our proposal to include hospitals, CAHs, and ACOs that would expand the list beyond the CJR collaborators adopted in the CRJ Final Rule (80 FR 73418).

We note that some of the potential contributions, such as integrating the data analytic infrastructure and services to optimize care to achieve quality goals, that were suggested by commenters as reasons to allow third parties, such as pharmaceutical, medical device, and medical technology companies as well as other types of convening organizations participating in other Innovation Center models, to be EPM collaborators can be achieved outside of the context of sharing arrangements through other relationships between the EPM participant and those entities. In response to the specific requests that we include APM entities on the list of EPM collaborators, given that an APM entity, as defined in § 414.1305, means an entity that participates in an APM or payment arrangement with a non-Medicare payer through a direct agreement or through federal or state law or regulation, we believe that adding all APM entities to the list of EPM collaborators would be overly expansive and risk loosening the clinical link between the EPM collaborator, EPM participant, and EPM beneficiary that we believe is important for improving the quality and reducing the cost of care under the EPM. With the exception of ACOs, PGPs, NPPGPs, and TGPs, we continue to believe that any EPM collaborator that receives a gainsharing payment must have furnished a billable service included in the episode to an EPM beneficiary and that the payment arrangements for gainsharing payments must be substantially based on the quality of care and the provision of EPM activities. In the case of ACOs, PGP, NPPGPs, and TGPs that are EPM collaborators, we require that the entity itself must have contributed to EPM activities and been clinically involved in the care of EPM beneficiaries in order to be eligible to receive a gainsharing payment or be required to make an alignment payment and at this point we are not convinced any APM entities could meet these eligibility criteria, other than ACOs. We also do not agree with the commenter who recommended that we not restrict the definition of EPM collaborators to any specific individuals or entities. We believe it is important for EPM participants to engage EPM collaborators that have a commitment to their local communities, local providers, and Medicare beneficiaries in order to create the greatest potential for sustained improvements in quality and reductions in cost under the EPM.

We appreciate the commenter's suggestion that Next Generation ACOs be included in the definition of ACOs that are on the list of EPM collaborators, so the Next Generation ACO may act on behalf of its ACO participants and ACO providers/suppliers to establish sharing arrangements with EPM participants for beneficiaries not assigned to the ACO. While we understand that the Next Generation ACO would like to enter into an EPM sharing arrangement as an EPM collaborator on behalf of its providers and suppliers, to be eligible to receive a gainsharing payment or be required to make an alignment payment under the sharing arrangement the Next Generation ACO itself must have contributed to EPM activities and been clinically involved in the care of EPM beneficiaries through activities such as 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 and reduce spending for EPM episodes; or 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. We are unclear of the role the Next Generation ACO itself would play in the care of EPM beneficiaries that are not assigned to the ACO, beyond serving as a contracting agent for its ACO participants and ACO providers/suppliers. We further believe that such an arrangement would require distinguishing activities on behalf of beneficiaries assigned to the ACO who are excluded from EPM episodes and beneficiaries not assigned to the ACO who are included in EPM episodes, and such distinctions could create confusion for beneficiaries, providers, and suppliers, as well as administrative complexity for the Next Generation ACO. Therefore, we do not believe it would be appropriate to include Next Generation ACOs in the definition of ACOs that may be EPM collaborators.

Finally, we note that as discussed in section III.D.6.c.(3) of this final rule, we are additionally finalizing the exclusion of beneficiaries from EPM episodes who are prospectively assigned to a Shared Savings Program ACO in Track 3. Therefore, for consistency with our policy for Next Generation ACOs whose assigned beneficiaries are also excluded from EPM episodes, we are excluding Shared Savings Program ACOs in Track 3 from the definition of ACOs that may be EPM collaborators. Thus, we are modifying our definition of ACO to read ''ACO means an accountable care organization, as defined at § 425.20 of this chapter, that participates in the Shared Savings Program and is not in Track 3.'' We emphasize that no EPM policy precludes providers or suppliers who are ACO participants or ACO providers/suppliers in a Next Generation ACO from entering into a sharing arrangement with an EPM participant on their own, provided they are on the list of EPM collaborators.

In summary, at this time we will not adopt a final policy that includes additional entities or individuals that are not providers or suppliers beyond those we proposed to be EPM collaborators. We selected acute care hospitals as the financially responsible entity for the EPM because we are interested in evaluating the impact of bundled payment and care redesign across a broad spectrum of hospitals with varying levels of infrastructure and experience in entering into risk-based payment arrangements. We believe that it is most appropriate to identify a single type of provider to bear financial responsibility for making repayment to CMS under the EPM. Given that hospitals perform a central role in coordinating episode-related care and ensuring smooth transitions for beneficiaries, this role factored in our decision to select IPPS hospitals as the financially responsible entity for this model. Under this structure, we believe that limiting the testing of gainsharing relationships to solely those between EPM participants, certain Shared Savings Program ACOs, and providers and suppliers enrolled in Medicare is most appropriate because we expect enrolled providers and suppliers to be most directly and specifically engaged with the EPM participants in care redesign and EPM episode care for beneficiaries. While we recognize that Shared Savings Program ACOs are not providers or suppliers, 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 make them suitable for a role as EPM collaborators. Further, by including such ACOs on the list of EPM collaborators, we are permitting 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 EPM's risks and rewards with EPM participants.

We are finalizing in § 512.2 the definition of ACO, with modification to mean an accountable care organization, as defined at § 425.20 of this chapter, that participates in the Shared Savings Program and is not in Track 3.

Comment: One commenter requested clarification about whether outpatient speech-language pathologists are considered providers of outpatient therapy services and, therefore, eligible to be EPM collaborators.

Response: We appreciate the opportunity to clarify that speech-language pathologists are eligible to be EPM collaborators if they are furnishing outpatient services as Medicare-enrolled speech-language pathologists in private practice. As discussed previously in this section, speech-language pathologists in private practice are included under the new definition of therapist in private practice when they are therapists that comply with the special provisions for services furnished by speech-language pathologists in private practice in § 410.62(c). In addition, a group of speech-language pathologists in private practice is included under the new definition of TGP when the group is entity that is enrolled in Medicare as a therapy group in private practice, includes at least one owner or employee that is a therapist in private practice, does not include an owner or employee who is a physician or nonphysician practitioner, and has a valid and active TIN. Both therapists in private practice and TGPs are included on the final list of types of providers and suppliers that may be EPM collaborators so individual speech-language pathologists in private practice, as well as speech-language pathology groups in private practice, are eligible to be EPM collaborators.

Final Decision: After consideration of the public comments received, we are finalizing the proposals in § 512.2 for the definition of EPM collaborator and other terms used in that definition, with modification to revise the definitions of provider of outpatient therapy services; and ACO; create new definitions for CORF, therapist in private practice, NPPGP, and TGP; and include additional individuals and entities on the list of EPM collaborators. 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) Therapist in private practice.
(8) CORF.
(9) Provider of outpatient therapy services.
(10) PGP.
(11) Hospital.
(12) CAH.
(13) NPPGP.
(14) TGP.

4. Sharing Arrangements Under the EPM

a. General

Similar to the CJR model (80 FR 73430), we proposed 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 was made pursuant to a sharing arrangement, we proposed to 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'' was proposed to be defined as a payment made by CMS to an EPM participant as determined in accordance with proposed § 512.305(d) and as discussed in section III.D.5. of the proposed rule (81 FR 50864 through 50867). ''Internal cost savings'' would be 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 would not include savings realized by any individual or entity that was not the EPM participant. Where a payment from an EPM collaborator to an EPM participant was made pursuant to an EPM sharing arrangement, we proposed to define that payment as an ''alignment payment.'' An alignment payment could consist only of a portion of the ''repayment amount,'' which would be the amount owed by an EPM participant to CMS, as reflected on a reconciliation report. An EPM participant would not be permitted to make a gainsharing payment or receive an alignment payment except in accordance with a sharing arrangement. We proposed that a sharing arrangement must comply with the provisions of proposed § 512.500 and all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.

We proposed 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 could not 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 were 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 were encompassed. We did 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 would be 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 took 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 would provide a safeguard against abuse.

Finally, we proposed that if an EPM participant entered 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 would provide a program integrity safeguard.

The proposals for the general provisions for sharing arrangements under the EPM were included in proposed § 512.500(a). We sought 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 were met.

The following is a summary of the comments received and our responses.

Comment: While many commenters expressed appreciation for CMS' proposal that would allow EPM participant choice regarding the formation of specific financial relationships with other individual and entities as determined by the EPM participant, several commenters expressed concern that engaging in sharing arrangements by EPM participants is voluntary for hospitals. One commenter stated that CMS' proposal to leave the choice of sharing reconciliation payments from episode savings achieved under the EPM to the responsible hospitals would have the unintended consequences of further consolidating control of care at the hospital level rather than with the community providers at the forefront of providing patient-centered care and could restrict beneficiary choice. Another commenter stated that because EPM participants are not required to distribute their episode savings as gainsharing payments, the proposed model design and financial arrangements would exclude post-acute care providers from having a significant role in the EPM. One commenter who expressed appreciation for CMS' proposal to allow ACOs to be EPM collaborators nevertheless asserted that under the current and proposed policies for EPM financial arrangements, model participants often have little or no incentive to collaborate with ACOs, a situation which threatens the continuity of care for patients. The commenter believes that participants in bundled payment models have a significant incentive to take advantage of an ACO's ongoing efforts to coordinate care over the course of the full year (which includes the EPM episode), which could lead to episode savings achieved by the ACO's efforts, rather than hospitals' efforts under the EPM. The commenter urged CMS to require sharing arrangements between EPM participants and unrelated ACOs in the same market or otherwise determine that all ACO-assigned beneficiaries would be excluded from EPM episodes. Finally, another commenter encouraged CMS, at a minimum, to add stronger language to encourage EPM participants to enter into sharing arrangements if CMS chooses to maintain the proposed policy which is permissive rather than directive.

Response: We appreciate the perspectives of the commenters regarding our proposal for financial arrangements under the EPM that would not require EPM participants to enter into sharing arrangement with collaborators under the model. As we finalize in section III.B.3. of this final rule for the EPM and as we finalized for the CJR model in the CJR Final Rule (80 FR 73288), we have selected acute care hospitals as the financially responsible entity for the EPM because we are interested in evaluating the impact of bundled payments and care redesign across a broad spectrum of hospitals with varying levels of infrastructure and experience in entering into risk-based financial arrangements. Our expectation that hospitals would perform a central role in coordinating episode-related care and ensuring smooth transitions for beneficiaries hospitalized for clinical conditions that are the focus of the EPM factored into our identification of hospitals as the financially responsible entity for the model.

While we proposed that hospitals would be the financially responsible entity for episodes under the EPM as they are under the CJR model, we agree with the commenters that effective care redesign for EPM episodes likely requires meaningful collaboration among acute care hospitals, CAHs, post-acute care providers, ACOs, physicians, and other providers and suppliers within communities to achieve the highest value care for Medicare beneficiaries. We believe it may be essential for key providers and suppliers to be aligned and engaged, financially and otherwise, with participant hospitals, and that they have the potential to share financial responsibility with those hospitals. We believe that close alignment and engagement of certain providers, suppliers, and ACOs with EPM participants may be especially important, given the clinical complexity of many beneficiaries in EPM episodes who are likely to have underlying chronic condition and risk factors, such as advanced age that led to the acute event of AMI or hip fracture or progressively worsening cardiac status resulting in CABG that are the focus of EPM episodes. Depending on a hospital's current degree of clinical integration, new and different contractual relationships among hospitals and other health care providers and suppliers may be important, although not necessarily required, for EPM success in a community. We do not believe, however, that it would be appropriate to require that EPM participants engage in sharing arrangements, including with any specific individuals or entities such as ACOs, since, under the EPM, the participant hospitals are solely responsible to CMS for financial risk under the models. While we are providing EPM participants with required parameters for any financial arrangements with collaborators that assist them in engaging other individuals and entities in care redesign toward the goals of improving EPM episode quality and reducing cost, we believe that model participants providing care in their own communities are best positioned to determine whether sharing arrangements would advance these goals. We refer to section III.D.6.c.(3) of this final rule for further discussion of our final policies regarding overlap of EPM beneficiaries with shared savings models and programs.

We emphasize that, although we allow sharing arrangements under the EPM, beneficiaries in EPM episodes retain their full rights to choose their providers and suppliers. EPM participants, providers, and suppliers are reminded that patient steering is not permissible and such entities and individuals must continue to comply with all applicable law and regulations. EPM participants and their collaborators that engage in sharing arrangements may not impede the rights of the beneficiary. Furthermore, we reiterate that sharing arrangements 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.

Comment: A number of commenters commended CMS for not requiring EPM participants to collaborate with certain groups of providers or suppliers, thereby allowing market forces to feed the creative innovation of model participants and their community partners to determine the financial partnerships that would be most beneficial to achieving the overarching goals of the EPM. One commenter stated that EPM participants should not be required to offer risk-sharing

arrangements to all post-acute care providers in their markets. Several commenters expressed support for CMS' proposal to require EPM participants to utilize quality criteria in the selection of collaborators, which is consistent with the goal of the EPM to improve the quality of episode care while reducing its cost.

Many commenters also agreed with CMS' intent that the selection requirements should prevent EPM participants from developing methodologies for selecting collaborators that take into account the volume or value of past or anticipated referrals between the parties. However, one commenter advocated that CMS permit EPM participants to consider a potential EPM collaborator's relevant experience in collaborator selection. The commenter seemed to be recommending that CMS permit collaborator selection criteria to consider factors such as the amount of procedures a physician has performed that would be subject to payment under an EPM episode or the amount of other services a potential collaborator has performed that would be considered EPM activities. The commenter urged CMS not to prohibit experience from being a qualifying factor in the selection of collaborators on the grounds that such a policy would compromise the model's stated goal of increasing quality while reducing cost. The commenter believed it was only appropriate to prohibit selection criteria that consider the historical amount of procedures (or other services that would constitute EPM activities) that the potential collaborator performed for beneficiaries treated at the EPM participant.

Several commenters expressed concern that allowing EPM participants discretion over the selection of collaborators for sharing arrangements could limit collaborators to a small group of preferred providers and lead to narrow referral networks to control costs, strategies that are not necessarily in the best interest of beneficiaries. The commenters encouraged CMS to modify the proposal for allowing EPM participants broad discretion to determine how they identify and choose EPM collaborators. The commenters further urged CMS to adopt stronger safeguards and to closely monitor referral patterns to ensure that the EPM is not diminishing patient choice or disrupting existing provider-patient relationships that are necessary for ensuring patient-centered continuity of care. A few commenters believed that EPM participant discretion in choosing collaborators should be limited and that EPM participants should be required to make gainsharing payments to all providers who care for EPM beneficiaries. One commenter requested that CMS require EPM participants to allow any interested provider who meets basic, minimum quality standards and sees a minimum number of EPM beneficiaries to be included on the list of collaborators with sharing arrangements. Another commenter requested that EPM participants' written policies for the selection of collaborators be made public to promote transparency. One commenter emphasized that without transparent contracting and financial data requirements, many independent PGPs are hesitant to participate in sharing arrangements for episode payment models like the EPM managed by hospitals.

A few commenters requested that CMS make available certain information to EPM participants or potential collaborators such as physician groups and post-acute care providers. With respect to information for EPM participants, the commenters recommended that CMS create a tool with a standardized methodology to compare costs so model participants could select the most cost-effective partner in the care that is included in the models for which they are financially responsible. Other commenters urged CMS to provide information to potential EPM collaborators about hospital accountability for episodes under the EPM, CJR model, and other CMS bundled payment models, explaining that it is currently challenging for physicians and post-acute care providers to determine what hospital owns which episodes in order to seek partnerships, especially when the hospitals may be located in other geographic areas. One commenter further recommended that CMS provide a path to identify the responsible entity for episodes in order to alleviate the administrative burden on post-acute care providers that are tracking financial risk and clinical responsibility for episodes in bundled payment models.

Response: We appreciate the commenters' support for our proposed requirements for EPM participants' policies for the selection of their collaborators. We proposed to allow financial arrangements in the EPM to incentivize higher quality care and reductions in episode spending through improved financial alignment between providers and suppliers furnishing services to beneficiaries during EPM episodes, while protecting against undue risk from beneficiary steering, care stinting, and inappropriate reductions in access to care that could otherwise result from the financial incentives in an episode payment model. The proposed requirements for the selection criteria for collaborators provide important safeguards for these financial arrangements.

We are mindful of the commenter's concern that the goals of EPM may be more difficult to achieve if EPM participants are prohibited from selecting collaborators based on their relative experience in providing services that would constitute EPM activities. We proposed that the written policies for selecting EPM collaborators must contain criteria related to, and inclusive of, the quality of care delivered by the potential EPM collaborator. We also proposed that the selection criteria cannot be based directly or indirectly on the volume or value of past or anticipated referrals or other business. Because sharing arrangements should be for the sole purpose of aligning the parties' financial incentives toward the EPM goal of improving the quality and efficiency of care, we do not believe that collaborators should be selected in a manner that is based on referrals or the generation of other business. We believe that imposing experience qualifications that are tied to referrals, rather than quality, presents a significant program integrity risk. Specifically, such criteria could be a proxy for rewarding past referrals or for encouraging the initiation of an excessive number of EPM episodes. Nevertheless, depending on the circumstances, the consideration of a potential collaborator's experience in performing services that would constitute EPM activities may further the quality and efficiency goals of the EPM. For example, an ACO's experience in providing care coordination services or implementing care redesign strategies may be relevant in evaluating the likelihood that a potential ACO collaborator will have the requisite expertise to contribute to the EPM participant's success in the model. Similarly, we recognize that, in an effort to ensure quality of care and successful outcomes for certain procedures, many hospitals require physicians to perform a reasonable minimum number of procedures as a condition of maintaining medical staff privileges to perform those procedures. Therefore, we are modifying the selection criteria provision in § 512.500(a)(3) to provide that a selection criterion requiring a potential EPM collaborator to have performed a reasonable minimum number of services that would qualify as EPM activities will be deemed not to violate the volume or value standard if

the purpose of the criterion is to ensure the quality of care furnished to EPM beneficiaries. We believe this standard appropriately balances the commenter's concerns and the relevant program integrity risks.

We do not agree with the commenters recommending that EPM participants be required to engage as collaborators all providers and suppliers caring for EPM beneficiaries or any interested provider meeting minimum standards for quality and model beneficiary volume. As discussed previously, there is no requirement that EPM participants enter into sharing arrangements under the EPM, in order to allow EPM participants who are financially responsible for EPM episodes the flexibility to determine whether sharing arrangements would advance the model goals. Should they choose to enter into financial arrangements with collaborators, we believe EPM participants are in the best position to select the collaborators, subject to the requirements we proposed, who are most willing to engage in the model participant's care redesign strategies and provide high quality care. However, we continue to believe it is appropriate to require EPM participants to create a written set of policies for selecting providers, suppliers, and ACOs for sharing risks and gains as EPM collaborators. We are adopting numerous safeguards to address patient steering and protect beneficiary freedom of choice, including the requirement that EPM beneficiaries be informed that they retain freedom of choice to choose providers and services; the requirement that EPM participants not restrict beneficiaries' ability to choose any Medicare-enrolled provider or supplier, or any physician or practitioner who has opted out of Medicare; the caps on gainsharing payments to physicians, nonphysician practitioners, PGPs, and NPPGPs; the requirement that the opportunity to make or receive gainsharing payments (or the opportunity to make or receive alignment payments) may not be conditioned on the volume or value of past or anticipated referrals; the requirement that gainsharing payments be distributed to EPM collaborators substantially based on the quality of care and the provision of EPM activities; and the requirement that opportunity to make or receive distribution payments or downstream distribution payments 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. In light of these safeguards, we believe that EPM participants should be allowed to enter into different sharing arrangements with various EPM collaborators. While we appreciate the reasons why some commenters recommended that we require EPM participants to enter into financial relationships with certain entities and individuals, we do not agree that such a requirement is necessary given these protections. Furthermore, we believe these safeguards are sufficient to protect beneficiary choice and ensure that the EPM does not disrupt existing provider-patient relationships.

We understand and agree with the commenters who believe that transparency in contracting under the EPM is important, so that providers, suppliers, and ACOs in communities that provide episode care for EPM beneficiaries are knowledgeable about any collaborators working with the EPM participant toward achieving the model goals and understand how the model participant selected those collaborators. This transparency is all the more significant in light of our decision not to require that EPM participants engage with any specific providers, suppliers, or ACOs. To the extent the commenter who mentioned PGP concerns about the transparency of contracting and financial data requirements for sharing arrangements was referring to the internal requirements of the EPM participant, we do not believe that sharing arrangements under the EPM are different in this regard from any other scenario in which a PGP contracts with a hospital. To address the transparency of the EPM participant's selection criteria for EPM collaborators that are required in § 512.500(a)(3), we are requiring EPM participants to make publicly available on the EPM participant's Web site their policies for selecting individuals and entities to be EPM collaborators and to update this information at least quarterly. The public availability of the collaborator selection policies complements the requirement for EPM participants to publicly post on their Web site accurate current and historical lists of all EPM collaborators, including EPM collaborator names and addresses, and to update such lists on at least a quarterly basis. The policy for the lists of EPM collaborators is discussed in section III.I.4.d. of this final rule for the EPM.

With regard to providing standard information to EPM participants that would allow them to select the most cost-effective providers and suppliers as collaborators, as discussed in section III.K.2 of this final rule for EPM participants, upon EPM participant request we are making available beneficiary-identifiable claims data no less frequently than on a quarterly basis for EPM episodes, as applicable to the participant. These data allow the EPM participant to examine episodes where model beneficiaries receive care by specific providers or suppliers in order to identify patterns in quality and cost that may help them identify providers and suppliers that meet the EPM participant's selection criteria for collaborators. However, we will not provide EPM participants with a tool that uses a standard methodology to analyze episode costs of care to allow for specific comparisons among potential collaborators. Instead, EPM participants will need to develop their own methodology to analyze the features of historical episodes that are relevant to their collaborator selection criteria.

We appreciate the interest of potential EPM collaborators in being able to identify the bundled payment model episodes and responsible hospitals for beneficiaries for whom they provide care in order to seek partnerships that may contribute to improvements in the quality of episode care and reductions in cost. We will continue to make available on the CMS Web site information about bundled payment models, model participants, and the episodes that each model participant is testing. We encourage potential EPM collaborators to review this information and to discuss the potential for collaboration with model participants both in their communities and where they have historically provided post-discharge care following hospitalization for the clinical conditions that are the focus of the EPM. Given the complexities of the provider and beneficiary overlap policies among different models and programs as discussed in section III.D.6. of this final rule, we are not able to provide any other specific information about the financially responsible entity for beneficiaries who are hospitalized and then receive related post-discharge care during their recovery.

We are finalizing the selection criteria for EPM collaborators in § 512.500(a)(3) as modified. We are finalizing in § 512.500(d)(1)(ii)(A) the requirement for public reporting and updating of the current and historical lists of EPM collaborators in § 512.500(d)(1)(ii)(A).

We are adding the requirement in § 512.500(d)(1)(ii)(B) that the EPM participant publicly post on the EPM participant's Web site the written policies for selecting individuals and entities to be EPM collaborators required by § 512.500(a)(3). We are eliminating as redundant the separate verbiage in proposed § 512.500(d)(1)(ii) to obligate the EPM participant to maintain accurate current and historical lists of all EPM collaborators because this obligation is encompassed in the obligations to publicly post and update such lists as required in § 512.500(d)(1)(ii) as finalized.

Comment: Several commenters expressed concern about the various ''volume or value'' standards that CMS proposed to use in the regulations for EPM and CJR financial arrangements. The commenters pointed out that CMS' proposal made clear that the criteria for the selection of collaborators and the determination of who shall be eligible to make or receive alignment or gainsharing payments cannot be based directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated between the parties, their various agents, and any individuals or entities affiliated with them or their agents. However, the commenters observed that the proposal did allow for the ''amount of EPM activities'' to be taken into account in the methodology for calculating gainsharing payments. With respect to the calculation of alignment payments, the commenters observed that CMS proposed that EPM participants may not ''directly'' take into account the volume or value of past or anticipated referrals, proposing this different ''volume or value'' standard for these payments. One commenter believes that the varying standards are confusing and will have little effect on the integrity of the models, while EPM participants and CJR participant hospitals will need to seek substantial legal consultation to avoid placing themselves at risk of whistleblower lawsuits. The commenter requested that CMS revisit the reasoning behind the ''volume or value'' standard in the proposed EPM and CJR model which they believed was imported from the Stark law, while also taking into account the significant safeguards built into the models and the goal of provider-supplier alignment with EPM and CJR participants through financial arrangements. At minimum, the commenter urged CMS to streamline and clarify the provisions that include the ''volume and value'' standard.

Another commenter was concerned that EPM participants and CJR participant hospitals participants will avoid entering into financial arrangements due to the fear of liability under the Stark law and requested that CMS clarify specifically what does and does not constitute a violation of the ''volume or value'' standard for sharing and distribution arrangements. The commenter urged CMS to provide EPM participants and CJR participant hospitals with assurance that compliance with the CMS standard would not result in liability under the fraud and abuse laws. The commenters asserted that this would give model participants the confidence to enter into arrangements that will enable them to achieve the goals of the model.

Response: We appreciate the commenters' interest in streamlining and clarifying the proposed standards for various requirements of the EPM and CJR financial arrangements that utilize a specific standard related to ''volume or value.'' We proposed volume or value standards for three things: (1) The selection criteria for EPM collaborators; (2) the opportunity to make or receive a payment (gainsharing, alignment, distribution, or downstream distribution payment); and (3) the alignment payment methodology. Our proposal was designed to ensure that the sole purpose of any financial relationships in the CJR model and the EPM is to align the financial incentives of the participants, collaborators, collaboration agents, and downstream collaboration agents so that the models can achieve the goals of improved episode care quality and efficiency. For the reasons provided later in this section, we believe that the proposed volume or value standard is appropriate in all three instances.

First, we proposed in § 512.500(a)(3) that the selection criteria for EPM collaborators 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 (''affiliated individuals or entities''). We do not believe it would be appropriate to permit EPM collaborators to be selected based on the volume or value of their referrals to any of the enumerated parties. Without this prohibition, such arrangements could be used to reward collaborators for their referrals, including referrals for business outside the EPM.

Second, we proposed that the opportunity to make or receive a gainsharing payment, alignment payment, distribution payment, or downstream distribution payment could not be conditioned 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 affiliated individual or entity. As with the collaborator selection criteria, we do not believe that a payment opportunity should be used to reward referrals. We note that in proposed § 512.500(c)(7) (regarding the opportunity to make or receive a gainsharing payment or an alignment payment), we did not explicitly state that the payment opportunity could not be conditioned ''directly or indirectly'' on the volume or value of referrals or other business. We are revising the regulation text at § 512.500(c)(7) to include the words ''directly or indirectly'' before the volume or value standard. While we do not believe this revision effects a substantive change, we are mindful of the commenters' requests to clarify and streamline all the ''volume or value'' provisions. This change simply clarifies that the volume or value standard is the same in all payment opportunity provisions.

Finally, we proposed in § 512.500(c)(14) that 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 affiliated individual or entity. We deliberately avoided proposing that alignment payments must not ''directly or *indirectly*'' account for the volume or value of referrals or other business. Alignment payments represent a portion of the EPM participant's repayment liability to CMS, which is determined in part by summing actual EPM episode payments that could include payments for some items or services referred by the EPM collaborator. Thus, our proposal simply recognizes that alignment payments might indirectly account for the volume or value of an EPM collaborator's referrals. The commenters did not specifically object to the volume or value standard in § 512.500(c)(14), and we are finalizing the provision as proposed.

We did not propose a ''volume or value'' standard for the methodologies used to determine the amount of any gainsharing payment, distribution payment, or downstream distribution payment. As we discussed in the

proposed rule (81 FR 50923, 50926, and 50027), we proposed that these payments must be determined in accordance with a methodology that is substantially based on quality of care and the provision of EPM activities. We further proposed that the methodology may take into account the amount of EPM activities provided by one EPM collaborator, collaboration agent, or downstream collaboration agent relative to other EPM collaborators, collaboration agents, or downstream collaboration agents, as applicable to the type of payment. We proposed this standard because we recognized that a ''volume or value'' standard could be interpreted to prohibit a payment methodology that would result in higher compensation to individuals and entities that performed more EPM activities (which may result in referrals) compared to others. In response to the commenters who questioned the need for different standards for gainsharing payments and alignment payments, 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 EPM participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any affiliated individual or entity.

Table 46 summarizes the applicability of ''volume or value'' standards being finalized in this rule for EPM financial arrangements.

TABLE 46—FINAL STANDARDS RELATED TO ''VOLUME OR VALUE'' FOR EPM FINANCIAL ARRANGEMENTS

	Volume/value prohibition?	Scope of volume/value prohibition	Citation
Collaborator selection criteria.	Yes	Cannot be based *directly or indirectly* on past or anticipated referrals or business otherwise generated by, between or among: i. EPM participant ii. Collaborator iii. Collaboration agent iv. Downstream collaboration agent v. Any individual or entity affiliated with (i)–(iv)	§ 512.500(a)(3).
Opportunity to make or receive a payment.	Yes	Same as for collaborator selection criteria	§ 512.500(c)(7) (gainsharing or alignment payments). § 512.505(b)(4) (distribution payment). § 512.510(b)(4) (downstream distribution payment).
Alignment Payment Methodology.	Yes	Cannot *directly* account for volume or value of past or anticipated referrals or business otherwise generated by, between or among (i)–(v) above.	§ 512.500(c)(14).
Gainsharing Payment Methodology.	No	N/A—methodology must be substantially based on quality of care and the provision of EPM activities; may consider relative amount of EPM activities provided.	§ 512.500(c)(5) (gainsharing payments).
Distribution and Downstream Distribution Payment Methodologies.	No	N/A—same methodology standard as for gainsharing payments, except that amounts distributed by a PGP to a PGP member can also be determined in a manner that complies with § 411.352(g) of the physician self-referral regulations.	§ 512.505(b)(5), (6) (distribution payments). § 512.510(b)(5), (6) (downstream distribution payments).

Comment: Many commenters raised concerns about the burdens of writing EPM sharing arrangements and the overall complexity of the requirements for financial arrangements. Several commenters claimed that financial arrangements are underutilized in the BPCI initiative due to the complexity of CMS' requirements, the administrative burden associated with understanding and ensuring compliance with those requirements, and the lack of clearly articulated safe harbors from the fraud and abuse laws implicated by the arrangements. The commenters further asserted that few potential collaborators have sufficient volume of cases in episodes for the financial benefits of gainsharing to outweigh the administrative burdens to develop and maintain these arrangements.

Another commenter stated that it is infeasible for EPM participants to write sharing arrangements with each party where the EPM participant will transfer beneficiaries with AMI. The commenter recommended that CMS institute a default sharing arrangement which would come into force when there is no specific sharing arrangement between an EPM participant and another hospital in order to protect receiving hospitals from the effects of adverse patient selection that would inflate the transfer hospital's costs.

One commenter stated that the structure of CJR fraud and abuse waivers have hindered gainsharing arrangements because of CJR participant hospitals' concerns that they may lose waiver protection if they miss any one of the program requirements, including those that the commenter believes pose no fraud and abuse risk to any federal health care program. The commenter asserted that the program requirements for sharing arrangements do not appropriately balance CMS' program integrity interest with need for meaningful change.

Response: We appreciate the feedback of the commenters, as well as the information provided regarding the potential challenges associated with constructing and executing sharing arrangements, both in the EPM and CJR model and other CMS efforts such as the BPCI initiative. We understand that parties may want to consider a number of factors when assessing whether to enter into a sharing arrangement, including the number of episodes in which the collaborator will be engaged,

the quality measures used to measure performance, as well as purely contractual matters governing payment, appeals, and termination.

With respect to the overall complexity of the requirements for financial arrangements in the EPM, we note, as we discussed in the proposed rule (80 FR 50917), that in response to feedback from participant hospitals in the CJR model, other stakeholders, and the general public we have made an effort to simplify the requirements in comparison to what was adopted for the CJR model by removing duplication of requirements in similar provisions; streamlining and reorganizing many of the provisions for clarity and consistency; and providing additional flexibility. We believe that these efforts have resulted in a set of requirements that are more accessible to EPM participants and involved parties. Nevertheless, we note that an EPM participant's decision to enter into sharing arrangements remains voluntary—as it is for EPM collaborators, collaboration agents, and downstream collaboration agents—and as stated in the proposed rule, we expect that all parties will carefully consider the impact of entering into sharing arrangements in order to align the financial incentives of providers and suppliers with the EPM goals of improving the quality and efficiency of EPM episodes.

We note that we have proposed to exclude the term ''collaborator agreement'' from the EPM (and to amend the CJR model to remove this term). We believe that dispensing with this term and the associated mandates for the collaborator agreements removes an unnecessary level of regulatory complexity and offers useful flexibilities to parties developing their sharing arrangements and drafting the written agreements to memorialize those sharing arrangements.

A desire to allow for flexibility is the same reason we decline to develop a default template for written agreements to memorialize sharing arrangements, as requested by one commenter. Given the variation and potential complexity of financial arrangements between EPM participants and collaborators, we believe that a sharing arrangement template is more likely to be constrictive than helpful. We would expect that any template developed by the agency would include provisions to account the diversity of sharing arrangements that could be pursed and therefore would likely include a number of provisions that would be inapplicable or unnecessary for the written agreements in many sharing arrangements.

Regarding the specific concern of the commenter about the feasibility of EPM participants writing sharing arrangements with each party where a hospital will transfer beneficiaries with AMI, as discussed in section III.C.4.a.(5) of this final rule, we are finalizing a modification to our proposed policy and will cancel all AMI episodes when a beneficiary initiates an AMI episode at the initial treating hospital and then is transferred to another hospital for inpatient hospital care. We believe this revision to the proposed AMI model episode initiation and transfer attribution policy addresses the concerns of the commenter by eliminating the circumstances that would lead an initial treating hospital to enter into sharing arrangements with hospitals solely because such hospitals are receiving beneficiaries in transfer during AMI care because the initial treating hospital will no longer be responsible for an AMI episode when the beneficiary is transferred.

We emphasize that all the requirements in §§ 512.500, 512.505, and 512.510 for sharing arrangements, distribution arrangements, and downstream distribution arrangements, respectively, are EPM programmatic requirements. As noted previously, fraud and abuse waivers for the EPM are outside the scope of this rulemaking.

Comment: One commenter urged CMS to carefully consider the impact state law, particularly in California, would have on providers' ability to participate in the proposed EPM and allow time for agreements to be structured so hospitals are not put at risk for violating state law and can maintain their relationships with physicians. The commenter asserted that California's corporate practice of medicine prohibition makes financial alignment between EPM participants and certain collaborators particularly complicated because the prohibition mandates a strict separation of hospitals and physicians. They concluded that in developing sharing arrangements, EPM participants would need to undertake careful analysis of their compliance with both federal and state law, including the interaction of federal and state law requirements.

Response: We appreciate the information provided by the commenter about the challenges that may arise for EPM participants developing sharing arrangements that comply with the requirements of the EPM and applicable state laws. We are mindful of the time that EPM participants may need to prepare and put into place the sharing arrangements that they believe are necessary to align their financial incentives with those of their collaborators toward the goal of the EPM to improve the quality of care while reducing its cost. Given the first performance year of the EPM begins on July 1, 2017, EPM participants will have knowledge of the federal requirements for EPM financial arrangements several months prior to their implementation in the EPM, which we believe is sufficient for the early planning about these arrangements.

Final Decision: After consideration of the public comments received, we are finalizing the proposals in § 512.500(a) for the general requirements for EPM sharing arrangements, with modification to clarify that an EPM collaborator selection criterion that considers whether a potential collaborator has performed a reasonable minimum number of services that would qualify as EPM activities will be deemed not to violate the volume or value standard if the purpose of the criterion is to ensure the quality of care furnished to EPM beneficiaries. EPM sharing arrangements must comply with the following general provisions:

- 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.
- 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.
- 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. A selection criterion that considers whether a potential EPM collaborator has performed a reasonable minimum number of services that would qualify as

EPM activities will be deemed not to violate the volume or value standard if the purpose of the criterion is to ensure the quality of care furnished to EPM beneficiaries

- 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

We proposed a number of specific requirements for sharing arrangements to help ensure that their sole purpose was to create financial alignment between EPM participants and EPM collaborators toward the goals of the EPM while providing program integrity safeguards. We proposed that the sharing arrangement must be in writing, signed by the parties, and entered into before care was furnished to EPM beneficiaries under the sharing arrangement. In addition, participation in a sharing arrangement must be voluntary and without penalty for nonparticipation. It would be 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 believed that if a provider, supplier, or ACO entered 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 expected 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 had already occurred and where the financial outcome of the sharing arrangement terms would be known before signing.

We proposed that the sharing arrangement must require the EPM collaborator and its employees, contractors, and subcontractors to comply with certain requirements that would be important for program integrity under the arrangement. We noted that the terms contractors and subcontractors, respectively, included collaboration agents and downstream collaboration agents as defined later in this section. The sharing arrangement must require all of these individuals and entities to comply with the applicable provisions of proposed 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 of these individuals and entities 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 would be to ensure that the individuals and entities have the required enrollment relationship with CMS under the Medicare program, although we noted that they would not be responsible for complying with requirements that did not apply to them. Finally, the sharing arrangement must require individuals and entities to comply with all other applicable laws and regulations.

We proposed 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 did not negatively impact beneficiary protections under the EPM. The sharing arrangement must require the EPM collaborator to have a compliance program that included oversight of the sharing arrangement and compliance with the requirements of the EPM, just as we would require EPM participants to have a compliance program for this purpose as a program integrity safeguard. In the proposed rule, we noted our understanding that some stakeholders might 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 might be a disincentive for certain individuals and entities to be CJR collaborators in the CJR model. However, we noted that the CJR compliance program requirement did 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 noted our understanding of the variances and complexities within the industry and appreciated 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 did 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 proposed to adopt a substantially similar requirement for the EPM. We sought 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.

We observed it would be necessary that EPM participants have adequate oversight over sharing arrangements to ensure that all arrangements meet the proposed requirements of this section and provide program integrity protections. Therefore, we proposed 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 proposed 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 believed the activities that would fall under this proposed definition would 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 sought 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 contributed to improving the quality and efficiency of these episodes. We proposed to use the term EPM activities in identifying certain obligations of parties in a sharing arrangement that were described as ''changes in care coordination or delivery'' in the CJR regulations governing the contents of the written agreement memorializing the sharing arrangement. We noted that as discussed in section V.J. of the proposed rule (81 FR 50958), we proposed to define and use the term CJR activities in the CJR regulations just as we proposed to define and use the term EPM activities in the EPM regulations.

We proposed 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 proposed 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 proposed requirements were to ensure that the quality of care for EPM beneficiaries would not be negatively affected by sharing arrangements under the EPM.

The proposals for the requirements for sharing arrangements under the EPM were included in proposed § 512.500(b). We sought comment about all of the proposed 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 were met.

The following is a summary of the comments received and our responses.

Comment: In general, the commenters requested that CMS simplify the requirements for sharing arrangements and allow gainsharing to the fullest extent possible consistent with the goals of preventing fraud and abuse and unfair business practices.

One commenter asserted that the regulations lack a clear section laying out each and every requirement to be included in the written agreement memorializing the sharing arrangement. The commenter urged CMS to set forth in the final EPM and CJR regulations a comprehensive list of the requirements for the written sharing arrangement requirements.

Some commenters urged CMS to eliminate proposed requirements for financial arrangements that they believe are overly inclusive or technical. They singled out as unnecessary the requirement that the written agreement memorializing the sharing arrangement include management and staffing information. The commenters stated that it should be sufficient to spell out each party's obligations and allow greater latitude to determine how the management and staffing aspects of those obligations will be met. The commenters also identified as overly technical and confusing the requirement that all gainsharing payments and any alignment payments must be administered by the EPM participant in accordance with generally accepted accounting principles. The commenters asserted this requirement does not lessen the fraud and abuse risk posed by any sharing arrangement.

Response: We appreciate commenters' feedback on the requirements for sharing arrangements. With the specific exceptions noted later in this section, we continue to believe that the requirements with respect to financial arrangements in the EPM set forth in the proposed rule are necessary for program integrity purposes and to prevent the distribution and receipt of payments for reasons outside the goals of the EPM and we finalize those requirements here.

We direct the commenters suggesting that the regulations lack a clear section laying out each and every requirement to be included in the written agreement memorializing the sharing arrangement to § 512.500(b) of the regulation text, with particular emphasis on § 512.500(b)(7). This subsection sets forth the requirements for the written agreement memorializing the sharing arrangement. In addition to providing a list of specifications for the written agreement memorializing a sharing arrangement, § 512.500(b) is intended to offer flexibility to the parties to draft written agreements in a format most useful for them. We note that while EPM participants may conclude that additional provisions in their written agreements are the most appropriate tool to hold their EPM collaborators accountable for compliance with other programmatic requirements, we are not mandating that EPM participants adopt that approach.

As noted previously, we have endeavored to streamline the requirements for financial arrangements under the EPM in areas where we believe the program integrity risk is low. As also noted previously, the removal of the collaborator agreement requirement—a term present in the CJR Final Rule, not included in this final rule—represents a result of that effort. In addition, we agree with the commenters who recommended that we eliminate the requirement that the written agreement memorializing the sharing arrangement include management and staffing information, including the type of personnel or contractors that will be primarily responsible for carrying out EPM activities. Upon further consideration, we believe this requirement for the written agreement is unnecessary as a program safeguard. While we generally expect that EPM participants entering into sharing arrangements will have an EPM care redesign plan that includes management and staffing information, including the types of personnel or contractors that will be primarily be responsible for carrying out EPM activities, we understand that maintaining up-to-date management and staffing information as part of the written agreement for the sharing arrangement could be administratively burdensome to EPM

participants and EPM collaborators and reduce their flexibility to accommodate changes in personnel or in their plans for care redesign in response to their cost and quality performance under the EPM. Therefore, we are removing the proposed requirement in § 512.500(b)(7)(iv) that the written agreement include management and staffing information. However, we decline to remove provisions from the set of requirements for financial arrangements where we believe such changes would increase the risk for fraud and abuse or would be inconsistent with the goals of the model. We disagree with the commenters who suggested that we should remove the requirement that gainsharing payments and alignment payments be administered by the EPM participant in accordance with generally accepted accounting principles (GAAP). For purposes of program integrity, compliance, and monitoring, there is a benefit to all participants across the EPM applying a standard set of accounting principles to these types of payments. Thus, we decline to accept the commenters' suggestion to remove this requirement.

Comment: One commenter expressed concern about CMS' proposal to no longer use the term ''collaborator agreement'' in the CJR model and to not use this term in the EPM, although the commenter supported CMS' proposed definition of a sharing arrangement and the related requirements. They claimed that not all collaborator agreements would be sharing arrangements. For example, the commenter explained that hospitals that are EPM participants could have agreements with their employed physicians that cascade the programmatic requirements of the EPM, but do not necessarily alter the physicians' underlying compensation or include the potential for gainsharing payments. They urged CMS to retain the term collaborator agreement, rather than adopt the proposed change to sharing arrangement, as the term collaborator agreement would include both the agreements that cascade programmatic requirements as well as those that also create explicit financial arrangements. The commenter added that this distinction is important because CMS proposed to make a financial arrangement a prerequisite to being placed on the list of Affiliated Practitioners for the determination of Eligible Clinicians who could be considered QPs based on services furnished under the EPM and CJR model. However, MACRA states that the ''entity'' must bear more than nominal risk to qualify for an APM incentive payment, not the clinician. By altering the terms used in the EPM and CJR model to eliminate the term collaborator agreement, the commenter concluded that CMS was suggesting that a shift of risk is required for a clinician to be on the list of Affiliated Practitioners and thus qualify for a bonus, which they believe is inconsistent with the statute. The commenter recommended that CMS retain the term collaborator agreement and clarify that the agreements do not need to include financial arrangements for the clinicians to be placed on the Affiliated Practitioners list for the determination of Eligible Clinicians for QP determinations.

Response: We appreciate the information provided by the commenter on the agreements that hospitals may develop with their employed physicians and their support for the proposed requirements for sharing arrangements. However, the commenter appears to misunderstand the existing CJR provisions regarding collaborator agreements. As finalized in the CJR Final Rule (80 FR 73541), a collaborator agreement means a written, signed agreement between a CJR collaborator and a participant hospital that meets the requirements of § 510.500(c). Among other requirements, § 510.500(c) mandates that each collaborator agreement ''must contain a description of the sharing arrangement between the participant hospital and the CJR collaborator regarding gainsharing payments and alignment payments.'' (81 FR 73553). Therefore, an agreement between a CJR participant hospital and its employed physicians to require physicians to meet the programmatic requirements of the CJR model that does not also include the potential for gainsharing payments or alignment payments is not a collaborator agreement. Thus, the commenter's assumption that maintaining the CJR requirements for collaborator agreements and adopting those requirements for the EPM as a mechanism to include clinicians without sharing arrangements on the Affiliated Practitioners lists for these models is incorrect. As noted previously, in developing the proposed rule, we concluded that we could streamline the CJR requirements and adopted less burdensome requirements for the EPM by eliminating the concept of collaborator agreement and the separate requirements associated with these agreements. The example provided by the commenter does not meet the definition of a CJR collaborator agreement. We continue to believe that it is appropriate under the EPM and CJR model to focus on the requirements for a sharing arrangement, without imposing additional regulatory burdens associated with a collaborator agreement.

For discussion of the identity of the clinicians that are reported on the Affiliated Practitioner List for the EPM and CJR model and the opportunity for clinicians without financial arrangements under the EPM and CJR model to be included on those lists, we refer to sections III.A.2.c. and V.O.3. of this final rule, respectively.

Comment: A number of commenters commended CMS for its proposal that EPM sharing arrangements remain voluntary and without penalty for nonparticipation. One commenter added that this is especially important for those professionals that are non-patient facing providers who do not select their patients and whose contact, relationship, and services furnished to a beneficiary may occur during a short part of the episode.

Response: We agree with the commenters who supported the voluntary nature of sharing arrangements, and we continue to believe that it is essential that sharing arrangements be voluntary and without penalty for nonparticipation. We are not requiring EPM participants to offer sharing arrangements to all providers and suppliers caring for EPM beneficiaries. Likewise, EPM participants are prohibited from coercing or requiring individuals or entities to enter into a sharing arrangement. EPM participants may not penalize or discriminate against physicians, nonphysician practitioners, and other providers, suppliers, or ACOs on the grounds that they are not EPM collaborators. For example, EPM participants may not condition the ability of individuals or entities to receive future referrals from the EPM participant on the basis of EPM collaborator status or on criteria that are outside of the goals of the EPM

We are finalizing in § 512.500(b)(2) that participation in sharing arrangements be voluntary and without penalty for nonparticipation.

Comment: Several commenters expressed concerns about the level of control given to EPM participants over the amount of gainsharing payments and their allocation, urging CMS to modify its proposal to require greater input from collaborators on the methodology for sharing payments and to provide additional safeguards to ensure continued beneficiary choice of providers and fairness to providers. Specifically, they recommended that

providers who furnished services to EPM beneficiaries should be part of decision-making regarding the amount and allocation of gainsharing payments. The commenters suggested that providers furnishing a minimum percentage of EPM services should be required to be part of the EPM participant governance structure that develops written policies for collaborators and the sharing arrangement methodologies. The commenters urged CMS to establish a maximum amount of reconciliation payments that hospitals may keep and a minimum amount of gainsharing payments that must be paid to each collaborator. They concluded that these modifications would strengthen beneficiary choice and promote fairness.

Response: We appreciate the interest of the commenters in engagement of providers furnishing care to EPM beneficiaries in decision-making regarding gainsharing payment methodologies. As we discuss in our responses to other comments, as the financially responsible entities for EPM episodes, we believe that EPM participants should have as much flexibility as possible, subject to adequate program integrity safeguards, in decisions about financial arrangements, including whether or not to enter into them; the selection of collaborators; and the methodologies for determining the amounts of gainsharing payments and alignment payments. We do not believe it would be appropriate to specify certain membership of the board or other governing body that we proposed to require an EPM participant to charge with responsibility for 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. We expect that EPM participants will establish a board or other governing body with sufficient expertise to provide responsible oversight of those activities.

We have included safeguards in this final rule to protect beneficiary freedom of choice, to require that the potential for financial gain under EPM financial arrangements be based on activities for EPM beneficiaries that are focused on the goals of the EPM to improve quality and reduce the cost of care, and to limit the potential for undue financial gain by certain providers under the EPM. These safeguards include the requirement that EPM beneficiaries be informed that they retain freedom of choice to choose providers and services; the requirement that EPM participants not restrict beneficiaries' ability to choose any Medicare-enrolled provider or supplier, or any physician or practitioner who has opted out of Medicare; the cap on gainsharing payments to physicians, nonphysician practitioners, PGPs, and NPPGPs; the requirement that EPM collaborator selection must be based on written policies that contain criteria related to, and inclusive of, the quality of care delivered by the potential EPM collaborator and cannot be based directly or indirectly on the volume or value of past or anticipated referrals; the requirements that the opportunity to make or receive gainsharing payments, alignment payments, distribution payments, and downstream distribution payments 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; and the requirements that the amount of any gainsharing payments and, with limited exceptions, any distribution payments and downstream distribution payments be determined in accordance with a methodology that is substantially based on the quality of care and the provision of EPM activities. We believe these safeguards are sufficient to protect beneficiary choice and ensure that providers, suppliers, and ACOs that are EPM collaborators, collaboration agents, or downstream collaboration agents receive payments that are based on quality of care and activities specifically 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.

Comment: One commenter recommended that CMS enable individuals and entities, such as small PGPs, to participate in the EPM as collaborators without requiring major investments in infrastructure and electronic health records. The commenter urged CMS to provide appropriate resources and support to enable small practices to participate. They further requested that CMS monitor activities involving distribution of payment to guard against unfair business practices and to promote a fair and equitable distribution of gainsharing payments to all providers who are involved as collaborators. Finally, the commenter urged CMS to mandate distribution of gainsharing payments to EPM collaborators in a timely fashion.

Response: It is our intent that the models offer opportunities for providers and suppliers of all sizes to be EPM collaborators, provided they meet the criteria in this final rule. We note that the EPM does not include requirements for certain infrastructure or use of electronic health records. While we currently do not plan to provide specific resources targeted to providers, suppliers, and ACOs engaged in sharing arrangements with EPM participants, we will broadly disseminate to the public information that may be useful to model collaborators throughout implementation of the EPM.

In response to the commenters' desire to ensure that gainsharing payments are distributed fairly and equitably to EPM collaborators, as noted previously, we believe that the provisions of this final rule adequately address this point. We appreciate the commenter's concern about the potential for unfair business practices, but the regulation of such practices is outside the scope of our authority. Accordingly, we will not add a prohibition against unfair business practices. However, we believe that many of the program integrity provisions for sharing arrangements will also serve to deter unfair business practices, and we will be monitoring compliance with these requirements.

Regarding the timely distribution of gainsharing payments, we require that gainsharing payments be distributed on an annual basis. As discussed previously, we are not requiring EPM participants to enter into sharing arrangements with all providers and suppliers caring for EPM beneficiaries, but where an EPM participant does enter into one or more sharing arrangements, the model participant must not distribute any gainsharing payments more than once per year. We believe that this requirement ensures that gainsharing payments are timed to sufficiently maintain an EPM collaborator's commitment to lowering costs and improving quality of care. To the extent the commenter was requesting that CMS prohibit late payment of amounts owed to EPM collaborators, we believe that the consequences for breach of contract offer sufficient protection.

Comment: Many commenters expressed strong support for CMS' proposal to adopt the terms EPM

activities and CJR activities to describe activities in support of the goals of the models, as well as CMS' proposed approach of utilizing these definitions as the comprehensive framework for capturing both direct patient care and care redesign for EPM and CJR episodes. Several commenters also supported CMS' proposal that the methodology for determining gainsharing payments may take into account the amount of EPM or CJR activities provided by an EPM or CJR collaborator relative to other EPM or CJR collaborators, and the application of this same standard to distribution payments and downstream distribution payments. One commenter commended CMS for recognizing that risk-sharing between EPM participants and CJR participant hospital and their collaborators should involve more elasticity by accounting for the effects of the collaborator's overall participation and involvement. Another commenter claimed that this approach would provide EPM participants and CJR participant hospitals greater flexibility to incentivize care redesign by allowing more actively involved physicians who participate in care redesign to receive higher gainsharing payments as compared to physicians that may only care for a few model beneficiaries and may not be actively involved in care redesign. One commenter recommended that CMS should add to the definitions of EPM activities and CJR activities a consideration of the long-term patient experience and outcomes to ensure that these definitions do not undermine consideration of decisions that potentially impact long-term value beyond the episode.

Response: We appreciate the commenters' support for our proposal to adopt the terms EPM activities and CJR activities and to use these as a framework for capturing items and services furnished directly to beneficiaries in the EPM and CJR model and care redesign efforts for EPM episodes and CJR episodes. We also appreciate the commenters' support for our proposal that the methodology for determining gainsharing payments may take into account the amount of EPM activities or CJR activities provided by an EPM collaborator or CJR collaborator relative to other EPM collaborators or CJR collaborators, and the use of this same standard for distribution payments and downstream distribution payments. We agree with the commenters that this standard provides important flexibility for EPM participants and CJR participant hospitals to more effectively align the financial incentives of providers, suppliers, and ACO with the goals of the EPM and CJR model to improve the quality of care and reduce the cost of episode care by allowing financial arrangements to account for the level of the collaborator, collaboration agent, or downstream collaboration agent's overall participation and involvement in beneficiary care and care redesign.

While we appreciate the interest of the commenter who sought to ensure that care redesign under the EPM and CJR model does not lead to care pathways that may negatively impact long-term patient experience and outcomes, we do not believe it would be appropriate to add consideration of long-term patient experience and outcomes to the definition of EPM activities and CJR activities. The goals of the EPM and CJR model are focused on the quality and efficiency of episode care and, therefore, we believe that the definition of EPM activities and CJR activities that are part of the basis for payments under financial arrangements in the EPM and CJR model should include only those activities related to the immediate goals of the EPM and CJR model. However, as discussed in section IV. of this final rule, the evaluation of the EPM, like the evaluation of the CJR model (80 FR 73528 through 73530), will examine the impact of the EPM on outcomes and quality, including during the period following the end of episodes and on measures of relevant long-term quality.

We are finalizing in § 512.2 the definition of EPM activities and use that term throughout the regulations for EPM financial arrangements.

Comment: A commenter requested that CMS provide additional guidance on the compliance program required for EPM collaborators. The commenter expressed appreciation for the discussion in the proposed rule that a collaborator's compliance program need not take any one particular form and further, that there is no ''one size fits all'' compliance program. However, the commenter stated that the requirement that an EPM collaborator include oversight of not only the sharing arrangement, but compliance with the requirements of the entire EPM, is a large undertaking for any one collaborator, let alone a collaborator who is a solo practitioner. The commenter urged CMS to consider the practical implications of this compliance program requirement in the event an EPM participant contracts with a physician individually, and that physician is also a member of a PGP that is not an EPM collaborator.

Response: We appreciate the interest of the commenter in the implication of the proposed requirement for an EPM collaborator to have a compliance program, particularly for collaborators who are individuals. In our proposed requirements for sharing arrangements, we proposed in § 512.500(b)(4) that 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. Any individual or entity that wants the benefits of becoming a collaborator must also accept the responsibility to ensure that its collaboration complies with the requirements of the EPM. The proposal requires that each collaborator implement mechanisms to promote compliance, while giving each collaborator the discretion to determine which mechanisms are appropriate for that individual or entity. Our intent is to require the EPM collaborator's compliance program to monitor its own conduct and relationships only, in contrast with policing independent, third parties with whom it does not have any direct relationship. The goal is for the EPM collaborator's compliance efforts to look not just at its financial relationship with the EPM participant but at the collaborator's overall compliance with the requirements of the model (for example, collaborator performance of clinical care under the model; the propriety of any distribution arrangements). Moreover, we believe that the requirement for a collaborator to have a compliance program should not be understood as requiring each collaborator to independently maintain a separate compliance program, but rather that every collaborator must be covered by a compliance program that includes the required oversight. For example, it may not be practical for each member of a PGP to separately maintain his or her own compliance program. However, the EPM requirement could still be met if the PGP has a compliance program that covers the PGP member and that includes oversight of the PGP member's sharing arrangement and the PGP member's compliance with the requirements of the model.

Therefore, while we continue to believe that it is appropriate to require all EPM collaborators, including individual practitioners, to be covered by a compliance program that includes oversight of the sharing arrangement, we are clarifying that the collaborator's obligations may be met if the collaborator either has or is covered by a compliance program that includes the appropriate oversight of the collaborator, and that the requirements of the EPM that are relevant for the EPM

collaborator's compliance program are those requirements of the EPM that apply to its role as an EPM collaborator, including any distribution arrangements, rather than all requirements of the entire model.

We are finalizing in § 512.500(b)(4) that the EPM collaborator must have or be covered by a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the EPM that apply to its role as an EPM collaborator, including any distribution arrangements.

Comment: Several commenters requested clarification about the timing for entering into sharing arrangements, distribution arrangements, or downstream distribution arrangements with respect to EPM episodes in view of CMS' proposals that the three types of arrangements must be in writing and signed by the parties, and entered into before care is furnished to EPM beneficiaries under the applicable arrangement. One commenter further inquired about whether a sharing arrangement needs to be signed prior to an episode beginning in order for an EPM collaborator to receive a gainsharing payment for savings associated with the episode or whether it is also possible for a collaborator to receive a gainsharing payment for savings associated with the episode if the sharing arrangement is signed prior to an episode ending.

Response: We appreciate the need to understand when ''care is furnished to EPM beneficiaries under the applicable arrangement'' in order to ensure that execution of the written agreements is timely. A sharing arrangement, distribution arrangement, or downstream distribution arrangement requires that the amount of a gainsharing payment, distribution payment, or downstream distribution payment to an EPM collaborator, collaboration agent, or downstream collaboration agent, respectively be determined in accordance with a methodology that is substantially based on the quality of care and the provision of EPM activities, which by definition must be for EPM beneficiaries during EPM episodes. EPM activities include, but are not limited to, billable items and services furnished to EPM beneficiaries during EPM episodes. Therefore, ''care is furnished to EPM beneficiaries under the applicable arrangement'' when the individual or entity in the financial arrangement (or designee to the extent permitted by regulation) first provides EPM activities that may be considered in the methodology for determining the amount of the applicable payment. Accordingly, the written agreement memorializing the sharing arrangement, distribution arrangement, or downstream distribution arrangement must have been signed by the parties and entered into before the date the first EPM activities that may be considered in the methodology for determining the applicable payment amount are provided.

We note that once a sharing arrangement is signed by an EPM collaborator in a performance year, there is no restriction for that performance year on the timing of the specific episodes that result in savings that can be paid to the EPM collaborator as a gainsharing payment. According to our requirements in § 512.500(b)(2), 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, as well as meet the other criteria specific to the type of collaborator, namely directly furnished an item or service to an EPM beneficiary during an EPM episode; billed for an item or service that was rendered by one or more PGP member, NPPGP member, or TGP member respectively to an EPM beneficiary during an EPM episode, contributed to EPM activities, and been clinically involved in the care of EPM beneficiaries; or 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, 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.

Final Decision: After consideration of the public comments received, we are finalizing the proposals in § 512.500(b) for the requirements for EPM sharing arrangements, with modification to specify that the EPM collaborator must have or be covered by a compliance program which must include oversight of the sharing arrangement and compliance with the requirements of the EPM that apply to its role as an EPM collaborator, including any distribution arrangements. We are also modifying our proposal as discussed previously and removing the requirement that the written agreement memorializing a sharing arrangement include management and staffing information, a change which results in renumbering proposed § 512.500(b)(7)(v) (requiring the financial or economic terms for payment be specified in the written agreement about the sharing arrangement) to § 512.500(b)(7)(iv). EPM sharing arrangements must meet the following general requirements:

- 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.
- Participation in a sharing arrangement must be voluntary and without penalty for nonparticipation.
- 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:

++ 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; and

++ All other applicable laws and regulations.

- The sharing arrangement must require the EPM collaborator to have or be covered by a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the EPM that apply to its role as an EPM collaborator, including any distribution arrangements.
- 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 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.
- The written agreement memorializing a sharing arrangement must specify 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.

++ 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.

• 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.

c. Gainsharing Payment, Alignment Payment, and Internal Cost Savings Conditions and Restrictions

We proposed 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 proposed 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.

In the proposed rule, we discussed our belief 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 would be solely based on aligning financial incentives for EPM collaborators with the EPM goals of improving EPM episode quality and efficiency. With respect to the first requirement, we proposed 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 comprised the gainsharing payment. The quality of care criteria that would be established by the EPM participant must be directly related to EPM episodes. With regard to the second requirement, which is also applicable to being required to make an alignment payment, we proposed different criteria depending on the type of collaborator involved. We proposed that to be eligible to receive a gainsharing 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 comprised the gainsharing payment or was assessed a repayment amount. For purposes of this requirement, we considered a collaborator that is 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 comprised the gainsharing payment or was assessed a repayment amount. We explained that the phrase ''performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprised the gainsharing payment or was assessed a repayment amount'' did not mean the year in which the gainsharing payment was made. These proposed requirements would 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 believed the provision of direct care was essential to the implementation of effective care redesign, and the requirement would provide a safeguard against payments to EPM collaborators other than a PGP or an ACO that were unrelated to direct care for EPM beneficiaries during EPM episodes.

We proposed to establish variations on this requirement for PGPs and ACOs because these entities do not themselves directly furnish billable services. We proposed that for a PGP to be eligible to receive a gainsharing payment or required to make an alignment payment, 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 comprised the gainsharing payment or was assessed a repayment amount. We proposed that for an ACO to be eligible to receive a gainsharing payment or required to make an alignment payment, 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 comprised the gainsharing payment or was assessed a repayment amount. With respect to ACOs, we proposed that an ''ACO participant'' and ''ACO provider/supplier'' have the meaning set forth in § 425.20 of regulations. Thus, these proposed variations on the requirements for other collaborator types also required 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 proposed 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 comprised 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 were 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 might be shared through gainsharing payments with EPM collaborators, we proposed certain requirements for their calculation as a program integrity safeguard. 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 believed it would be 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 was not the EPM participant and ''paper'' savings from accounting conventions or past investment in fixed costs. In the proposed rule, we noted 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 did 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 believed it would be 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 might include internal cost savings, reconciliation payments, or both based on a methodology that met the requirements described later in this section. We proposed this same change to the internal cost savings calculation requirements for the CJR model in section V.J. of the proposed rule (81 FR 50961).

We proposed to limit the total amount of gainsharing payments for a performance year to EPM collaborators that were physicians, nonphysician practitioners, or PGPs. For EPM collaborators that were physicians or nonphysician practitioners, that proposed limit was 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 comprised the gainsharing payment being made. For EPM collaborators that were PGPs, the proposed limit was 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 comprised the gainsharing payment being made. These proposed limits were consistent with those in the CJR model (80 FR 73430).

We proposed that the amount of any gainsharing payments must be determined in accordance with a methodology that was substantially based on quality of care and the provision of EPM activities. The methodology could take into account the amount of such EPM activities provided by an EPM collaborator relative to other EPM collaborators. While we emphasized in the proposed rule 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 was 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 believed that accounting for the relative amount of EPM activities by EPM collaborators in the determination of gainsharing payments did not undermine this objective. Rather, the proposed requirement would allow 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 might contribute to both the internal cost savings and EPM participant's reconciliation payment that might be available for making a gainsharing payment. Greater contributions of EPM activities by one EPM collaborator versus another EPM collaborator that resulted in greater differences in the funds available for gainsharing payments could 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 was an EPM collaborator who treated 100 EPM beneficiaries during EPM episodes that resulted in high quality, less costly care could receive a larger gainsharing payment than a physician who was an EPM collaborator who treated 10 EPM beneficiaries during episodes that similarly resulted in high quality, less costly care.

However, we did 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 were 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 did 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 proposed that the methodology for determining alignment payments could not directly take into account the volume or value of past or anticipated referrals or business generated by, between or among the parties.

We proposed a change to this same standard for gainsharing payments under the CJR model as discussed in section V.J. of the proposed rule (81 FR 50961 through 50962). We sought comment on this proposal for gainsharing payments, where the methodology may take into account the amount of EPM activities provided by an EPM collaborator relative to other EPM collaborators. We were 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 achieved improvements in EPM episode quality and efficiency. In addition, we were interested in comments on whether additional safeguards or a different standard was 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 were met.

We proposed that for a performance year, the aggregate amount of all gainsharing payments that were derived from a reconciliation payment must not exceed the amount of the reconciliation payment the EPM participant received 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 proposed that an EPM participant must not make a gainsharing payment to an EPM collaborator that was 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, we proposed that 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 would provide program integrity safeguards for gainsharing under sharing arrangements.

With respect to alignment payments, we proposed that alignment payments from an EPM collaborator to an EPM participant may be made at any interval that was 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 did not owe a repayment amount. The EPM participant must not receive any amounts under a sharing arrangement from an EPM collaborator that were not alignment payments.

We also proposed certain limitations on alignment payments that were consistent with the CJR model (80 FR 73430). For a performance year, we proposed that 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 believed it was 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 owed $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, we proposed that 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 was not an ACO and 50 percent of the EPM participant's repayment amount for an EPM collaborator that was an ACO. We proposed to allow a higher percentage of the EPM participant's repayment amount to be paid by an ACO than by EPM collaborators that were 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 met all requirements for such arrangements, including that participation in the sharing arrangement must be voluntary and without penalty for nonparticipation as discussed previously. We sought 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 in the proposed rule illustrated the effects of the proposed limitations on alignment payments. In one scenario, upon receipt of a reconciliation report indicating that the EPM participant owed $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 was one of the EPM participant's EPM collaborators that was not an ACO. In the second scenario where an ACO was 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 proposed 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 proposed that all gainsharing payments and alignment payments must be made by check, electronic funds transfer, or another traceable cash transaction. We noted that while the CJR model required gainsharing payments and alignment payments to be made by electronic funds transfer (EFT) (80 FR 73431), we proposed a different requirement for the EPM to provide additional flexibility for entities making gainsharing payments and alignment payments. We made 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

proposed a change to adopt this same standard under the CJR model as discussed in section V.J. of the proposed rule (81 FR 50962). We sought 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 were included in proposed § 512.500(c). We sought 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 were met.

The following is a summary of the comments received and our responses.

Comment: Some commenters opposed CMS' proposal that gainsharing payments be distributed on annual basis, but not more than once per year. The commenters believe this periodicity is too restrictive and creates an unintended advantage for BPCI participants who distribute gainsharing payments monthly and quarterly. While one commenter acknowledged that CMS responded to this same concern in the CJR Final Rule based primarily on operational considerations regarding the frequency of the reconciliation process, the commenter does not believe that such challenges should be resolved at the expense of an effective gainsharing program for EPM participants and CJR participant hospitals. The commenter pointed out that current CJR participant hospitals choosing to make gainsharing payments containing NPRA are prohibited from making any gainsharing payment until after the annual reconciliation process, which may take up to 18 months from the start of a performance year. They claimed that this lengthy process is stifling meaningful change and ultimately reducing quality and cost savings because the potential rewards for CJR collaborators are so far removed from the care for beneficiaries during CJR episodes. The commenter requested that quarterly gainsharing payments be permitted under the EPM and CJR model. As an alternative, the commenter recommended that CMS consider adopting a modified gainsharing payment schedule, limiting gainsharing payments to no more than once per performance year for the initial performance year and then thereafter allow for quarterly gainsharing payments. They believe this alternative could alleviate some of the operational concerns, while allowing EPM participants and CJR participant hospitals the flexibility to create a more impactful, long-term gainsharing strategy.

Response: We appreciate that some commenters are interested in aligning the periodicity for gainsharing payments under the EPM and CJR model with the periodicity of similar payments permitted in the BPCI models. However, we believe the differences in periodicity are warranted in light of the substantive difference between BPCI and the EPM and CJR model. Under the BPCI initiative, the frequency of gainsharing of internal cost savings is not specified, while quarterly gainsharing of reconciliation payments is permitted in association with the BPCI quarterly reconciliation process. BPCI participants are also required to submit their gainsharing methodologies in an implementation plan for review and acceptance by CMS prior to their use. In contrast, as finalized for the CJR model (80 FR 73386) and as discussed and finalized for the EPM in section III.D.5. of this final rule, the reconciliation process for the EPM and CJR model will be conducted annually, and specific gainsharing methodologies are not required to be submitted to CMS, although the EPM and CJR gainsharing methodologies must meet all the requirements finalized in this final rule.

We note again that gainsharing payments may only consist of reconciliation payments and internal cost savings, although, as discussed in more detail later in this section, we expect a majority of gainsharing payments to not include internal cost savings, and thus would contain only dollars from reconciliation payments. Given that gainsharing of reconciliation payments cannot be carried out until after reconciliation is performed and the funds available are known to the model participant, we cannot change the permissible frequency of gainsharing payments derived from reconciliation payments to allow a closer temporal linkage between the gainsharing payment and the performance period for which the EPM participant or CJR participant hospital earned the reconciliation payment without carrying out the reconciliation process more frequently. Under our annual reconciliation process, there is a delay of 6 to18 month between the time EPM episode care occurs and savings are represented in a reconciliation payment from which gainsharing payments can be made. We do not believe the commenters are requesting that quarterly reconciliation payments be permissible after the reconciliation payment is made under an annual reconciliation process, which would only lead to an even longer delay between the EPM episode care that occurred and the gainsharing payment that ultimately was made. Thus, the only way to allow more frequent gainsharing payments than annually, and to shorten the time lag between EPM episode care and gainsharing payments derived from reconciliation payments, would be to carry out the reconciliation process on a more frequent basis, such as quarterly. However, for the reasons discussed in section III.D.5. of this final rule, we will not conduct the reconciliation process more frequently than annually for any performance years of the EPM, including for any performance year after the first year of the EPM.

While an EPM participant's calculation of internal cost savings could occur more frequently than annually, because internal cost savings do not rely on determinations by CMS, to allow more frequent gainsharing of internal cost savings would increase the documentation burden on EPM participants. Based on the comments received, we believe the commenters' primary interest is in being able to make more frequent gainsharing payments derived from reconciliation payments, rather than those derived from internal cost savings. Additionally, based on the implementation plans submitted by BPCI Awardees and anecdotal information from CJR participant hospitals, we expect that few EPM participants will choose to distribute gainsharing payments derived from internal cost savings. Therefore, while we will consider whether a change may be warranted in the future to allow more frequent gainsharing of internal cost savings under the EPM and CJR model as we gain implementation experience with the models, we are not making a change now to allow gainsharing payments to be made more frequently than annually because we do not expect the increased complexity of such a policy would be useful to EPM participants and CJR participant hospitals.

Given that the BPCI initiative is scheduled to end late in CY 2018 and no longer is adding participants, we do not believe the different EPM and CJR gainsharing payment periodicity policies in comparison with those of the BPCI initiative provide any meaningful advantage to BPCI Awardees for those EPM participants and CJR participant

hospitals seeking to enter into sharing arrangements with EPM collaborators and CJR collaborators. While we appreciate the potential financial reward for EPM collaborators and CJR collaborators may be initially 6 to 18 months removed from their contributions of EPM activities and CJR activities to beneficiaries in the EPM and CJR model, we expect that many collaborators will have sustained engagement in the EPM and CJR model and will understand that assessing the cost and quality outcomes of care redesign for episodes requires a substantial period of time for relevant, reliable performance information to become available. For EPM collaborators and CJR collaborators that do have sustained engagement in the model(s), gainsharing payments to those collaborators could potentially be distributed as early as two quarters following the end of the performance year. We also expect that some EPM participants and CJR participant hospitals who request beneficiary-identifiable data as discussed in section III.D.K.2. of this final rule will be monitoring episode spending performance throughout the EPM and CJR performance years. Thus, model participants may be able to provide their collaborators with interim information regarding their estimates of episode spending performance and the implications for gainsharing payments that may ultimately be available to help sustain collaborator engagement throughout the performance years.

We are finalizing in § 512.500(c)(1)(ii) the annual distribution of gainsharing payments (not more than once per calendar year).

Comment: A number of commenters urged CMS to allow EPM participants to financially reward collaborators through gainsharing payments on the basis of the individual collaborator's performance as CMS proposed. One commenter in favor of this approach interpreted CMS' proposal as requiring payment of gainsharing payments to post-acute care providers based on the pool of post-acute care providers with which the EPM participant had a sharing arrangement rather than based on individual collaborator performance. Another commenter requested that CMS advise EPM participants to treat advanced practice nurses and physicians equally in their gainsharing methodologies. In general, many commenters urged CMS to ensure reconciliation payments are distributed in a fair and equitable manner to collaborators.

MedPAC expressed support for the proposed gainsharing safeguards in the EPM. In addition, they recommended that gainsharing payments to individual physicians and nonphysician practitioners who are part of the same sharing arrangement should not be allowed to vary based on whether these practitioners were involved in high- or low cost-episodes. MedPAC claimed this requirement would reduce practitioners' incentive to treat primarily low-cost patients and steer high-cost patients to other physicians or nonphysician practitioners at the EPM participant. To operationalize this policy, MedPAC suggested that if a gainsharing arrangement results in hospital internal cost savings or savings on episode spending, the total gainsharing payment under that sharing arrangement should be divided evenly among all the episodes that are part to the arrangement. In other words, the per-episode gainsharing payment amount should be equal for all practitioners in the arrangement, although practitioners who are responsible for more episodes could receive higher total payments, yet they would receive the same per-episode gainsharing payment as all physicians and nonphysician practitioners who are part of the same sharing arrangement.

MedPAC further urged CMS to adopt safeguards similar to those they recommended for gainsharing between EPM participants and physicians for sharing arrangements between hospitals and post-acute care providers. They recommended that EPM participants not be required to offer risk-sharing arrangements to all post-acute care providers in their markets and that model participants should be able to discontinue their risk-sharing arrangements with post-acute care providers that do not contribute to lowering episode spending. MedPAC further suggested that the risk or reward should be calculated for all post-acute care providers in the arrangement, not on a patient-specific or post-acute care provider-specific basis. They stated that pooling the savings on episode spending and quality performance of the post-acute care providers would create incentives for them to cooperate to jointly lower EPM episode spending. Under this approach, the risk-sharing arrangement between an EPM participant and its post-acute care provider collaborators would be based on the change in per-episode spending in the performance period, resulting in the same per-episode gainsharing payment for all post-acute care providers in the arrangement.

Response: We appreciate the interest of the commenters in ensuring that reconciliation payments are distributed in a fair and equitable manner to collaborators, including different types of individual providers and post-acute care providers. We further appreciate the support of the commenters for our proposal to allow EPM participants to use a methodology for determining a gainsharing payment that is substantially based on quality of care and the provision of EPM activities for each collaborator, without requiring standardization of the methodologies across any groups of collaborators. Thus, our proposal would allow each sharing arrangement to be based on the contributions of the specific collaborator. With regard to the commenter who interpreted our proposal as requiring gainsharing payment based on a pool of post-acute care providers with which the EPM participant enters into sharing arrangements, rather than based on individual collaborator performance, we note that we did not propose any pooling of funds for making gainsharing payment to groups of collaborators under the EPM.

While we understand the potential benefits of a policy standardizing sharing arrangements to protect against selection of low-cost patients and the resulting patient steering, as well as to provide an incentive for providers of the same type to cooperate to jointly improve quality and reduce episode spending, we believe that EPM participants may have legitimate reasons to enter into a sharing arrangement with a particular provider, supplier, or ACO that differs from the EPM participant's arrangements with other similar providers, suppliers, or ACO. For example, it is possible there may be instances in which a particular SNF that has greater capacity to monitor the cardiac status of beneficiaries or has resources that an EPM participant believes will especially benefit beneficiaries with cognitive impairments who are recovering from hip fracture surgery. In these instances, it may be prudent for an EPM participant to enter into a different sharing arrangement with that SNF, as opposed to other SNFs. Furthermore, EPM participants may have legitimate reasons to enter into different sharing arrangements with EPM collaborators that agree to take on a portion of the EPM participant's downside risk, such as one particular ACO, compared to sharing arrangements with other EPM participants, including other ACOs that do not take on such downside risk. The EPM policies that hold EPM participants responsible for episode quality and cost performance will

encourage EPM participants to seek EPM collaborators that are especially supportive of these goals. As discussed earlier in our response to comments on EPM participant policies for selecting collaborators, we have included robust safeguards in this final rule to address concerns about patient steering and protect beneficiary freedom of choice.

We believe the MedPAC recommendation to require the same per-episode payments for collaborators of the same type (physicians and post-acute care providers) would likely limit physician and post-acute care provider commitment to the goals of the EPM, resulting in less chance of model success. Our experience in other models that incorporate gainsharing has indicated that the financially responsible entity may have legitimate reasons to construct different sharing arrangements with different physicians, depending on factors such as the involvement of the physician in the entity's care redesign efforts, adoption of leadership roles requiring direction and instruction of other physicians, and the number and magnitude of disruptions in the physician's existing practice patterns. Similarly, the responsible entity may have legitimate reasons to construct different sharing arrangements with different post-acute care providers, such as the higher care capacity of a SNF that allows the SNF to accept an EPM beneficiary earlier than typical post-surgery or greater capacity of one HHA versus other to closely coordinate care for frail beneficiaries discharged directly to home following a hospitalization.

We stress that there is no requirement that EPM participants enter into sharing arrangements with any providers, suppliers, or ACOs. Accordingly, EPM participants are not required to enter into sharing arrangements with all post-acute care providers in their markets. There also are no requirements for EPM participants to continue any specific sharing arrangements, so EPM participants would be able to discontinue sharing arrangements if they believe those arrangements are not contributing to meeting the EPM goals, subject to any contract termination provisions in their contracts with EPM collaborators.

We are finalizing in § 512.500(c)(5) that the amount of any gainsharing payments must be determined in accordance with a methodology that is substantially based on the 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.

Comment: One commenter urged CMS to amend the proposed regulation in § 512.500(c)(6) which states, ''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.'' The commenter asserted that this text is unclear regarding whether the gainsharing amount can also include internal cost savings. The commenter believes the proposed text is confusing because it either suggests that the total dollars available for gainsharing are limited to the total reconciliation payment amount, which is inconsistent with the definition of gainsharing, or it suggests that the proportion of the gainsharing that is from the reconciliation payment cannot be more than that payment, which by definition is true.

Response: We appreciate the commenter's suggestion that we clarify whether a gainsharing payment may include internal cost savings; however, we believe that the commenter's suggested change to the proposed provision in § 512.500(c)(6) is inadvisable. The purpose of this requirement is to ensure that the total amount of all gainsharing payments made to collaborators and derived from the reconciliation payment the EPM participant receives from CMS does not exceed the amount of that reconciliation payment. The commenter is correct that as specified in § 512.500(c)(1)(i), gainsharing payments, if any, must be derived solely from reconciliation payments, or internal cost savings, or both. We believe it would be confusing to revise § 512.500(c)(6) as the commenter suggested to add that the gainsharing amount can include internal cost savings, as that is specified elsewhere in regulation and is not necessary for this requirement specific to gainsharing payments derived from a reconciliation payment. However, we believe that reordering of the terms in the provision eliminates any confusion about the requirement. Therefore, we are modifying § 512.500(c)(6) to state, ''For a performance year, the aggregate amount of all gainsharing payments that are derived from a reconciliation payment the EPM participant receives from CMS must not exceed the amount of that reconciliation payment.''

We are finalizing in § 512.500(c)(6) the limit on the aggregate amount of all gainsharing payments that are derived from a reconciliation payment with the modifications discussed.

Comment: While several commenters, including MedPAC, supported CMS' proposal to cap the amount of gainsharing payments to physicians, nonphysician practitioners, and PGPs, most commenters either recommended that CMS eliminate the caps for PGPs; eliminate the caps altogether for PGPs, physicians, and nonphysician practitioners; or apply the caps on a different basis than CMS' proposal of 50 percent of the Medicare-approved amounts under the PFS for items and services furnished by the physician or nonphysician practitioner to the EPM participant's EPM beneficiaries during the 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.

One commenter who objected to the proposed caps on physicians stated that physicians are singled out for different treatment than other provider and supplier types because the commenter believed physicians were the only type of EPM collaborator with a cap, and contended that the cap dampens the ability of gainsharing to support physician behavior change by relegating payments to a nominal amount. Another commenter claimed that the proposed EPM financial arrangements may not be sufficiently flexible for the breadth of agreements EPM participants may wish to set up with PGPs, noting that the proposed gainsharing cap of 50 percent was based on services furnished by individual physicians in the PGP to EPM beneficiaries as opposed to the BPCI initiative where the commenter believes the cap is set at 50 percent for the entire physician group. They claimed that under CMS' proposal, there is no way for a PGP to stabilize risk among higher- and lower-performing physicians and, therefore, the group risk-sharing potential will be less than 50 percent in total.

A number of commenters recommended changes to the proposed methodology for setting the cap on physician, nonphysician practitioner, and PGP gainsharing payments. One commenter asserted that due to the importance of primary care management in preventing readmissions, it is likely that the potential value of care management services provided during the post-discharge period is significantly greater than the total PFS payments a physician will receive for these services. The commenter urged CMS to increase the proposed 50 percent cap to reflect the value provided by these primary care physicians' services. Several other commenters requested that if the cap was not

dropped altogether, the cap should be set at 50 percent of episode savings rather than Part B billings, reasoning that limiting the cap based on the Medicare-approved amounts paid under the PFS negatively impacts EPM participants' flexibility in determining the amount of savings to share, as well as targets physicians individually. The commenters reasoned that physicians are the key to driving improved quality and efficiency due to their direct relationships with patients, access to the patient's current health status, and ability to recommend the appropriate level of post-acute care services, and that the proposed cap would eliminate meaningful financial incentives for physicians to fully engage in the EPM. Several commenters further added that because CMS has entrusted hospitals with the responsibility to oversee and implement EPM care redesign, CMS should grant hospitals greater flexibility in designing their respective gainsharing programs and determining the amount of episode savings to share with their EPM collaborators.

Other commenters interpreted CMS' proposal as allowing EPM participants to share up to 50 percent of savings achieved via Part B services with physicians and recommended that the cap be revised to include savings from both Part A and Part B services in gainsharing payments. The commenters asserted that accounting for unplanned care necessitating Part B services is critical, and that to improve patient outcomes, unplanned clinically appropriate care must be accounted for which potentially results in more physician involvement than originally anticipated. They concluded that significant reductions in Part A spending may be achieved through reducing the lengths-of-stay and unnecessary readmissions during EPM episodes, but those savings are unlikely to be accomplished without active physician participation and, therefore, physicians should be eligible to share in those Part A savings.

Response: We acknowledge the many different perspectives of the commenters on the proposed cap on gainsharing payments to physicians, nonphysician practitioners, and PGPs in the EPM. We reiterate that we proposed to limit the total amount of gainsharing payments for a performance year to EPM collaborators, collaboration agents, or downstream collaboration agents that are physicians, nonphysician practitioners, or PGPs. For physicians and nonphysician practitioners the proposed limit was 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 is included in the payment being made to the physician or nonphysician practitioner. For PGPs, the proposed limit on gainsharing payments was 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 is included in the payment being made to the PGP. We note that the proposed EPM gainsharing caps for PGP members operate in the same way as the caps on PGP member gainsharing in the BPCI initiative. In both instances, the cap is set at 50 percent of the total Medicare-approved amounts under the PFS for services furnished by the physician or nonphysician practitioner PGP member to model beneficiaries during the applicable time period. Accordingly, it is not correct that the proposal for gainsharing caps under the EPM provides less flexibility than under the BPCI initiative.

We do not agree with commenters that the proposed caps on payments under EPM financial arrangements to physicians, nonphysician practitioners, and PGPs should be eliminated because we proposed these caps for a specific purpose. The purpose of the cap is to serve as a safeguard against the potential risks of stinting, steering, and denial of medically necessary care due to financial arrangements specifically allowed under the EPM by providing an upper limit on the potential additional funds a physician, nonphysician practitioner, or PGP can receive for their engagement with EPM participants in caring for EPM beneficiaries beyond the FFS payments that those suppliers are also paid and that are included in the actual episode spending calculation for the episodes.

We do not believe it would be appropriate to identify certain types of physicians, such as those providing primary care management services, for higher caps under the EPM because we believe EPM participants should have the flexibility to enter into sharing arrangements with those EPM collaborators that help them execute their care redesign plans, which we expect to vary from EPM participant to EPM participant. We further note that the proposed caps were based on the Medicare-approved amounts under the PFS paid to physicians and nonphysician practitioners for care furnished to EPM beneficiaries, and not based on Part B episode savings as some commenters interpreted the proposal. Therefore, we do not agree with concerns of some commenters that Part B spending could increase even if total episode spending decreased and, therefore, could affect the potential for physician gainsharing payments because we do not specify where the episode savings included in a reconciliation payment must come from (Part A or Part B) in order for part of the reconciliation payment to be paid to a physician, nonphysician practitioner, or PGP as a gainsharing payment. While we appreciate the information provided by the commenters regarding the valuable role physicians may play in reducing Part A spending, we do not believe it would be appropriate to cap physician, nonphysician practitioner, and PGP gainsharing payments at 50 percent of total episode savings beyond the quality-adjusted target price. Historical EPM episodes include average episode spending ranging from approximately $23,000 to $47,000, with Part B spending (predominantly PFS) accounting for 7 percent to 14 percent of the total.[129] Thus, depending on actual episode savings experienced by the EPM participant, we believe the proposed cap at 50 percent of Part B billings would generally allow a physician, nonphysician practitioner, or PGP to receive a gainsharing payment that is comprised of a reconciliation payment that includes Part A savings. Further, setting the gainsharing cap based on Part B billings for physicians, nonphysician practitioners, and PGPs helps to maintain a connection between their gainsharing payments and their payments under the PFS for items and services furnished to EPM beneficiaries so as not to create a disproportionate opportunity and associated program integrity risk for physicians, nonphysician practitioners, and PGPs to dramatically increase their payments on behalf of Medicare beneficiaries based on their participation in EPM financial arrangements.

We emphasize that we have applied the 50 percent cap on gainsharing payments to physicians, nonphysician

[129] 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 the proposed rule that began in CYs 2012 2014.

practitioners, and PGPs in the CJR model as well as the BPCI initiative, and participants have not voiced significant complaints that this financial limitation has hampered their ability to engage physicians, nonphysician practitioners, and PGPs in care redesign to improve episode quality and reduce costs. We acknowledge the important role physicians play in providing quality, efficient health care to beneficiaries, but we believe that allowing a physician, nonphysician practitioner, and PGP to be paid up to 50 percent more for engagement with the episode care of EPM beneficiaries than the payments they are paid for furnishing direct services to those beneficiaries under the PFS provides EPM participants with substantial flexibility to develop and implement meaningful financial arrangements that align the financial interests of physicians, nonphysician practitioners, and PGPs with the quality and cost goals of the EPM participant under the EPM.

We note that as discussed previously in this section, we are adding NPPGPs to the list of EPM collaborators. Consistent with our cap on gainsharing payments to PGPs, as well as our cap on gainsharing payments to physicians and nonphysician practitioners, we are adding NPPGPs to § 512.500(4)(ii) where we specify the cap on gainsharing payments to PGPs so that those caps are also applied to gainsharing payments to NPPGPs.

We are finalizing in §§ 512.500(4)(i) and 512.500(4)(ii) the caps on the total amount of gainsharing payments for a performance year paid to physicians, nonphysician practitioners, PGPs, and NPPGs.

We note that our proposals were not clear or consistent regarding whether caps applied to individual therapists or TGPs. We did not propose to cap gainsharing payments to EPM collaborators that are providers or suppliers of outpatient therapy services, which include individual therapists and therapy group practices, and we did not propose to cap the distribution payments to therapists who are members of a PGP under proposed § 512.505(8)(i). However, we proposed that therapists who are members of a PGP and receive downstream collaboration payments would have their payments capped under proposed § 512.510(b)(7) as members of the PGP. As discussed in section III.I.3. of this final rule, we have created new terms and revised certain proposed terms for this final rule to separately define therapist in private practice and TGP and the revised definition of EPM collaborator now separately identifies therapists in private practice and TGPs as eligible to be collaborators. While capping gainsharing payments to therapists and TGPs would be most consistent with our treatment of gainsharing payments to other individual clinicians and their practice groups and it would be possible to apply such caps in view of the new definitions of therapist in private practice and TGP adopted in this final rule, we do not believe it would be appropriate to adopt gainsharing caps for therapists in private practice or TGPs because we did not solicit comment on caps for any providers or suppliers of outpatient therapy services, including therapists in private practice and TGPs. However, our reasoning for the caps on gainsharing payments to physicians, nonphysician practitioners, PGPs, and NPPGs could similarly apply to therapists and TGPs. Namely, a cap on therapists and TGPs could serve as a safeguard against the potential risks of stinting, steering, and denial of medically necessary care due to financial arrangements specifically allowed under the EPM by providing an upper limit on the potential additional funds the clinician or group can receive for their engagement with EPM participants in caring for EPM beneficiaries beyond the FFS payments that those suppliers are also paid and that are included in the actual episode spending calculation for the episodes. Therefore, while we are not adopting gainsharing caps for therapists in private practice and TGPs in this final rule and we are revising proposed § 512.510(b)(7) which is final § 512.510(b)(8) to remove the cap as applied to therapists who are PGP members, we will monitor payments under financial arrangements to these individuals and entities and may consider proposing caps in the future if we have program integrity concerns during EPM implementation.

We are finalizing the in § 512.500(c)(4) the cap on the aggregate amount of gainsharing payments for a performance year paid to physicians, nonphysician practitioners, and PGPs, with modification to also apply the cap to NPPGPs.

Comment: Some commenters urged CMS to eliminate the proposed caps on alignment payments at the entity level, specifically mentioning ACOs, PGPs, and post-acute care providers in their discussion. One commenter was concerned that under CMS' proposal a single EPM collaborator other than an ACO could possibly be accountable for up to 25 percent of an EPM participant's repayment amount, highlighting that such an amount could post serious financial jeopardy to the EPM collaborator's existence. To mitigate this risk, the commenter recommended that all the EPM collaborators other than ACOs in aggregate would pay no more than 25 percent of the EPM participant's repayment amount or, alternatively would pay proportionally based upon the Medicare-approved amounts the EPM collaborator was paid for items and services furnished to EPM beneficiaries.

Response: We appreciate the commenters' recommendation to eliminate caps on alignment payments by entities that are EPM collaborators. We note that we proposed 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. In regards to the 50 percent cap on the aggregate amount of alignment payments, the commenters did not provide specific justification for eliminating this cap on alignment payments provided to EPM participants. As such, given that the EPM participant is responsible for developing and coordinating care redesign strategies in response to its EPM participation, we believe it is important that the EPM participant retain a significant portion of its responsibility for repayment to CMS. Therefore, we are maintaining the cap on the aggregate amount of all alignment payments at 50 percent of the EPM participant's repayment amount, ensuring that EPM participants retain a minimum of 50 percent of the repayment amount as their responsibility.

In addition, we proposed that the aggregate amount of all alignment payments from an EPM collaborator other than an ACO to the EPM participant may not be greater 25 percent of the EPM participant's repayment amount. In response to the commenter's concern about the potential for an EPM collaborator that is not an ACO to experience serious financial jeopardy due to this amount, we emphasize that there is no requirement that any provider, supplier, or ACO enter into a sharing arrangement as an EPM collaborator, including a sharing arrangement that requires them to make an alignment payment. We also emphasize that the 25 percent cap on alignment payments represents the upper threshold for risk sharing that a single EPM collaborator may assume, and that the parties may agree to lower amounts. Furthermore, participation in sharing arrangements must be voluntary and without penalty for nonparticipation. Thus, we cap the aggregate amount of all alignment payments from an EPM collaborator

other than an ACO at 25 percent of the EPM participant's repayment amount as a broad safeguard for EPM collaborators and EPM participants from excessive financial risk or undue influence from the EPM participant's contractual relationship with a single EPM collaborator. However, this cap is not a substitute for the deliberation of both the EPM participant and EPM collaborator before entering into a sharing arrangement that would require the EPM collaborator to make an alignment payment to the EPM participant if the EPM participant has a repayment amount due to Medicare. We believe that the EPM collaborator is best-positioned to make financial decisions on its own behalf and to bear the consequence of those decisions, and that flexibility in sharing arrangements between different parties is important. Therefore, we see no need to provide a more protective cap on the accountability for a single EPM collaborator by aggregating the accountability of all EPM collaborators or requiring that the EPM collaborator only assume accountability for paying a portion of the EPM participant's repayment amount that is proportionate to the EPM episode spending on items and services furnished by that EPM collaborator. Therefore, we are maintaining the cap on the aggregate amount of all alignment payments from an EPM collaborator other than an ACO to the EPM participant at 25 percent of the EPM participant's repayment amount.

We are finalizing in §§ 512.500(c)(12) and 512.500(c)(13) the cap on the aggregate amount of all alignment payments received by the EPM participant and the cap on alignment payments that may be made by EPM collaborators to the EPM participant.

Comment: One commenter opposed CMS' proposal to cap the aggregate amount of all alignment payments from an EPM collaborator that is an ACO to an EPM participant at 50 percent of the EPM participant's repayment amount, arguing that setting such a limit interferes the negotiations between an EPM participant and its collaborators. The commenter asserted that ACOs should be able to use their substantial expertise and resources to contribute to the EPM's dual goals of limiting spending and increasing quality. They urged CMS to permit an EPM participant and its collaborators to jointly agree on the terms and conditions of a sharing arrangement, including specifics around gainsharing or repayment percentages, because it is unnecessary to place limits on repayment amounts as long as they do not collectively exceed the amount the EPM participant would have to repay. Another commenter pointed out that the risk threshold for an EPM consisting of beneficiaries discharged from several MS–DRGs is substantially less than that of two-sided risk ACO models, approximately $500,000 versus $2,000,000 for a small ACO, respectively. They suggested that CMS consider the risk alignment of ACOs and the EPM as an opportunity for ACOs to phase-in downside risk incrementally and at a substantially lower entry point of dollars than current two-sided ACO options. The commenter believes that adopting such an approach would encourage ACOs to take on more downside risk.

Response: We appreciate the commenter's recommendation to eliminate the proposed cap on alignment payments made by an EPM collaborator that is an ACO to an EPM participant. We agree with the commenter about the expertise that ACOs may offer EPM participants with regard to managing the cost and quality of care Medicare beneficiaries receive. We proposed that 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 proposed 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 that can may benefit EPM episode spending and quality performance.

We have constructed a framework for EPM financial arrangements that we believe leaves EPM participants and EPM collaborators relatively unconstrained to develop sharing arrangements in a manner they see fit based on the contributions of different parties to the goals of the EPM, provided that all the requirements for financial arrangements included in this final rule are met. We did not propose that EPM participants would need to use a particular methodology for determining alignment payments that are made by either an EPM collaborator that is an ACO or an EPM collaborator that is not an ACO. However, as discussed in the response to the previous comment, given that the EPM participant is responsible for developing and coordinating care redesign strategies in response to its EPM participation, we believe it is important that the EPM participant retain a significant portion of its responsibility for repayment to CMS. The EPM was not designed to test the phase-in of ACO downside risk or specifically encourage ACOs to take on more downside risk, but rather to test the EPM where acute care hospitals are the financially accountable entity to CMS for episode quality and cost performance, with sufficient flexibility to share their upside and downside risk with EPM collaborators based on the financial alignment needs arising from EPM episode care redesign.

Therefore, we are maintaining the cap on the aggregate amount of all alignment payments at 50 percent of the EPM participant's repayment amount, while allowing an ACO to assume responsibility for the remaining 50 percent of the repayment amount through an alignment payment to be made to the EPM participant. While we appreciate the commenter's view that we should let the market determine the best arrangements for the parties without constrain, in the early performance years of the first required episode payment models and in our first experience with ACOs as model collaborators, we believe the alignment payment limit allows sufficient flexibility for the development of market-based arrangements between EPM participants and ACOs, while providing assurance of the EPM participant's active involvement in developing and implementing EPM care redesign strategies.

Comment: One commenter urged CMS to apply a cap on gainsharing payments to all EPM collaborators, arguing that because CMS proposed caps only on gainsharing payments to physicians, nonphysician practitioners, and PGPs that EPM participants may conclude that sharing arrangements with other types of providers, such as post-acute care providers, is not encouraged by CMS. The commenter further contended that CMS' proposal to cap gainsharing payments for physician, nonphysician practitioners, and PGPs at a certain percentage of the amount billed to Medicare is ill-advised given that the goal of the EPM is to reduce costs to Medicare by better managing services and reducing unnecessary services. They recommended that CMS adopt a gainsharing cap policy that specifies that no one type of collaborator (for example, physicians) nor individual provider or organization can receive more than 50 percent of the available gainsharing amount in order to ensure that all EPM collaborators may be eligible for a gainsharing payment

should they meet the requirements of their sharing arrangement.

Response: We do not agree with the commenter that the lack of a proposed cap on gainsharing payments to providers, suppliers, and ACOs other than physicians, nonphysician practitioners, and PGPs in our proposal implies that these other individuals and entities are not worthy of consideration by EPM participants as potential EPM collaborators. We note that we proposed to add ACOs, hospitals, and CAHs, none of whom have gainsharing caps, to the list of types of providers and suppliers that may be EPM collaborators, thereby expanding the list initially adopted for the CJR model.

The purpose of the final cap on gainsharing payments for physicians, nonphysician practitioners, PGPs, and NPPGs (as adopted in this final rule) is to serve as a safeguard against the potential risks of stinting, steering, and denial of medically necessary care due to financial arrangements specifically allowed under the EPM by providing an upper limit on the potential additional funds a physician, nonphysician practitioner, PGP, or NPPGP can receive for their engagement with EPM participants in caring for beneficiaries in the EPM beyond the FFS payments that those suppliers are also paid and that are included in the actual episode spending calculation for the episodes. With the exception of physicians, nonphysician practitioners, PGPs, and NPPGPs, we do not limit the amount of gainsharing payments to other eligible EPM collaborators. As discussed earlier in this section, as the financially responsible entities for EPM episodes, we believe that EPM participants should have as much flexibility as possible, subject to adequate program integrity safeguards, in decisions about financial arrangements, including whether or not to enter into them; the selection of collaborators; and the methodologies for determining the amounts of gainsharing payments and alignment payments. Therefore, we do not believe it would be appropriate to limit the gainsharing payment of an EPM participant to any EPM collaborator or single type of EPM collaborator based on the available gainsharing amount in order to ensure that all EPM collaborators receive a portion of the gainsharing amount that is available.

Comment: One commenter claimed that CMS' proposal applies some unnecessary limits to when an EPM collaborator can receive a gainsharing payment. The commenter reasoned that if the goal of the EPM is to redesign care, then the possibility should be considered that an EPM collaborator may furnish a service that is not ''billable'' under Medicare FFS today and yet could play an important role in changing the outcomes and cost under an EPM episode. They recommended that CMS not limit the eligibility for receiving gainsharing payments to just services that are billable but instead allow the EPM collaborator to receive some payment after the fact for a service or item that contributed positively to the EPM episode. To accomplish this change, the commenter specifically suggested that CMS delete ''billable'' in proposed § 512.500(c)(2)(ii) where CMS proposed to require that 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. They believe it is unlikely that this change would be abused as it is not in the EPM participant's best interest to issue a gainsharing payment to an EPM collaborator that offered them no benefit in the EPM.

The commenter further recommended that the proposed gainsharing eligibility criteria for ACOs, specifically that their involvement in an EPM beneficiary's care was either: 1) related to the provision of care coordination services and/or 2) related to engaging in care redesign strategies and helping to implement those strategies, be added to the gainsharing eligibility requirement for other EPM collaborators that are not ACOs or PGPs in § 512.500(c)(2)(ii). They believe that providers and suppliers should also be eligible for gainsharing if they engage in those tasks. The commenter concluded that making both of their recommended changes to § 512.500(c)(2)(ii) would contribute to comparable gainsharing opportunities being available for EPM collaborators carrying out the same activities to advance the goals of the EPM.

Response: We appreciate the commenter's detailed suggestions about changes to the proposed gainsharing eligibility criteria for EPM collaborators that are not PGPs or ACOs to ensure comparable gainsharing opportunities for different types of EPM collaborators. First, we want to clarify that while our proposal would require an EPM collaborator other than a PGP or an ACO to 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 to be eligible to receive a gainsharing payment, there is no requirement that the gainsharing payment methodology rely only upon billable items and services. As proposed in § 512.500(c)(5), the amount of any gainsharing payments must be determined in accordance with a methodology that is substantially based on the quality of care and the provision of EPM activities. We proposed that EPM activities means activities related to promoting accountability for the overall 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 that reduce costs and improves quality, or carrying out any other obligation of duty under the EPM. Thus, all EPM collaborators may receive a gainsharing payment determined by a methodology that takes into account their contribution of items and services that are not billable but which contributed to changes in EPM episode outcomes and cost, an outcome which is consistent with the commenter's recommendation.

For those EPM collaborators who can directly furnish items and services to Medicare beneficiaries, which are all EPM collaborators that are not ACOs, PGPs, NPPGPs, or TGPs, we believe a connection to the actual care of EPM beneficiaries is essential so that the financial incentives of providers furnishing billable items and services to EPM beneficiaries are aligned with those of EPM participants to improve the quality of care and reduce the costs of episode. It is difficult to contemplate how model success can be achieved without significant care redesign that involves billable items and services furnished by the providers and suppliers actually caring for EPM beneficiaries. The requirement that EPM collaborators other than ACOs, PGPs, NPPGPs, and TGPs directly furnish billable items or services to EPM beneficiaries to be eligible for gainsharing payments ensures a nexus between the financial incentives and actual care to EPM beneficiaries. This requirement also provides a program integrity safeguard against the free flow of gainsharing payments to an EPM collaborator who does not furnish items or services to EPM beneficiaries as a

means of impacting the referral patterns of the EPM collaborator to particular hospitals. Thus, we do not believe that adopting the recommendation of the commenter that we use the criteria for ACOs, that do not directly furnish items or services to beneficiaries, to define the clinical involvement of EPM collaborators that are not ACOs PGPs, NPPGPs, or TGPs in the care of EPM beneficiaries that is required for gainsharing eligibility is necessary or appropriate. It is only in the case of ACOs, PGPs, NPPGPs, and TGPs that do not directly furnish items or services to EPM beneficiaries that we needed to develop another definition for the clinical involvement that is a requirement for gainsharing payment eligibility. We expect that EPM collaborators that are not ACOs, PGPs, NPPGPs, or TGPs will commonly provide care coordination services to EPM beneficiaries, engage in care redesign strategies, and perform a role in implementing such strategies, just as we expect similar activities for ACOs, PGPs, NPPGPs, and TGPs that are EPM collaborators. We further note that an EPM participant can factor these types of activities into the methodology that determines the amount of the gainsharing payment for EPM collaborators. However, for the reasons described previously, we will not allow EPM collaborators that are not ACOs, PGPs, NPPGPs, or TGPs to be eligible for gainsharing payments if they have not directly furnished a billable item or service to an EPM beneficiary during an EPM episode during the applicable time period. We believe that the gainsharing payment eligibility policies provide the potential for comparable gainsharing opportunities for all types of EPM collaborators, while taking into consideration the reality that individuals and entities with different potential for providing billable services to EPM beneficiaries may be EPM collaborators.

We are finalizing in § 512.500(c)(2)(ii) that to be eligible to receive a gainsharing payment or to be required to make an alignment payment, an EPM collaborator that is not an ACO, PGP, NPPGP, or TGP must have directly furnished a billable item or service to an EPM beneficiary during an EPM episode.

Comment: Several commenters expressed concern about the proposed restrictions on paper savings in the methodology used to calculate the EPM participant's internal cost savings from which the participant may make gainsharing payments to EPM collaborators. The commenters claimed that very few hospital accounting systems can clearly separate ''paper'' savings from ''real'' savings. They claimed that introducing systems to account for savings will require time and resources that may restrict ability of many EPM participants to meet the proposed requirements, yet ''paper'' savings may yield real benefits for patients. As an example, one commenter pointed out that ''paper'' savings due to reductions in nursing time may permit that time to be dedicated to other patients improving coverage and benefiting the quality of care.

Response: We appreciate the information provided by the commenters on the types of internal cost savings that EPM participants might achieve based on care redesign under the EPM. We note that we proposed in § 512.500(c)(3)(ii) that 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 in § 512.500(c)(3)(ii)(B) proposed that the methodology must exclude ''paper'' savings from accounting conventions or past investment in fixed costs.

In considering the EPM participant's methodology for calculating internal cost savings achieved based on their implementation of EPM activities, EPM participants should consider all of these requirements and others we proposed for internal cost savings in their totality. We believe that any methodology that meets the proposed requirements for the methodology to calculate internal cost savings would require some system to account for savings. Moreover, we do not believe it would be appropriate to allow gainsharing payments derived from an EPM participant's internal cost savings that cannot be specifically accounted for due to the program integrity risk that such payments may pose. We appreciate that accounting for the savings resulting from the implementation of EPM activities by the EPM participant could require accounting systems of different complexities based on the specific types of internal cost savings that the EPM participant wants to capture for purposes of making gainsharing payments. For example, internal cost savings due to physician collaboration to achieve device standardization in EPM episodes that results in the EPM participant being able to purchase the device at a lower price reflecting volume discounts may be relatively easily accounted for by comparing device purchase invoices during the EPM performance year to those during the immediately prior period. On the other hand, reductions in nursing time for EPM beneficiaries due to a shorter hospital stay that results from streamlined discharge planning may require more complex systems to track and compare nursing time and its associated hospital cost for EPM beneficiaries during the EPM performance period to those during the immediately prior period. Thus, while we recognize the challenges identified by the commenters in tracking real savings associated with EPM care redesign, given that we proposed to allow EPM participants to select their own methodologies for calculating internal cost savings (provided that such methodologies meet the requirements in this final rule to be included in gainsharing payments to EPM collaborators), we believe that we have provided sufficient flexibility to allow each EPM participant the ability to develop a methodology for calculating internal cost savings that aligns with its technical capacity to track those savings. We note that the purpose of this prohibition on paper savings is to bar the distribution of gainsharing payments comprised of funds that did not derive from real savings, as well as bar payments made for purposes other than the provision of EPM activities by EPM collaborators that results in reduced episode spending or increased quality. As such, we believe the proposed requirements prohibiting EPM participants from sharing internal cost savings that results merely from paper savings—rather than real savings arising from the successful implementation of care redesign strategies by the EPM participant—are necessary as a program integrity safeguard, and so we are declining to accept the commenters' suggestion.

We are finalizing in § 512.500(c)(3)(ii)(B) that the methodology used to calculate internal cost savings must exclude paper savings from accounting conventions or past investment in fixed costs.

Comment: One commenter requested clarification regarding CMS' proposal that an EPM participant must not make a gainsharing payment to an EPM collaborator that is subject to any action for noncompliance with the EPM requirements or fraud and abuse laws, or for the provision of substandard care in EPM episodes or other integrity problems. The commenter expressed concerns regarding the absence of a bright line standard EPM participants could use to ensure compliance with this standard. The commenter expressed particular concern about how a participant could determine if a collaborator was subject to an action for

the ''provision of substandard care in EPM episodes or other integrity problems.'' The commenter further recommended that CMS should apply a reasonable knowledge standard to compliance with this provision.

Response: We appreciate the commenter's interest in additional clarification regarding how a participant can ensure it complies with this payment restriction. We believe that we can provide additional clarity to the standard for not making a gainsharing payment by establishing that this provision only restricts an EPM participant's ability to make a gainsharing payment if CMS notifies the EPM participant of the action that would trigger the payment restriction. Specifically, we are modifying the provision to state, ''An EPM participant must not make a gainsharing payment to an EPM collaborator if CMS has notified the EPM participant that such collaborator 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 has other integrity problems.'' This change should eliminate any uncertainty by the EPM participant about circumstances in which an EPM collaborator must not be paid a gainsharing payment, while also providing a sufficient safeguard against gainsharing with individuals and entities that present risk of patient harm or program abuse. Therefore, we are revising § 512.500(c)(8) accordingly.

We believe that adopting the alternative approach recommended by the commenter and using a reasonable knowledge standard would make enforcing this prohibition of distributing gainsharing payments to EPM collaborators under certain circumstances highly challenging, if not impossible. We believe the notification approach discussed previously allows for the ''bright line'' that the commenter was seeking, while maintaining the agency's ability to prevent gainsharing payments to an EPM collaborator that has program integrity concerns.

We are finalizing in § 512.500(c)(8) that an EPM participant must not make a gainsharing payment to an EPM collaborator if CMS has notified the EPM participant that such collaborator 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 has other integrity problems.

Comment: Several commenters requested that CMS extend financial arrangements permitted under the EPM and CJR model to scenarios that extend beyond EPM episodes. The commenters believe that these requests would require fraud and abuse law waivers. One commenter encouraged CMS to allow for gainsharing on commercial and Medicaid episode payment arrangements that are similar to the CJR model or proposed under the EPM to increase the volume of cases on which hospitals can share gains with collaborators. Another commenter urged CMS to allow EPM participants and CJR participant hospitals to provide care management tools and services to beneficiaries and providers prior the start of the episode, consistent with activities contemplated by the Medicare Shared Savings Program, ACO participation waiver. While acknowledging that CMS is not inclined to start the episode prior to the date of the admission for the anchor hospitalization, the commenter explained that pre-episode services have been proven to not only improve patient outcomes and satisfaction but also to result in the delivery of more efficient and higher quality care. The commenter provided examples of pre-episode services they requested be allowed under the EPM and CJR model: comprehensive patient evaluation to assess a beneficiary's overall condition and chronic comorbid conditions' patient education videos and materials; discharge planning review and counseling; home safety reviews; and patient and caregiver education. Finally, another commenter requested that EPM participants and CJR participant hospitals be able to provide other providers, including post-acute care providers and PGPs in their communities with whom they collaborate, necessary telehealth equipment, health IT support, and items and services necessary to achieve the type of care integration necessary for the EPM and CJR model without fear of liability under anti-kickback, physician self-referral, and beneficiary inducement prohibitions.

Response: We appreciate the descriptions provides by the commenters of additional care redesign strategies beyond care for EPM and CJR beneficiaries that could ultimately contribute to improvements in the quality of care and reductions in the cost of EPM and CJR episodes. While we understand that being able to share cost savings based on a larger volume of cases that includes patients in similar episode payment arrangements under Medicaid and commercial insurers could provide EPM participants and CJR participant hospitals more funds for aligning the financial incentives of their collaborators with the goals of the episode payment arrangements, we will not regulate arrangements for beneficiaries outside of those in EPM and CJR episodes in this rulemaking because it would be inappropriate to do so.

We are finalizing the initiation of EPM episodes with admission for the anchor hospitalization as discussed in sections III.4.a.(2) through (4) of this final rule, just as we finalized that same policy for the CJR model (80 FR 73318). We note that all AMI and SHFFT beneficiaries, as well as a significant percentage of CABG and CJR beneficiaries, would be admitted emergently to the EPM participant or CJR participant hospital, making pre-episode services not possible for these beneficiaries even if we were to permit them under the models. We did not propose to allow sharing arrangements for pre-episode services under the EPM and CJR model because we believe there are significant program integrity risks of patient steering and adverse patient selection for admissions for elective surgery, such as some CABG surgery and LEJR, that would be difficult to overcome if EPM participants and CJR participant hospitals were permitted to furnish pre-episode services beyond those allowed under current laws and regulations, including the fraud and abuse laws.

Similarly, we did not propose parameters for the provision of equipment and other items and services by EPM participants and CJR participant hospitals to their collaborators to aid in care integration beyond those that are permissible under current laws and regulations, including the fraud and abuse laws. We believe that it would be very challenging to establish sufficient safeguards to protect beneficiary freedom of choice and guard against patient steering in such EPM and CJR model scenarios where EPM participants and CJR participant hospitals provided resources to collaborators that were not specifically based on the quality of care and the provision of EPM activities or CJR activities for beneficiaries in EPM episodes or CJR episodes by that collaborator.

Comment: One commenter recommended that disclosure of sharing arrangements be required by the EPM participant to receive a reconciliation payment, so that CMS can confirm that hospitals have contracts in place with all the involved clinicians and post-acute care providers. The commenter further urged CMS to also require full disclosure of the total amount of all gainsharing payments and how much is

being distributed to each provider or supplier who furnished care to an EPM beneficiary, in order to ensure that payments for care delivery are as transparent as possible. Another commenter requested that CMS collect documents related to the calculation, distribution, receipt, or recoupment of gainsharing payments, alignment payments, distribution payments, and downstream distribution payments and other savings-related payments and the distribution to collaborating physicians and other healthcare professionals. The commenter believes that CMS could utilize these data for future efforts and to ensure program integrity, as well as to help examine the extent to which savings are equitably being shared by EPM participants with collaborating physicians and other healthcare professionals

Response: As discussed previously in this section, we do not require EPM participants to enter into sharing arrangements, and we do not require that those sharing arrangements include any specific groups of providers, suppliers, or ACOs. Thus, we do not need to confirm the sharing arrangements that are in place with specific EPM collaborators prior to making a reconciliation payment to an EPM participant. However, we do require that EPM participants report the historical and current lists of collaborators on a Web page on the EPM participant's Web site of EPM collaborators as discussed in section III.I.4.d. of this final rule, which provides transparency regarding the identities of collaborators with EPM participants. In addition, CMS has the ability to request this information from EPM participants under the provisions regarding access to records and retention for the EPM.

We appreciate the requests that CMS consider routinely collecting specific information on the calculation, distribution, receipt, or recoupment of gainsharing payments, alignment payments, distribution payments, and downstream distribution payments and other savings-related payments and the distribution to collaborators. While EPM participants are required to provide this information to CMS upon request under the access to records and retention provisions for the EPM and CMS will exercise this authority where appropriate, we believe the routine submission of this information would create a substantial and unnecessary administrative burden on EPM participants given the large number of potential EPM collaborators and the expected varied nature of their respective arrangements with EPM participants. We also are mindful of the challenges associated with creating a universal collection tool that would account for all the various iterations of financial arrangements into which EPM participants and their collaborators may enter into.

We agree with the commenters that transparency is important to ensure program integrity and to assist with evaluation of the model. We have tried, where possible, to ensure transparency regarding sharing, distribution, and downstream distribution arrangements without imposing undue administrative burden on the individuals and entities that enter into such arrangements. Because documenting financial arrangements is consistent with general business practices, we believe that our documentation requirements impose minimal additional administrative burden on EPM participants, their collaborators, collaboration agents, and downstream collaboration agents. The regulations require contemporaneous documentation of all arrangements and the written agreements 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 arrangement. The written agreement for sharing arrangements also must specify the purpose and scope of the sharing arrangement, the identities and obligations of the parties, management and staffing information, and the financial or economic terms for payment. We believe that the goals of transparency and program integrity can be achieved by requiring EPM participants, EPM collaborators, collaboration agents, downstream collaboration agents, and any other individual and entities performing EPM activities maintain documentation for at least 10 years following the last day of the EPM participant's participation in the EPM and allowing CMS, OIG, HHS, and the Comptroller General or their designees access to such records. The evaluation for the EPM intends to examine factors associated with variations in success under the EPM and the likelihood of experiencing unintended consequences. Factors of interest include variations in how gainsharing, distribution, and downstream distribution payments are implemented between the parties. At this time, it is intended that such information on payments will be collected through mechanisms such as provider surveys, interviews and in case studies.

Final Decision: After consideration of the public comments received, we are finalizing the proposals in § 512.500(c) for EPM gainsharing payment, alignment payment, and internal cost savings conditions and restrictions, with modifications. In addition to the modifications previously discussed in this section, we are specifying that like PGPs, to be eligible to receive a gainsharing payment or to be required to make an alignment payment, a NPPGP or TGP must have billed for an item or service that was rendered by one or more NPPGP member or TGP member respectively 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. In addition, like PGPs, the NPPGP or TGP 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. Gainsharing payments, alignment payments, and internal cost savings must meet the following conditions and restrictions:

- 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, 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.

++ To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, an EPM collaborator other than an ACO, PGP, NPPGP, or TGP 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.

++ To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, an EPM collaborator that is a PGP, NPPGP, or TGP must meet the following criteria:

—The PGP, NPPGP, or TGP must have billed for an item or service that was rendered by one or more PGP member, NPPGP member, or TGP member respectively 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

—The PGP, NPPGP, or TGP 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, NPPGP, or TGP 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 other providers and suppliers (such as PGP members, NPPGP members, or TGP members; the EPM participant; and post-acute care providers), implementing strategies designed to address and manage the comorbidities of EPM beneficiaries.

++ 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:

—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

—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—

^^ 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 and reduce spending for EPM episodes; or

^^ 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.

++ 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 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.

• 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:

++ 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.

++ In the case of an EPM collaborator that is a PGP or NPPGP, 50 percent of the Medicare-approved amounts under the PFS for items and services billed by that PGP or NPPGP and furnished to the EPM participant's EPM beneficiaries by the PGP members or NPPGP members respectively 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.

• 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.

• For a performance year, the aggregate amount of all gainsharing payments that are derived from a reconciliation payment the EPM participant receives from CMS must not exceed the amount of that reconciliation payment.

• 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 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.

• An EPM participant must not make a gainsharing payment to an EPM collaborator if CMS has notified the EPM participant that such collaborator is subject to any action for noncompliance with this part or the fraud and abuse laws, or for the provision of substandard care to EPM beneficiaries or other integrity problems.

• 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.

• 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—

++ 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.

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.

• The aggregate amount of all alignment payments from an EPM collaborator to the EPM participant may not be greater than—

++ With respect to an EPM collaborator other than an ACO, 25 percent of the EPM participant's repayment amount; or

++ With respect to an EPM collaborator that is an ACO, 50 percent of the EPM participant's repayment amount.

• The amount of any alignment payments must be determined in accordance with a methodology that does 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.

• 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).

• All gainsharing payments and alignment payments must be made by check, electronic funds transfer, or another traceable cash transaction.

d. Documentation Requirements

To ensure the integrity of the sharing arrangements, we proposed that EPM participants must meet a variety of documentation requirements for these arrangements. Specifically, we proposed that 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 proposed 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 proposed 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 proposed § 512.110.

The proposals for the requirements for documentation of sharing arrangements under the EPM were included in proposed § 512.500(d). We sought 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 were met.

We received no specific comments on the proposed documentation requirements for EPM sharing arrangements other than the comment discussed previously requesting further documentation related to the criteria for selection of EPM collaborators.

Final Decision: We are finalizing the proposals in § 512.500(d) for EPM documentation requirements, with the modification previously discussed to require the EPM participant to publicly post the written policies for selecting EPM collaborators on a Web page on the EPM participant's Web site and the reorganization to consolidate and streamline the documentation requirements related to public posting. EPM sharing arrangements must meet the following documentation requirements:

• The EPM participant must do all of the following:

++ Document the sharing arrangement contemporaneously with the establishment of the arrangement.

++ Publicly post (and update on at least a quarterly basis) on a Web page on the EPM participant's Web site:

++ Accurate current and historical lists of all EPM collaborators, including EPM collaborator names and addresses.

++ Written policies for selecting individuals and entities to be EPM collaborators required by § 512.500(a)(3).

++ 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:

—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.

—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.

• The EPM participant must keep records 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.

++ Its plan to track gainsharing payments and alignment payments.

• 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.

5. Distribution Arrangements Under the EPM

a. General

Similar to the CJR model, we proposed that certain financial arrangements between EPM collaborators and other individuals or entities called ''collaboration agents'' be termed ''distribution arrangements.'' A distribution arrangement would be a financial arrangement between an EPM collaborator that was an ACO or PGP and a collaboration agent for the sole purpose of sharing a gainsharing payment received by the ACO or PGP. We proposed that a collaboration agent would be an individual or entity that was not an EPM collaborator and that was either a PGP member that had entered into a distribution arrangement with the same PGP in which he or she was an owner or employee or an ACO participant or ACO provider/supplier that had entered into a distribution arrangement with the same ACO in which it was participating. Where a payment from an EPM collaborator to a collaboration agent was made pursuant to an EPM distribution arrangement, we proposed to define that payment as a ''distribution payment.'' A collaboration agent could only make a distribution payment in accordance with a distribution arrangement which complied with the provisions of proposed § 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 were included in proposed § 512.505(a). We sought 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 were met.

We received no specific comments on the proposed general provisions for distribution arrangements under the EPM.

Final Decision: We are finalizing the proposals in § 512.505(a) for the general requirements for EPM distribution arrangements, with modification to allow NPPGPs or TGPs to enter into distribution arrangements with NPPGP members or TGP members respectively. Similar to PGPs when they are EPM collaborators, we believe it is appropriate to allow NPPGPs or TGPs to enter into distribution arrangements with NPPGP members or TGP members respectively for the sole purpose of sharing a gainsharing payment received by the NPPGP or TGP. Distribution arrangements under the EPM must comply with the following general provisions:

• An ACO, PGP, NPPGP, or TGP 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.

• 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

We proposed a number of specific requirements for distribution arrangements as a program integrity safeguard to help ensure that their sole purpose was 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 paralleled 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 proposed 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 was furnished to EPM beneficiaries under the distribution arrangement. Furthermore, we proposed 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 proposed 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 proposed more flexible standards for the determination of the amount of distribution payments from ACOs and PGPs for the same reasons we proposed this standard for the determination of gainsharing payments. Specifically, for ACOs we proposed that the amount of any distribution payments must be determined in accordance with a methodology that was 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. In the proposed rule, we discussed our belief that the amount of a collaboration agent's provision of EPM activities (including direct care) to EPM beneficiaries during EPM episodes might contribute to the EPM participant's internal cost savings and reconciliation payment that might be available for making a gainsharing payment to the EPM collaborator with which the collaboration agent had a distribution arrangement. Greater contributions of EPM activities by one collaboration agent versus another collaboration agent that resulted in different contributions to the gainsharing payment made to the EPM collaborator with which those collaboration agents both had a distribution arrangement might be appropriately valued in the methodology used to make distribution payments to those collaboration agents. Accordingly, we believed this would be the appropriate standard for determining the amount of distribution payments from an ACO to its collaboration agents.

We noted 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 was substantially based on quality of care and the provision of EPM activities might be more limiting in how a PGP paid its members than was allowed under existing law. Therefore, to retain existing flexibility for distribution payments by a PGP to PGP members, we proposed 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 complied with § 411.352(g). We noted 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 complied with § 411.352(g) was not currently permitted under the CJR model, although we proposed this change for

the CJR model in section V.J. of the proposed rule (81 FR 50965). 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 were 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 included the monies contained in a gainsharing payment. We believed this would be 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 sought comment on this proposal and specifically whether there were additional safeguards or a different standard was 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 were 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 furnished or billed for items and services, except for a distribution payment from a PGP to a PGP member that complied with § 411.352(g), we proposed that a collaboration agent would be 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 comprised the gainsharing payment being distributed. We noted that all individuals and entities that fell within our proposed definition of collaboration agent might either directly furnish or bill for items and services rendered to EPM beneficiaries. This proposal ensured that, absent the alternative safeguards afforded by a PGP's distribution payments in compliance with § 411.352(g), there would be the same required relationship between direct care for EPM beneficiaries during EPM episodes and distribution payment eligibility that we proposed to require for gainsharing payment eligibility. We believed this requirement would provide a safeguard against payments to collaboration agents that were unrelated to direct care for EPM beneficiaries during EPM episodes when the amount of the distribution payment was not determined in a manner that complies with § 411.352(g).

Except for a distribution payment from a PGP to a PGP member that complied with § 411.352(g), we proposed the same limitations on the total amount of distribution payments to physicians, nonphysician practitioners, and PGPs as we proposed for gainsharing payments. In the case of a collaboration agent that was a physician or nonphysician practitioner, we proposed 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 comprised the gainsharing payment being distributed. In the case of a collaboration agent that was a PGP, we proposed 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 comprised the gainsharing payment being distributed. In the proposed rule, we discussed our belief 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 were the same as those for proposed for gainsharing payments to physicians, nonphysician practitioners, and PGPs, were 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 believed 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 were an ACO participant if that ACO played 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 proposed 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 proposed 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, we proposed that 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 were medically unnecessary.

We proposed that the EPM collaborator must maintain contemporaneous documentation regarding distribution arrangements in accordance with proposed § 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 proposed 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 would ensure that the proposed separate limitations on the total amount of gainsharing payment and distribution payment to PGPs, physicians, and nonphysician practitioners that were substantially based on quality of care and the provision of EPM activities were 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 was disproportionate to the quality of care and provision of EPM activities by that individual or entity. Finally, we proposed 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 proposed § 512.110.

The proposals for requirements for distribution arrangements under the EPM were included in proposed § 512.505(b). We sought 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 were met. In addition, we sought comment on how the regulation of the financial arrangements under this proposal might interact with how these or similar financial arrangements are regulated under the Medicare Shared Savings Program.

The following is a summary of the comments received and our responses.

Comment: One commenter who expressed support for the proposed cap on distribution and downstream distribution payments by PGPs to individual clinicians at 50 percent of the total Medicare-approved amounts under the PFS for items and services furnished by the clinician to the EPM participant's EPM beneficiaries during EPM episodes in the applicable time period opposed CMS' proposal to eliminate the requirements to link quality to these payments and for the clinicians to provide services to EPM beneficiaries in EPM episodes for PGP payments to clinicians under a methodology that complies with § 411.352(g). The commenter observed that under CMS' proposal, distribution arrangements would be subject to many of the same requirements as sharing arrangements. They claimed that while some PGPs may want to cascade funds in the same way as other funds that are paid in accordance with § 411.352(g), a provision that prohibits physicians in a group practice from being directly or indirectly compensated based on the volume or value of his or her referrals, the commenter believes that the provision of all payments under EPM financial arrangements, including gainsharing payments, distribution payments, and downstream distribution payments, should have a direct association with high-quality, cost-effective care furnished to EPM beneficiaries.

Response: We appreciate the commenter's concerns about our proposal to allow distribution payments and downstream distribution payments to be made by a PGP to PGP members either based on a methodology 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. Under the latter methodology, we proposed that the PGP member who is a collaboration agent or a downstream collaboration agent would be eligible to receive a payment if he or she furnished or billed for an item or service rendered to an EPM beneficiary during an EPM episode during the applicable time period and the total amount of payment for a performance year would be subject to a cap. These requirements would not apply to distribution or downstream distribution payments by a PGP to PGP members based on a methodology that complies with § 411.352(g).

We remain concerned that without the § 411.352(g) exception that we proposed, the distribution and downstream distribution methodologies would be more limiting in how a PGP pays its members than is allowed under existing law. Our proposal would allow a PGP the choice either to comply with the standard under the EPM that the amount of a distribution payment or downstream distribution payment must be substantially based on quality of care and the provision of EPM activities or to provide its members a financial benefit under the general standard at § 411.352(g) without consideration of the PGP member's individual quality of care. In the latter case, PGP members who are not collaboration agents or downstream 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 or distribution payment. We continue to believe this is an appropriate exception to the standard created under the EPM 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 note that even in such cases, our proposal includes some requirements to ensure a nexus between the financial arrangements and the care provided by PGP members to beneficiaries in EPM episodes. In addition to the requirement in § 512.500(c)(2)(i) that for any EPM collaborator to be eligible receive a gainsharing payment, the EPM collaborator must meet quality of care criteria for the performance year, under § 512.500(c)(2)(iii) we further specify that for PGPs to be eligible to receive a gainsharing payment the PGP also 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 during the applicable time period and that the PGP must have contributed substantially to EPM activities and been clinically involved in the care of EPM beneficiaries during that same time period. We believe these requirements for gainsharing eligibility establish a clear link between the quality of care furnished to EPM beneficiaries by PGP members and EPM activities by the PGP and the subsequent financial arrangements between the PGP and its members. In addition, we require in § 512.505(b)(5) that the amount of any distribution payments from an ACO (including those to a PGP) must be determined in accordance with a methodology that is substantially based on quality of care and the provision of EPM activities. Therefore, we believe there is a sufficiently close link between distribution payments and downstream distribution payments that comply with § 411.352(g) and the quality of care furnished to EPM beneficiaries by PGP members and EPM activities by the PGP that allowing payments by the PGP to its members that comply with § 411.352(g) does not substantially threaten the important relationship between payments under the EPM financial arrangements and the quality of furnished to EPM beneficiaries in EPM episodes.

We are finalizing in §§ 512.505(6) and 512.510(6) that the amount of any distribution payments or downstream distribution payments from a PGP to a PGP 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.

Comment: One commenter requested clarification about whether a provider of outpatient therapy services can receive distribution payments or downstream distribution payments as either a member of a PGP who is an EPM collaborator or as a member of a PGP that is an ACO participant in an ACO that has a distribution arrangement with an EPM collaborator.

Other commenters sought to clarify whether groups of nonphysician

practitioners could enter into financial arrangements under the EPM.

Response: The definition of a member of a PGP or PGP member means ''a physician, nonphysician practitioner, or therapist who is an owner or employer of a PGP and who has reassigned to the PGP his or her right to receive Medicare payment.'' Thus, therapists who are PGP members may be eligible to receive distribution payments or downstream distribution payments when those PGPs enter into financial arrangements under the EPM in accordance with all the requirements in this final rule. We are finalizing in § 512.2 the definition of member of the PGP or PGP member to include therapists.

Moreover, as we discussed previously, in response to commenters' confusion regarding the permissibility of financial arrangements for therapists both as individuals and as part of groups we adopt multiple clarifications in this final rule to affirm the permissibility of such arrangements and to clarify the applicable requirements. In addition to the adoption of new definitions that clarify the sharing arrangements available to therapists in private practice or TGPs as discussed previously, this final rule adopts parameters for TGPs and therapists in private practice to receive distribution payments from an ACO that is an EPM collaborator, for TGPs to make distribution payments and downstream distribution payments to their members, and for therapists to receive distribution payments and downstream distribution payments as either members of NPPGPs or members of TGPs.

Similarly, in response to commenters seeking clarity on whether groups of nonphysician practitioners are eligible to enter into financial arrangements under the EPM that mirror those expressly permitted for PGPs, in this final rule, we affirm the permissibility of and parameters for such arrangements for NPPGPs. In addition to the provisions discussed previously and as discussed further later in this section, the final rule establishes parameters for distribution payments to NPPGPs that directly parallel the parameters we proposed and now finalize for such payments to PGPs. Similarly, as is also discussed further later in this section, the parameters for distribution payments and downstream distribution payments by an NPPGP to its members directly parallel the parameters for distribution payments and downstream distribution payments by a PGP to its members as proposed and adopted in this final rule except for, due to the inapplicability of the physician self-referral law and its exceptions, NPPGPs do not have the options afforded to PGPs to make distributions to their members in a manner that complies with § 411.352(g) of this chapter.

Final Decision: After consideration of the public comments received, we are finalizing the proposals in § 512.505(b) for the requirements for EPM distribution arrangements, with modification to include policies for NPPGPs or TGPs that enter into distribution arrangements with NPPGP members or TGP members respectively. Like a PGP, an NPPGP that is an ACO participant in an ACO that is an EPM collaborator may enter into distribution arrangement with the ACO. The distribution payments to the NPPGP are subject to the same requirements as the distribution payments to PGPs that are collaboration agents. The NPPGP is eligible to receive a distribution payment only if the collaboration agent 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. The distribution payment to the NPPGP is capped at 50 percent of the total Medicare-approved amounts under the PFS for items and services billed by the NPPGP for items and services furnished by NPPGP members 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.

If an NPPGP is an EPM collaborator, it may enter into a distribution arrangement with a NPPGP member, who is a nonphysician practitioner or therapist who is an owner or employee of a NPPGP and who has reassigned to the NPPGP his or her right to receive Medicare payment. The requirements for NPPGP distribution payments under those distribution arrangements are the same as those for PGPs, except that we allow the amount of any distribution payments from a PGP to a PGP member to be determined in a manner that complies with § 411.352(g). While CMS has determined that under the physician self-referral law payments from a group practice as defined under § 411.352 to its members that comply with § 411.352(g) are appropriate, NPPGPs do not fall under this definition of group practice. Therefore, the amount of any distribution payments from a NPPGP to a NPPGP member must always be determined in accordance with a methodology that is substantially based on quality of care and the provision EPM activities, the same standard that applies to PGP distribution payments that are not determined in a manner that complies with § 411.352(g). Like the requirement for PGP members when a distribution payment does not comply with § 411.352(g), a NPPGP member is eligible to receive a distribution payment only if the collaboration agent furnished an item or service 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. Finally, the total amount of distribution payments paid for a performance year to the NPPG member may not exceed 50 percent of the total Medicare-approved amounts under the PFS for items and services furnished by the NPPGP member 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 addition, with respect to the distribution of any gainsharing payment received by a NPPGP, 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 a PGP and NPPGP, a TGP that is an ACO participant in an ACO that is an EPM collaborator may enter into distribution arrangement with the ACO. The distribution payments to the TGP are not subject to the cap that applies to PGPs and NPPGPs. While we cap distribution payments to physicians and nonphysician practitioners, we will not cap such payments to therapists in private practice for the same reasons discussed for gainsharing payments to these individuals and, therefore, we will not cap distribution payments to TGPs. Like PGPs and NPPGPs, the TGP is eligible to receive a distribution payment only if the collaboration agent 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.

If a TGP is an EPM collaborator, it may enter into a distribution arrangement with a TGP member, who is a therapist who is an owner or

employee of a TGP and who has reassigned to the TGP his or her right to receive Medicare payment. Like distribution payments from a NPPGP to a NPPGP member, the amount of any distribution payments from a TGP to a TGP member must be determined in accordance with a methodology that is substantially based on quality of care and the provision EPM activities, the same standard that applies to PGP distribution payments that are not determined in a manner that complies with § 411.352(g). Like the requirement for PGP members when a distribution payment does not comply with § 411.352(g) and for NPPG members, a TGP member is eligible to receive a distribution payment only if the collaboration agent furnished an item or service 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 will not cap the total amount of distribution payments paid for a performance year to a TGP member for the reasons discussed previously for not applying caps on gainsharing payments to therapists in private practice. Finally, with respect to the distribution of any gainsharing payment received by a TGP, 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.

Distribution arrangements under the EPM must comply with the following requirements:

- 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.
- Participation in a distribution arrangement must be voluntary and without penalty for nonparticipation.
- The distribution arrangement must require the collaboration agent to comply with all applicable laws and regulations.
- 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.
- The amount of any distribution payments from an ACO, from a NPPGP to a NPPGP member, or from a TGP to a TGP member 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.
- The amount of any distribution payments from a PGP 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.
- Except for a distribution payment from a PGP to a PGP member that complies with § 411.352(g) of this chapter, 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.
- Except for a distribution payment from a PGP to a PGP member that complies with § 411.352(g) of this chapter, the total amount of distribution payments for a performance year paid to a collaboration agent must not exceed the following:

++ In the case of a collaboration agent that is a 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.

++ In the case of a collaboration agent that is a PGP or NPPGP, 50 percent of the total Medicare-approved amounts under the PFS for items and services billed by that PGP or NPPGP for items and services furnished by PGP members or NPPGP members 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.

- With respect to the distribution of any gainsharing payment received by an ACO, PGP, NPPGP, or TGP, 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.
- 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.
- 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.

- The EPM collaborator must maintain contemporaneous documentation regarding distribution arrangements in accordance with § 512.110, including the following:

++ 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.

- 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.
- 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.

6. Downstream Distribution Arrangements Under the EPM

a. General

We proposed that the EPM allow for certain financial arrangements within an ACO between a PGP and its members. Specifically, we proposed that certain financial arrangements between a collaboration agent that was both a PGP and an ACO participant and other individuals termed ''downstream collaboration agents'' be termed a ''downstream distribution arrangement.'' A downstream distribution arrangement would be a

financial arrangement between a collaboration agent that was 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. We proposed that a downstream collaboration agent would be an individual who was not an EPM collaborator or a collaboration agent and who was a PGP member that had entered into a downstream distribution arrangement with the same PGP in which he or she was an owner or employee, and where the PGP was a collaboration agent. Where a payment from a collaboration agent to a downstream collaboration agent was made pursuant to a downstream distribution arrangement, we proposed to 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 complied 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 were included in proposed § 512.510(a). We sought 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 were met.

We received no specific comments on the proposed general provisions for downstream distribution arrangements under the EPM; however, the comments described previously regarding commenters' confusion regarding the permissibility of financial arrangements for individuals and groups of therapists and nonphysician practitioners under our proposal are relevant to these provisions.

Final Decision: We are finalizing the proposals in § 512.510(a) for the general requirements for EPM downstream distribution arrangements, with modification to allow NPPGPs or TGPs to enter into downstream distribution arrangements with NPPGP members or TGP members respectively. Downstream distribution arrangements under the EPM must comply with the following general provisions:

- An ACO participant that is a PGP, NPPGP, or TGP 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.
- 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

We proposed a number of specific requirements for downstream distribution arrangements as a program integrity safeguard to help ensure that their sole purpose was to create financial alignment between collaboration agents that were PGPs which were also ACO participants and downstream collaboration agents toward the goals of the EPM to improve the quality and efficiency of EPM episodes. These proposed requirements largely paralleled those proposed in proposed § 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 proposed 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 was furnished to EPM beneficiaries under the downstream distribution arrangement. Furthermore, we proposed 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 proposed 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 proposed the more flexible standard for the determination of the amount of downstream distribution payments for the same reasons we proposed 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 was 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. In the proposed rule, we discussed our belief that the amount of a downstream collaboration agent's provision of EPM activities (including direct care) to EPM beneficiaries during EPM episodes might contribute to the EPM participant's internal cost savings and reconciliation payment that might be available for making a gainsharing payment to the EPM collaborator that was then shared through a distribution payment to the collaboration agent with which the downstream collaboration agent had a downstream distribution arrangement. Greater contributions of EPM activities by one downstream collaboration agent versus another downstream collaboration agent that resulted in different contributions to the distribution payment made to the collaboration agent with which the downstream collaboration agents both had a downstream distribution arrangement might be appropriately valued in the methodology used to make downstream distribution payments to those downstream collaboration agents. Just as we proposed an alternative to a methodology that was 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 proposed an alternative that the amount of a downstream distribution payment from a PGP to a PGP member may be determined in a manner that complied with § 411.352(g)

Similar to our proposed requirements for distribution arrangements for those EPM collaborators that were PGPs, we proposed that, except for a downstream distribution arrangement that complied with § 411.352(g), a downstream collaboration agent would be 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 comprised the gainsharing payment from which the ACO made the distribution payment to the PGP that was an ACO participant. This proposal would ensure that, absent the alternative safeguards afforded by a

PGP's downstream distribution payments in compliance with § 411.352(g), there would be the same required relationship between direct care for EPM beneficiaries during EPM episodes and downstream distribution payment eligibility that we proposed to require for gainsharing and distribution payment eligibility. We believed this requirement would provide a safeguard against payments to downstream collaboration agents that were unrelated to direct care for EPM beneficiaries during EPM episodes when the amount of the downstream distribution payment was not determined in a manner that complied with § 411.352(g).

We proposed the same limitations on downstream distribution payments to downstream collaboration agents as we proposed for distribution payments by EPM collaborators that were PGPs. We proposed 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 comprised the gainsharing payment from which the ACO made the distribution payment to the PGP. We believed 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 was the same as those for distribution payments to physicians and nonphysician practitioners was 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 agent.

We further proposed 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 was an ACO participant) from the ACO that was an EPM collaborator. Like gainsharing, alignment, and distribution payments, we proposed 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 were medically unnecessary.

We proposed that the PGP must maintain contemporaneous documentation regarding downstream distribution arrangements in accordance with proposed § 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 proposed that the PGP may not enter into a downstream distribution arrangement with any PGP member who had a sharing arrangement with an EPM participant or distribution arrangement with the ACO the PGP was a participant in. This proposal would ensure that the proposed separate limitations on the total amount of gainsharing payment, distribution payment, and downstream distribution payment to PGP members that were substantially based on quality of care and the provision of EPM activities were 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 proposed 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 proposed § 512.110.

The proposals for requirements for downstream distribution arrangements under the EPM were included in proposed § 512.510(b). We sought 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 were met.

We received no specific comments on the proposed requirements for downstream distribution arrangements under the EPM; however, the comments described previously regarding commenters' confusion regarding the permissibility of financial arrangements for individuals and groups of therapists and nonphysician practitioners under our proposal and regarding the request to simplify and reduce the burdens associated with the programmatic requirements are relevant to these provisions.

Final Decision: We are finalizing the proposals in § 512.510(b) for the requirements for EPM downstream distribution arrangements, with modification to include policies for NPPGPs or TGPs that enter into downstream distribution arrangements with NPPGP members or TGP members respectively. Consistent with commenters' overall request that we streamline the regulations, we are also modifying proposed § 512.510(b)(6), which is final § 512.510(b)(7), to eliminate one of the two proposed requirements for eligibility of a downstream collaboration agent to receive a downstream distribution payment, specifically the requirement that the PGP bill for the item or service furnished by the downstream collaboration agent. Instead, we base downstream collaboration agent eligibility only on whether the downstream collaboration agent furnished an item or service 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 from which the ACO made the distribution payment to the PGP, NPPGP, or TGP that is an ACO participant. This approach is parallel to § 512.505(b)(7), which applies to distribution payments from ACOs to ACO participants or ACO providers/suppliers and certain distribution payments from PGPs to PGP members, and ensures that the member of the PGP, NPPGP, or TGP receiving the downstream distribution payment furnished items and services to an EPM beneficiary during an EPM episode, without explicitly requiring that the PGP, NPPGP, or TGP to which the member of the PGP, NPPGP, or TGP would have reassigned his or her benefits also billed for the item or service. This latter additional requirement adds complexity that is unnecessary when our objective of the

requirement is only to ensure that the recipient of the downstream distribution payment furnished an item or service to an EPM beneficiary during an EPM episode in order to link the payment to actual care. Finally, as discussed previously, in order to achieve consistency in the parameters for gainsharing payments and distribution payments to therapists and to streamline programmatic requirements, we are revising proposed § 512.510(b)(7), which is final in § 512.510(b)(8), by removing the cap on downstream distribution payments to PGP members as applied to therapists who are PGP members.

A NPPGP that is an ACO participant that has entered into a distribution arrangement with an EPM collaborator that is an ACO may enter into a downstream distribution arrangement with a NPPGP member, who is a nonphysician practitioner or therapist who is an owner or employee of a NPPGP and who has reassigned to the NPPGP his or her right to receive Medicare payment. The requirements for NPPGP downstream distribution payments under those downstream distribution arrangements are the same as those for PGPs, except that we allow the amount of any downstream distribution payments from a PGP to be determined in a manner that complies with § 411.352(g). The amount of any downstream distribution payments from a NPPGP to a NPPGP member must be determined in accordance with a methodology that is substantially based on quality of care and the provision EPM activities, the same standard that applies to PGP downstream distribution payments that are not determined in a manner that complies with § 411.352(g). Like the requirement for PGP members when a downstream distribution payment does not comply with § 411.352(g), a NPPGP member is eligible to receive a downstream distribution payment only if the downstream collaboration agent furnished an item or service 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 from which the ACO made the distribution payment to the NPPGP that is an ACO participant. Finally, the total amount of downstream distribution payments paid for a performance year to the NPPGP member who is a nonphysician practitioner may not exceed 50 percent of the total Medicare-approved amounts under the PFS for items and services furnished by the NPPGP member 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 NPPGP that is an ACO participant. In addition, 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 NPPGP from the ACO.

A TGP that is an ACO participant that has entered into a distribution arrangement with an EPM collaborator that is an ACO may enter into a downstream distribution arrangement with a TGP member, who is a therapist who is an owner or employee of a NPPGP and who has reassigned to the TGP his or her right to receive Medicare payment. Like downstream distribution payments from a NPPGP to a NPPGP member, the amount of any downstream distribution payments from a TGP to a TGP member must be determined in accordance with a methodology that is substantially based on quality of care and the provision EPM activities, the same standard that applies to PGP distribution payments that are not determined in a manner that complies with § 411.352(g). Like the requirement for PGP members when a distribution payment does not comply with § 411.352(g) and for NPPG members, a TGP member is eligible to receive a distribution payment only if the downstream collaboration agent furnished an item or service 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 from which the ACO made the distribution payment to the NPPGP that is an ACO participant. We will not cap the total amount of downstream distribution payments paid for a performance year to a TGP member. Finally, 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 TGP from the ACO.

Like PGPs, NPPGPs and TGPs must maintain contemporaneous documentation regarding downstream distribution arrangements. Similarly, the NPPG or TGP may not enter into a downstream distribution arrangement with any NPPG member or TGP member respectively who has a sharing arrangement with an EPM participant or a distribution arrangement with the ACO the NPPG or TGP is a participant in.

Downstream distribution arrangements under the EPM must comply with the following requirements:

- 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.
- Participation in a downstream distribution arrangement must be voluntary and without penalty for nonparticipation.
- The downstream distribution arrangement must require the downstream collaboration agent to comply with all applicable laws and regulations.
- 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.
- The amount of any downstream distribution payments from a NPPGP to a NPPGP member or from a TGP to a TGP member 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 downstream collaboration agent relative to other downstream collaboration agents.
- The amount of any downstream distribution payments from a PGP 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 by a downstream collaboration agent relative to other downstream collaboration agents.
- Except for a downstream distribution payment from a PGP to a PGP member that complies with § 411.352(g) of this chapter, a downstream collaboration agent is eligible to receive a downstream

distribution payment only if the downstream collaboration agent furnished an item or service 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, NPPGP, or TGP that is an ACO participant.

• Except for a downstream distribution payment from a PGP to a PGP member that complies with § 411.352(g) of this chapter, the total amount of downstream distribution payments for a performance year paid to a downstream collaboration agent who is a physician or nonphysician practitioner and is either a PGP member or NPPGP member must not exceed 50 percent of the total Medicare-approved amounts under the PFS for items and services 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 distribution payment being distributed.

• 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, NPPGP, or TGP from the ACO.

• All downstream distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction.

• 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.

• The downstream distribution arrangement must not—

++ Induce the downstream collaboration agent to reduce or limit medically necessary services to any Medicare beneficiary; or

++ Reward the provision of items and services that are medically unnecessary.

• The PGP, NPPG, or TGP must maintain contemporaneous documentation regarding downstream distribution arrangements in accordance with § 512.110, including the following:

++ The relevant written agreements.

++ The date and amount of any downstream distribution payment.

++ 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.

• The PGP, NPPGP, or TGP may not enter into a downstream distribution arrangement with any PGP member, NPPGP member, or TGP member who has—

++ A sharing arrangement with an EPM participant; or

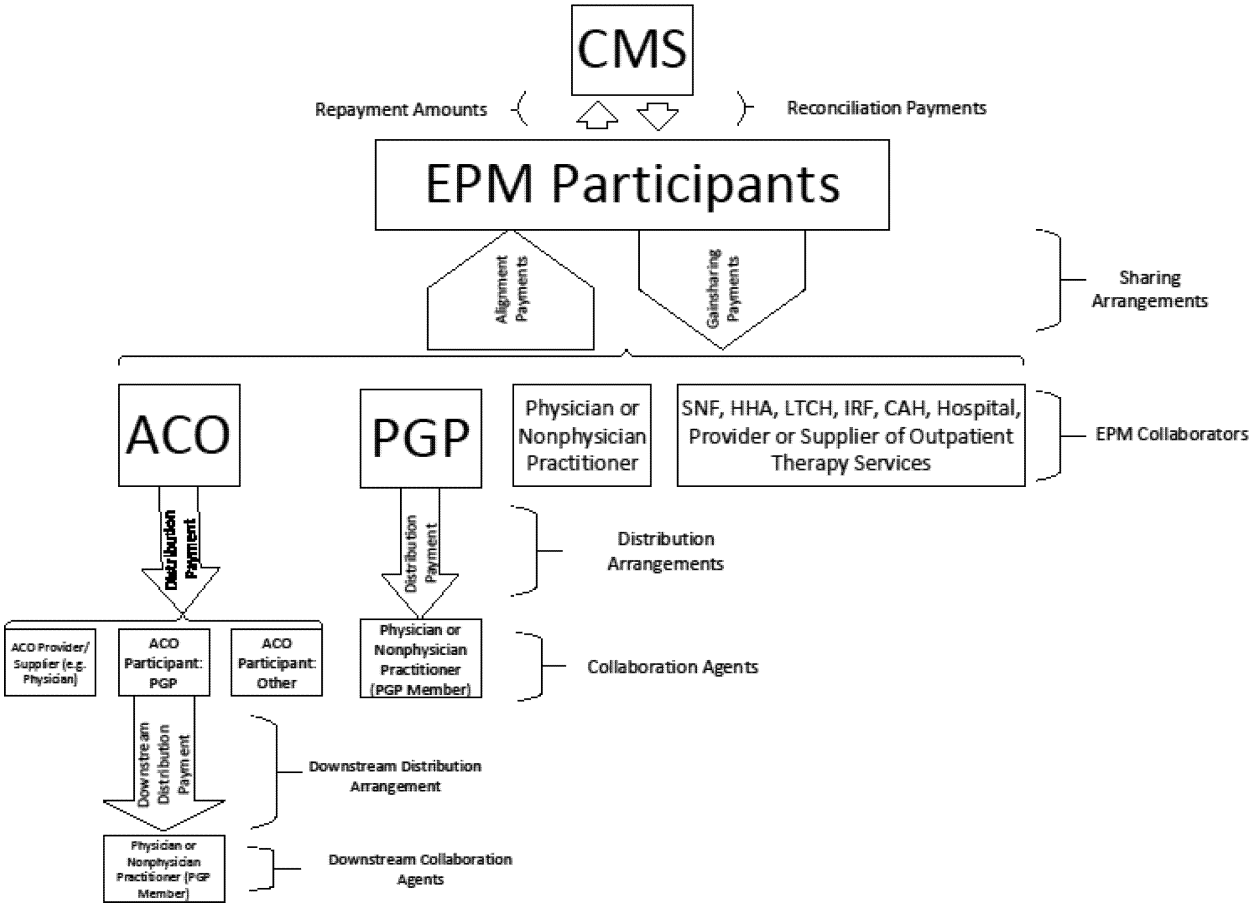
++ A distribution arrangement with the ACO that the PGP, NPPGP, or TGP is a participant in.

• The PGP, NPPGP, or TGP 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.

7. Summary of Policies for Sharing, Distribution, and Downstream Distribution Arrangements Under the EPM

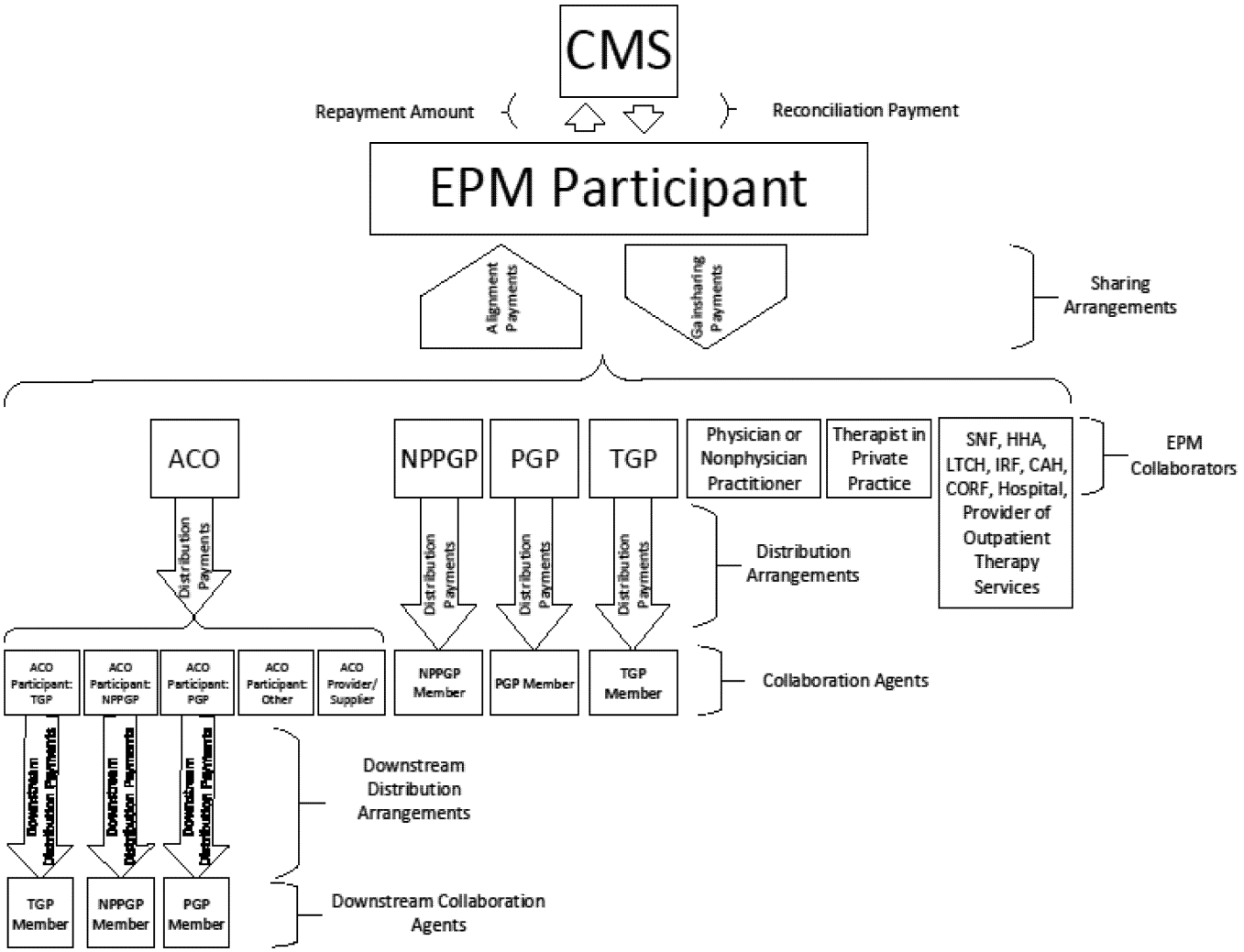
Figure 2 summarizes the proposals for the defined terms and financial arrangements discussed in sections III.I.4. through 6. of the proposed rule (81 FR 50920 through 50929).

Figure 2: PROPOSED EPM FINANCIAL ARRANGEMENTS



Our final policies for financial arrangements reflect a number of changes to the proposals for EPM financial arrangements in response to comments on the proposed rule. Accordingly, Figure 2 summarizes the final policies for the defined terms and financial arrangements discussed in sections III.I.4. through 6. of this final rule.

Figure 3: FINAL EPM FINANCIAL ARRANGEMENTS



8. Enforcement Authority

As discussed in the proposed rule, 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 would limit or restrict the authority of any other Government Agency to do the same.

The proposals for enforcement authority under the EPM were included in proposed § 512.520. We sought 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 were met.

We received no comments on the proposals for enforcement authority under the EPM.

Final Decision: We are finalizing the proposals in § 512.520 for the enforcement authority for the EPM, without modification. The final provisions include—

- 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; and
- 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.

9. Beneficiary Engagement Incentives under the EPM

a. General

Similar to our reasoning for the CJR model (80 FR 73433 through 73437), in the proposed rule, we discussed our belief 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 believed that one mechanism that might be useful to EPM participants in achieving these goals would be 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 believed that certain conditions on these incentives were necessary to ensure that their provision was solely for the purpose of achieving the EPM goals of improving episode quality and efficiency.

We proposed 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 were EPM collaborators. However, as discussed in section III.B.3. of the proposed rule (81 FR 50813 through 50814), given our belief that the EPM participant was best positioned to coordinate the care of beneficiaries in the EPM, we believed that EPM participants would also be better suited than other individuals and entities to provide beneficiary incentives.

We proposed 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 was more valuable to the beneficiary than equipment that was reasonably necessary for the patient's post-hospital discharge care, such as a smartphone. In such circumstances, a reasonable inference would arise that the technology would not be reasonably connected to the medical care of the patient. Among other things, this safeguard precluded incentives that might serve to inappropriately induce beneficiaries to receive other medical care that was not included in the episode. We also proposed that the incentive must be a preventive care item or service or an item or service that advanced 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 proposed 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 would provide safeguards against the provision of in-kind patient engagement incentives to steer beneficiaries toward certain providers or suppliers for care.

We proposed 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 would provide 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 would not be 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 did 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 did we intend for these arrangements to shift the patient severity for an EPM participant or cause access problems for Medicare beneficiaries. Finally, we proposed 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 were included in proposed § 512.525(a). We sought comment on our proposed general provisions for beneficiary incentives and welcomed comment on additional or alternative program integrity safeguards. We summarize the comments and provide our responses in section III.I.9.d. of this final rule.

b. Technology Provided to an EPM Beneficiary

In some cases, items or services involving technology might be useful as beneficiary engagement incentives that could 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, in the proposed rule we discussed our belief that specific enhanced safeguards were necessary for these items and services to prevent abuse, and our proposals were consistent with the CJR model policies (80 FR 73437). Specifically, we proposed 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 proposed 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 proposed 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 understood that EPM participants may not always be able to retrieve these items after the EPM episode ends, such as when a beneficiary died or moved to another geographic area, documented, diligent, good faith attempts to retrieve items of technology would 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 were included in proposed § 512.525(b). We sought comment on our proposed requirements for beneficiary engagement incentives that involve technology and welcomed comment on additional or alternative program integrity safeguards for this type of beneficiary engagement incentive, including whether the financial thresholds proposed in this section were reasonable, necessary, and appropriate. We summarize the comments and provide our responses in section III.I.9.d. of this final rule.

c. Clinical Goals of the EPM

As discussed in section III.C.3. of the proposed rule (81 FR 50829 through 50834), the proposed EPMs were broadly defined to include most Part A and Part B items and services furnished during EPM episodes that would extend 90 days following discharge from the anchor or chained anchor

hospitalization that began the episode, excluding only those Part A and Part B services that were unrelated to the EPM episode based on hospital readmissions or diagnoses for which care was unrelated to the EPM episode diagnosis and procedures based on clinical rationale. Therefore, in the proposed rule we discussed our belief that in-kind patient engagement incentives might appropriately be provided for managing acute conditions arising from EPM episodes, as well as chronic conditions if the condition was likely to have been affected by care during the EPM episode or when substantial services were likely to be provided for the chronic condition during the EPM episode.

We proposed that the following were the clinical goals of the EPM, which might 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 was not a preventive care item or service must be intended to advance were included in proposed § 512.525(c). We sought 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 might better advance the overarching goals of the EPM while maintaining appropriate program integrity safeguards. We summarize the comments and provide our responses in section III.I.9.d. of this final rule.

d. Documentation of Beneficiary Engagement Incentives

As a program safeguard against misuse of beneficiary engagement incentives under the EPM, we proposed that EPM participants must maintain documentation of items and services furnished as beneficiary engagement incentives that exceeded $25 in retail value. In addition, we proposed 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 was provided.
- The identity of the beneficiary to whom the item or service was provided.

We further proposed that the documentation regarding items of technology exceeding $100 in retail that were 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 reiterated that documented, diligent, good faith attempts to retrieve items of technology would be deemed to meet the retrieval requirement. Finally, we proposed that the EPM participant must retain and provide access to the required documentation in accordance with proposed § 512.110.

Our proposals for the documentation requirements for beneficiary engagement incentives under the EPM were included in proposed § 512.525(d). We sought comment on our proposed documentation requirements, including whether additional or different documentation requirements might provide better program integrity safeguards.

The following is a summary of the comments received and our responses on all proposals for beneficiary engagement incentives under the EPM.

Comment: Some commenters opposed the proposed requirements that EPM participant must maintain documentation of items and services furnished as beneficiary engagement incentives that exceed $25 in retail value. The commenters recommended that CMS increase the documentation threshold, for example to $50, in order to reduce record keeping for inexpensive beneficiary engagement incentives and to minimize unnecessary administrative requirements. One commenter also recommended that CMS allow beneficiary engagement incentives greater than $25.

Response: We appreciate the perspectives of the commenter on our proposed requirements for documentation of all items and services provided as beneficiary engagement incentives whose value exceeds $25, including the date and the identity of the beneficiary to whom the item or service was provided. We proposed a $25 retail value threshold for documentation because we recognized that a beneficiary could receive many incentives that are each of low dollar value but in the aggregate constitute an excessively high value to the beneficiary. While we considered setting a cumulative threshold on the retail value of beneficiary engagement incentives received by an EPM beneficiary during an EPM episode above which documentation would be required, we believe such an approach would be even more burdensome than our proposal to require documentation beginning at $25 in retail value for each incentive that exceeds that value. A documentation requirement based on a cumulative threshold would require documentation of every expense for beneficiary engagement incentives (including those below $25) to ensure compliance with required documentation of the cumulative retail value of incentives that exceed the threshold. Therefore, we believe it is prudent to maintain a per-item/per-service documentation threshold and to not increase the documentation threshold, thereby keeping the threshold at a modest level for all beneficiary incentives in order to monitor compliance with the requirements for providing these items and services. We continue to believe that the $25 threshold represents an appropriate balance between the benefits of beneficiary incentives and burden of the documentation requirement.

For clarification, we did not propose that EPM participant may only provide in-kind beneficiary engagement incentives less than $25. With the exception of beneficiary engagement incentives involving technology which we proposed may not exceed $1,000 in retail value for any one beneficiary in any one EPM episode, there is no limit on the retail value of a single item or service provided as an in-kind patient engagement incentive to a beneficiary in an EPM episode, or to the aggregate of such incentives provided to the beneficiary in the episode.

We are finalizing in § 512.515(d)(1) the requirement that an EPM participant must maintain documentation of items and services furnished as beneficiary engagement incentives that exceed $25 in retail value. Under § 512.515(d)(4), we set forth the requirement that the EPM participant must retain and provide access to the required documentation in accordance with § 512.110.

Comment: In regards to beneficiary engagement incentives involving technology, one commenter requested that the items or services involving technology provided to an EPM beneficiary not be capped at $1,000 given that CMS' proposal would require the EPM participant to pick up the technology from the EPM beneficiary if its retail value is greater than $100. The same commenter recommended that CMS increase the proposed cap of $100 to $500 for items of technology that must remain the property of the EPM participant and be retrieved from the beneficiary at the end of the EPM episode because under the proposed threshold, the commenters believes it

would cost the EPM participant more to pick up the item of technology from the EPM beneficiary than the item of technology is worth.

Several commenters suggested that CMS eliminate altogether the proposed requirement that items of technology provided as beneficiary engagement incentives be retrieved from the beneficiary at the end of the EPM episode. One commenter claimed that there may be situations where the patient may continue to benefit from the use of items of technology that were originally provided as EPM beneficiary engagement incentives beyond the 90-day post-discharge episode duration. They speculated that continued use of the technology could reduce the future need for urgent or emergent care and impact the overall future cost to Medicare to care for the beneficiary. The commenter urged CMS to establish a process or criteria to evaluate whether a beneficiary should be able to keep the technology and continue using it after the EPM episode ends, ensuring that any new policies take into the account the need for flexibility at the local level to provide benefits to patients, the community, and the health system as a whole. Finally, the commenter requested that if CMS decides not to establish a process to allowed continued use of the technology after the EPM episode ends, then CMS should require that documentation of beneficiary engagement incentives include written acknowledgement by the beneficiary or their representative that the technology remains the property of the EPM participant and must be returned upon completion of the episode.

Another commenter pointed out remote patient monitoring equipment that could be provided as a beneficiary engagement incentive under the EPM must be linked to particular a particular provider to be effective and sought clarification about how devices provided in conjunction with remote patient monitoring could avoid being tied to a particularly provider. They further explained the Medicare program does not provide any payment for remote patient monitoring or other items and services provided to patients for improved self-management and believes that EPM participants are likely to engage in these activities only if they believe that improved episode quality or cost savings will result. The commenter asserted that so long as the provision of technology to beneficiaries is reasonably related to the clinical goals of the EPM, EPM participants should be encouraged to explore the use of remote patient monitoring through efforts that are not constrained by limitations CMS proposed.

Response: We appreciate the requests by the commenters for additional flexibility with respect to items and services involving technology provided as EPM beneficiary engagement incentives. We proposed that items or services involving technology provided to as a beneficiary engagement incentive may not exceed $1,000 in retail value for any one beneficiary in any one EPM episode. While one commenter requested that we raise this limit because any technology exceeding $100 in retail value would remain the property of the EPM participant, no commenters provided information about items and services involving technology that would exceed this amount and that EPM participants would specifically wish to provide to advance the goals of the EPM to improve the quality and reduce the cost of care. Therefore, we are maintaining the limit of $1,000 in retail value for items or service involving technology provided to any one beneficiary during any one EPM episode even though the beneficiary's use of the technology costing more than $100 in retail value would be limited to the EPM episode. We believe that providing beneficiaries with more expensive technology could pose a program integrity risk of patient steering and that a higher limit is not necessary under the EPM.

We understand the administrative burden on EPM participants that tracking and retrieval requires, but believe that a higher retrieval threshold, such as $500, is not warranted. Similarly, we do not believe it would be appropriate to eliminate the retrieval threshold altogether, even for items of technology that may provide additional health benefits to beneficiaries after the EPM episode ends and/or lead to reduced expenditures on health care. It would be inappropriate for EPM participants to furnish items of technology with a retail value of over $100 for beneficiaries' permanent use because the high value of these items could unduly influence the beneficiary to receive services from the EPM participant, particularly services outside of the EPM episode. We do not believe the potential longer-term benefits of continued use or the administrative burden of retrieving items involving technology with a retail value in excess of $100 outweigh the program integrity benefits of retrieval.

We propose documentation requirements for beneficiary engagement incentives that exceed $25 in retail value as a safeguard against abuse, including the date the incentive is provided, the identity of the beneficiary to whom the item or service is provided, and contemporaneous documentation of attempts to retrieve items of technology exceeding $100 in retail value. However, we believe that any additional documentation requirements such as the commenter's suggestion of written acknowledgement by the beneficiary or their representative that the technology remains the property of the EPM participant and must be returned upon completion of the episode would be unnecessarily prescriptive and burdensome for EPM participants. For items of technology with a retail value exceeding $100 that remain the property of the EPM participant, it is up to the EPM participant to determine how they can best ensure that EPM beneficiaries understand the ownership of the technology while minimizing the burden on the EPM participant needed for successful retrieval or the documentation of retrieval attempts.

Finally, with respect to the clarification requested by the commenter about how items of technology for remote monitoring could meet the requirement for EPM beneficiary engagement incentives that the item or service must not be tied to the receipt of items or service from a particular provider or supplier, we note that the intent of this latter requirement is as a safeguard from the use of beneficiary engagement incentives as a way to steer beneficiaries toward a certain provider or type of services. We understand that remote monitoring information that is collected from EPM beneficiaries must be sent to a treating provider for review and interpretation in order for the remote-monitoring to guide clinical care. However, in this case the remote monitoring technology would be linked to a provider that is treating the beneficiary, rather than being provided to steer the beneficiary to a particular treating provider, so we believe that remote monitoring equipment may be provided as a beneficiary engagement incentive without violating the requirement that the item or service not be tied to the receipt of items or services from a particular provider or supplier.

Comment: Some commenters requested that CMS allow other beneficiary engagement incentives in the EPM to be provided by EPM participants, such as forgiving primary care or all beneficiary copayments for items and services included in the episode and making available supportive services that are otherwise in short supply or of inadequate quality, rather than just those closely tied to the

medical issues. The commenters provided examples of in-kind assistance they believe could be helpful to improve the quality and reduce the cost of EPM episode care, such as meal delivery or other food assistance for beneficiaries and the family caregiver; enhanced homemaker and personal care aide services; and housing assistance for homeless patients. One commenter noted that while this would be a more expansive view of beneficiary engagement incentives for the EPM than CMS proposed, such an approach would allow targeted services to address key social determinants of health that could improve the quality and reduce the cost of EPM episodes by improving beneficiary outcomes and reducing readmissions. Another commenter urged CMS to provide guidance on specific circumstances where these or other social support services would be permissible, including applicable patient screening protocols and expenditure caps. The commenters encouraged CMS to allow EPM participants, who would be required to take on financial risk for cardiac and orthopedic episodes of care under the EPM, to use a full suite of tools to provide economically challenged patients the social supports necessary to minimize the risk of readmissions.

Other commenters requested clarification about whether examples of beneficiary engagement incentives more directly related to medical issues would meet CMS' proposed requirements, such paying for a beneficiary's medications for management of coronary artery disease (either copayment or entire prescription in the instance of a patient who lacks Part D) or paying for a beneficiary's medications for management of an exacerbating chronic disease (for example, diabetes) (either copayment or entire prescription in the instance of a patient who lacks Part D).

Response: We appreciate the commenters' recommendations for additional beneficiary engagement incentives under the EPM, as well as their requests for clarification about certain items and services that EPM participants may wish to provide as beneficiary engagement incentives. Regarding requests for CMS to waive copayments for items and services included in EPM episodes, most beneficiaries in traditional Medicare have supplemental coverage, specifically employer-sponsored, Medicaid, and Medigap in descending order of prevalence.[130] In 2011, 81 percent of beneficiaries in traditional Medicare had supplemental coverage. While we recognize that without supplemental coverage the copayments associated with an EPM episode could be significant, most beneficiaries would not experience significant out-of-pocket costs for the items and services themselves because their supplemental coverage would help to cover those costs. For the subset of beneficiaries without supplemental coverage, we note that, under current law, hospitals and other providers and suppliers are permitted to waive copayments under certain limited conditions and that copayment waivers that comply with existing law continue to be permitted under the EPM. In light of these factors, we will not waive copayments for items and services covered by Medicare under the EPM.

No commenters suggested that our specific proposal for the purpose of the items and services provided as beneficiary engagement incentives, specifically that they must be preventive care items or services or items and services that advance a clinical goal for a beneficiary in an EPM episode by engaging the beneficiary in better managing his or her own health, were not appropriate for the EPM. Several commenters who urged us to allow them the flexibility to provide support services as beneficiary engagement incentives presented specific arguments about how those items and services would reduce readmissions or enhance beneficiary adherence to the treatment plan, which are on the proposed list of clinical goals of the EPM. On the other hand, some commenters expressed concern that social support services that have the potential to advance EPM goals might not meet the proposed requirements because they are not closely tied to medical issues and, therefore, would not meet the requirement that the item or service must be reasonably connected to medical care provide to an EPM beneficiary during and EPM episode. While we appreciate that social issues have a significant influence on beneficiary health, we are testing the EPM as an innovative payment approach for Medicare beneficiaries, which focuses on improving care coordination following inpatient hospitalization for treatment of a clinical condition included in the EPM to improve the quality and reduce the cost of health care. The EPM is an APM that is being tested as an alternative to FFS Medicare. Therefore, we continue to believe that it is important to maintain the requirements of a reasonable connection between the item or service provided as a beneficiary engagement incentive and a beneficiary's medical care and that the item or service advance a meaningful clinical goal for the EPM beneficiary. These requirements both protect against EPM participants' incentives to influence the beneficiary's choice of providers and types of care in the EPM and ensure that the EPM as implemented with a standardized episode payment design in a large number and wide variety of EPM participants can be appropriately evaluated in comparison with FFS Medicare.

We will not provide additional interpretation of the requirements for beneficiary engagement incentives that we are finalizing in this final rule, nor provide other guidance at this time. Instead, we encourage EPM participants considering offering items or services as beneficiary engagements incentives to EPM beneficiaries to closely consider those potential items and services and ensure that their provision would meet all the requirements of § 512.525 before deciding to provide those items or services as beneficiary engagement incentives under the EPM.

Comment: One commenter requested that CMS address a specific scenario where an EPM participant already has a program in place prior to implementation of the EPM to encourage beneficiaries to follow through on their plan of care after hospital discharge. The commenter requested that CMS clarify whether the incentives under the existing program become beneficiary engagement incentives under the EPM and, therefore, subject to the requirements of the EPM, or whether the existing incentives would only be considered beneficiary engagement incentives under the EPM if they are specifically being offered to encourage improvement of clinical goals based on the EPM care redesign for the EPM episode.

Response: We appreciate the request for clarification about the relationship of a hospital's existing incentives provided to Medicare beneficiaries following hospital discharge to encourage adherence to the beneficiary's care plan to EPM beneficiary engagement incentives provided by an EPM participant that must meet the specific requirements proposed in § 512.515 and all other applicable laws and regulations, including the applicable fraud and abuse laws. If an EPM participant has a program already in place to provide incentives to beneficiaries following hospital discharge, we expect that all such

[130] The Henry J. Kaiser Family Foundation. An Overview of Medicare. April 1, 2016. *http://kff.org/medicare/issue-brief/an-overview-of-medicare.*

incentives offered would comply with all current laws and regulations, including the fraud and abuse laws. Therefore, if an EPM participant provides beneficiary engagement incentives to EPM beneficiaries during EPM episodes, those incentives must either comply with all current laws and regulations, including the fraud and abuse laws, or with the requirements for EPM beneficiary engagement incentives in § 512.515 and all other applicable laws and regulations, including the applicable fraud and abuse laws. We note that any waivers of fraud and abuse laws for the EPM or revisions to the existing CJR waivers are outside the scope of this rulemaking.

Final Decision: After consideration of the public comments received, we are finalizing the proposals in §§ 512.525(a) through (d) for the EPM general provisions, technology provided to an EPM beneficiary, clinical goals of the EPM, and documentation of beneficiary incentives, without modification. Beneficiary engagement incentives under the EPM must meet the following conditions and requirements:

EPM participants may choose to provide in-kind patient engagement incentives to beneficiaries in an EPM episode, subject to the following conditions:

- 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.
- The item or service provided must be reasonably connected to medical care provided to an EPM beneficiary during an EPM episode.
- 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.
- The item or service must not be tied to the receipt of items or services outside the EPM episode.
- The item or service must not be tied to the receipt of items or services from a particular provider or supplier.
- 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.
- 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.

Beneficiary engagement incentives involving technology are subject to the following additional conditions:

- 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.
- 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.
- Items of technology exceeding $100 in retail value must—

++ 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. Documented, diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement.

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.

Documentation of beneficiary engagement incentives:

- EPM participants must maintain documentation of items and services furnished as beneficiary engagement incentives that exceed $25 in retail value.
- 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.

- 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 previously in this section.
- The EPM participant must retain and provide access to the required documentation in accordance with § 512.110.

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, will be promulgated separately from this final 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.

As discussed in the proposed rule, 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 the proposed rule and provisions of this final rule.

J. 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.

As discussed in the proposed rule, in testing EPMs, we 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, we stated in the proposed rule that before adopting the same waivers as we adopted in the CJR model for EPMs, we stated that 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 proposed waivers under the AMI, CABG, and SHFFT models and for which we invited 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 proposed to waive the physician definition to allow a qualified nonphysician practitioner to perform specific physician functions.

We proposed 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 the 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 did not receive any comments on this policy therefore, we are adopting this policy in this final rule.

We also generally sought 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.

The following is a summary of the comments received and our responses.

Comment: Many commenters recommended the CMS include other program waivers in addition to the proposed EPM waivers. In general, these suggestions were similar to the suggestions received during the CJR rulemaking process. Specifically, one commenter recommended that CMS expand more innovation to the post-acute care provider community in models such as CJR, EPM, and BPCI by allowing them to participate more robustly in these models through waiving some of the provider-specific rules, such as the IRF 60-percent rule and 3-hour therapy guideline. Another commenter recommended that CMS include a waiver to allow advance practice registered nurses to certify hospitalized patients for home health care services for the CJR model and the EPMs. Some commenters urged CMS to waive discharge planning requirements that prohibit hospitals from specifying or otherwise limiting information about post-acute care services, waive the regulatory constraints on how therapy services are delivered to EPM-eligible beneficiaries, and promote parity across Medicare programs by ensuring similar flexibilities are available to Medicare Advantage Organizations so that all Medicare beneficiaries can benefit from these services or removal of barriers. Another commenter urged CMS to waive audits of post-acute care and other collaborators participating in an EPM or CJR episode since the episode-managing entity is financially accountable for the provision of those services. Some commenters recommended that because certain arrangements may not meet the requirements of a ''sharing arrangement'' as outlined in the EPM proposed rule, CMS should waive fraud and abuse, beneficiary inducement, and physician self-referral liability for EPM entities.

Response: In the CJR Final Rule (80 FR 73439), we responded to numerous comments to include additional waivers under the CJR model. The final regulations issued for the CJR model reflect our responses to those comments. We stated in the CJR Final Rule that while we were not making any changes to the proposed waivers, we would continually monitor the data from early testing of the CJR model. The CJR model was implemented on April 1, 2016 thus data is currently not available to evaluate if changes to the program waivers are warranted. We stated that if the early CJR model testing data supports changes to the program waivers then we would do so in future rulemaking.

Our goal for implementing program waivers for EPMs was to replicate the general aspects of the waivers that were issued in the CJR final regulations. However, we stated in the EPM proposed rule that 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. Thus, for the EPMs we proposed the following waivers that are similar to the adopted CJR waivers;

- 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 home visits and;
- Provide waivers on the number of post-discharge home visits and for the SNF 3-day stay, made on an EPM episode basis.

We anticipate that if the CJR model testing data supports additions or changes to the CJR program waivers, then we would consider extending those revisions to CJR waivers in future rulemaking to the EPMs if those waivers would be clinically appropriate for the clinical conditions that are the focus of the EPM. Hence, our responses to the EPM waiver comments in this section reflect this common relationship with the final CJR model waivers.

Final Decision: We address the specific Medicare program waivers we proposed in the EPM proposed rule in the following sections. We decline at this time to waive any additional Medicare program requirements. We will review the information provided by the commenters and our early CJR model and EPM experience and may

consider waiving additional requirements during the course of the CJR model and EPM test.

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 for 7 of the last 12 months 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

As discussed in the proposed rule, 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

As stated in the proposed rule, 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 are implementing in this final 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

As discussed in the proposed rule, the following Table 47 shows the discharge destination and post-acute care usage for the cardiac related episodes (CABG, PCI, and AMI) in the BPCI model.

TABLE 47—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

TABLE 47—DISCHARGE DESTINATION FOR BPCI CARDIAC DIAGNOSES *—Continued

[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
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 47 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

As discussed in the proposed rule, Table 48 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 48—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
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

TABLE 48—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
	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 48 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.

As discussed in the proposed rule, based on our analysis of the available data, we believe that minimal program and patient outcome vulnerabilities exist with adopting 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, in conjunction with the comments received, we are adopting, as proposed, the waivers for these program requirements for EPMs as discussed in the sections that follow.

In addition, as discussed in the proposed rule, based on our analysis of the available data, we believe some program and patient outcome vulnerabilities may exist with the adoption of the same CJR regulatory waivers for the following program requirements for some EPMs:

• The SNF 3-day rule.

• The number of post-discharge home visits allowed during the model episode.

Therefore, in conjunction with the comments received, we are adopting, as proposed, 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 as discussed in the sections that follow.

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 discuss in section III.A.1. of this final 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.[131] 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 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.

[131] 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.

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 did not propose 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.

The following is a summary of the comments received and our responses.

Comment: Some commenters stated the CMS should waive the homebound requirement for the EPMs. One commenter stated that hospitals would not have an incentive to direct patients to home health when a less costly option, such as outpatient therapy, also would be clinically appropriate and that CMS should allow physicians, working together with participating hospitals, to determine the most clinically appropriate plan for a patient's post-acute care, unimpeded by regulatory barriers. Another commenter suggested the establishment of a homebound waiver to fit the circumstances described in the ''incident to'' waiver. Other commenters recommended that CMS incrementally test a waiver of the homebound requirement for the home health benefit by using a limited waiver. Other commenters recommended that CMS waive the home health homebound rule in accordance with the new Star Rating program for homecare providers

Response: While we appreciate the commenters' requests that we waive the homebound requirement for home health services, we disagree that waiving the homebound requirement is necessary for the test of the EPMs. In the CJR model Final Rule (80 FR 73440 through 73441) we responded to similar comments regarding the home health homebound requirement. Under the EPMs, we continue to believe that waiving the homebound requirement is not appropriate for the same reasons stated in the CJR model Final Rule.

As discussed in the EPM proposed rule, we proposed to waive the ''incident to'' direct physician supervision requirement for post-discharge home visits in order to allow clinical staff to furnish post-discharge home visits to EPM beneficiaries who do not meet the requirements for home health services. We believe that this would allow the home visits by clinical staff for non-homebound EPM beneficiaries that we believe are necessary for testing the model. As we discussed in the EPM proposed rule, we believe many EPM beneficiaries should qualify for home health services under the existing program rules, especially immediately after discharge from the hospital or discharge from an institutional setting such as a SNF to their residence. Furthermore, as a retrospective payment model, all providers and suppliers are paid for services furnished to model beneficiaries at their usual rates, and program payments for home health services are set based on the needs of Medicare beneficiaries who are truly homebound. The resources required to care for homebound beneficiaries in the home are likely greater than those required for EPM beneficiaries who are not homebound. Therefore, waiving the homebound requirement would lead to inappropriate payment for post-discharge home visits to EPM beneficiaries and could result in increased EPM actual spending, which is counter to the goals of the EPM.

Final Decision: After consideration of the public comments we received, we are finalizing our proposal, without modification, to maintain the existing Medicare requirements for home health services, including the requirement that the beneficiary be homebound, when home health services are furnished to EPM beneficiaries.

For the EPMs, we proposed to adopt program requirement waivers similar to the post-discharge home visit waivers implemented for the CJR model. We proposed 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 services furnished 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 services furnished under the waiver to be billed under the PFS by the physician or nonphysician practitioner who is supervising the licensed clinical staff or by the hospital to which the supervising physician has reassigned his or her benefits if all other requirements are met. In the latter scenario, we note that the post-discharge home visit services will not be ''hospital services,'' even when furnished by licensed 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 proposed 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 proposed 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 proposed 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 proposed 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.

The following is a summary of the comments received and our responses.

Comment: Most commenters supported the ''incident to'' waiver to allow general supervision rather than direct supervision. A few commenters recommended that the post-discharge home visits be available to all EPM beneficiaries, including those who qualify for home health services. Some commenters requested that CMS issue a clarification that specifically permits a hospital or community physician or nonphysician practitioner to contract with an HHA for home nursing visits under the ''incident to'' waiver and that this clarification should also provide that the Medicare home health agency Conditions of Participation do not apply to such visits.

Response: In the CJR Final Rule, we responded to similar comments regarding the ''incident to'' direct supervision waiver (80 FR 73442 through 73444). While we appreciate the commenters' suggestions that we provide maximal flexibility to participant hospitals to deliver the configuration of services the hospital believes to be most appropriate to manage a beneficiary's care, under the EPMs we continue to believe that home visits furnished under the ''incident to'' direct physician supervision waiver should be limited to model beneficiaries who otherwise would not qualify for home health services. We note that while home health episodes are 60 days in duration, payment adjustments are made for beneficiaries who require only a few visits during the episode or who are discharged during the home health episode. Therefore, EPM beneficiaries who qualify for home health services could receive home health services that would be appropriately paid even if they qualified for such services for less than 60 days. Those beneficiaries who qualify for home health services for any duration of time during the EPM episode would not need to receive post-discharge home visits under the ''incident to'' direct physician supervisions waiver. Furthermore, we expect that homebound EPM beneficiaries may typically need other types of services provided under the home health benefit than just post-discharge home visits by clinical staff, including skilled nursing services, therapy services, medical supplies, and medical social services. We would not expect that post-discharge home visits provided under the ''incident to'' direct physician supervision waiver would adequately substitute for home health services under the more comprehensive Medicare home health benefit. For those beneficiaries receiving home health care, paying additionally for post-discharge home visits under the ''incident to'' direct physician supervision waiver would be duplicative of services that should be furnished under the home health episode and could lead to ineffective care coordination and management due to the involvement of multiple clinical staff working for different organizations or physician practices.

Although we proposed to waive the direct physician supervision requirement in § 410.26(b)(5) as previously discussed, licensed clinical staff providing post-discharge home visits as ''incident to'' services would still need to be considered ''auxiliary personnel'' (employed, contracted, or leased employee of the physician or same employing organization as physician) as required by § 410.26(a)(1) and § 410.26(b)(6). Therefore, it would not be permissible for HHAs, community-based organizations, hospitals, or others to provide post-discharge home visits under the proposed ''incident to'' direct physician supervision waiver as these entities would not meet the definition of ''auxiliary personnel'' as outlined in regulation. At this time, we are declining to waive any additional requirements of the ''incident to'' rules that would be necessary for these other entities to furnish EPM post-discharge home visits because we continue to believe that the post-discharge home visits should always be ''incident to'' a physician's professional services, including that they are an integral, although incidental, part of the physician's professional services in the course of the diagnosis or treatment of an illness of injury, and that they are furnished by auxiliary personnel (if not by the physician or practitioner with an ''incident to'' benefit), who by definition are linked to the physician (or employing organization of the physician) by employment, contract, or lease. We believe the ''incident to'' relationship of post-discharge home visits to a physician's professional services is critical due to the importance of robust care coordination and close care management to episode cost and quality performance, given the lengthy, broadly defined EPM episodes. We note that in the case where a post-discharge home visit is furnished by licensed clinical staff employed by the hospital, the hospital could bill under the PFS if the supervising physician who is an employee or a contractor of the hospital has reassigned his or her benefits to the hospital. As a result, we are not providing additional waivers for post-discharge home visits to EPM beneficiaries who otherwise do not qualify for Medicare home health services.

Comment: Most commenters supported the additional allowance of visits for AMI model patients, but were not clear what the clinically appropriate number should be for any particular

patient. Some commenters suggested that CMS not place any limits on the number of visits since in some cases this may result in readmissions during the episode that may be avoided with additional home monitoring. Other commenters were concerned that differential rules about the number of visits permitted for specific EPM episodes may be confusing for model participants. Some commenters supported CMS' proposal for differential post-discharge visit limits at this time, but urge the agency to monitor care patterns and consider refinements in the future with an eye toward consistency through future rulemaking.

Response: In the CJR Final Rule, we responded to similar comments regarding the limit on the number of post-discharge home visits (80 FR 73444). While we understand that some commenters would prefer no limit or a higher limit on the number of post-discharge home visits, as discussed previously these visits are restricted to model beneficiaries who do not quality for home health services. As discussed in the CJR Final Rule, we continue to believe it is appropriate to limit the number of post-discharge home visits that can be paid under an episode-based payment model to mitigate the risk of overutilization, especially in the early years of the model where EPM participants have no, or limited, repayment responsibility for excess actual episode spending above the quality-adjusted target price. As with the CJR post-discharge home visits, we believe that a limit on the number of visits is appropriate for the EPMs. In addition, we believe that the average post-acute care length of stay data supports differences in post-acute care usage for each of the EPMs as discussed in the proposed rule. Thus, we continue to believe that it is clinically appropriate to account for these differences on an episode-specific basis when setting the limits on the number of visits covered under the waiver.

As with the post-discharge home visit waiver for the CJR model, we are not prescribing the periodicity, pattern, or number of these visits for model beneficiaries. We will monitor utilization of these visits and may revisit the maximum number of visits over the course of the EPMs based on the implementation experience of EPM participants.

Comment: Some commenters urged CMS to require more specific identification of all the clinicians who provide services that are billed incident to another practitioner.

Response: While we believe this ''incident to'' waiver can be a significant tool to support a participant's success with the EPM, we believe that the administrative complexity of changing the billing requirements in order to collect this additional information outweighs the potential usefulness of this information in evaluating this aspect of the EPMs.

Final Decision: After consideration of the public comments we received, we are finalizing the proposal, without modification, to waive the ''incident to'' direct physician supervision requirement set forth at § 410.26(b)(5), to allow 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 EPM episode following discharge from an anchor hospitalization, limited to 13 visits for the AMI model, 9 visits for the CABG model, and 9 visits for the SHFFT model. We will allow practitioners to bill for services provided by licensed clinical staff, such as nurses, who are considered ''auxiliary personnel'' as defined in § 410.26(a)(1), when provided under the general, rather than direct, supervision of a physician or nonphysician practitioner. In some situations the clinical staff providing these services may be employees of the participant hospital and, as long as these clinical staff are supervised by the billing physician or nonphysician practitioner and the appropriate relationship exists between the physician and the clinical staff, payment under the PFS can be made. We plan to monitor utilization patterns of post-discharge home visits under the EPMs to monitor for overutilization and significant reductions in medical home health services.

Similar to the CJR model, we proposed that the service be reported 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 estimated that it would be 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. We proposed that final RVUs under the CY 2017 PFS for the proposed new HCPCS code for AMI, CABG, and SHFFT home visits will be included in this final rule. In addition, we proposed 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 proposed to waive current Medicare billing rules in order to allow the separate reporting of these post-discharge home visits during surgical global periods. The 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, when there is a transfer of care, by the practitioner to whom care is transferred. 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 proposed to waive the global surgery billing rules to allow the surgeon or other practitioners to furnish and bill for the post-discharge home visits during surgical global periods.

Comment: Several commenters supported the proposal to waive current Medicare billing rules for global surgeries to allow the separate billing of these post-discharge home visits by the physician or nonphysician practitioner who performed the EPM procedure.

One commenter supported the proposal, but urged CMS to clarify how this policy will interact with the PFS proposal for CY 2017 to require billing HCPCS G-codes during the global period to collect information on post-surgical visits.

Response: We appreciate the support on these issues. In response to the request for clarification, we note that since the post-discharge home visits furnished to EPM beneficiaries are being paid for, they do not need to be separately reported under the global surgery data collection requirements under the PFS. (See the CY 2017 PFS Final Rule, 81 FR 80170, for the finalized policies related to the global surgery data collection requirements under the PFS.)

Final Decision: Services furnished under the waiver will be billed under the PFS by the physician or nonphysician practitioner or by the entity, including a hospital, to which the supervising physician or nonphysician practitioner has reassigned his or her benefits. We are also waiving current Medicare billing rules in order to allow the separate reporting by the physician who performed a procedure during the anchor hospitalization of the EPM episode of these post-discharge home visits during surgical global periods when he or she is providing the general supervision of the post-discharge home visit.

The post-discharge home visit will be billed with the new HCPCS code G9863, displayed in Table 49. This code will be payable for EPM model beneficiaries beginning July 1, 2017, the start date of the first EPM performance year as discussed in section III.D.2. of this final rule. Rather than finalizing the specific RVUs for this new HCPCS code in this final rule, we are finalizing them through reference to the RVUs for another HCPCS G-code paid under the PFS. Specifically, the RVUs for this new code will be based upon the same inputs used to determine the payment rate for HCPCS code G9187 (BPCI initiative home visit for patient assessment performed by a qualified health care professional for individuals not considered homebound including, but not limited to, assessment of safety, falls, clinical status, fluid status, medication reconciliation/management, patient compliance with orders/plan of care, performance of activities of daily living, appropriateness of care setting; (for use only in the Medicare-approved BPCI initiative); may not be billed for a 30-day period covered by a transitional care management code), the specific HCPCS G-code currently used to report post-discharge home visits under BPCI. We are crosswalking the RVUs for new HCPCS code G9863 to the RVUs for the existing post-discharge home visit HCPCS G-code for the BPCI model because, given our view of the similarities between these two services in the two different models and the similar HCPCS G-code descriptors, we expect the resources required to be the same so the two codes are assigned the same inputs under the standard PFS ratesetting methodologies. In summary, we are finalizing the policy in this EPM final rule that the new HCPCS code G9863 for EPM post-discharge home visits will have the same RVUs as HCPCS code G9187 for BPCI model post-discharge home visits.

The CY 2017 RVUs, geographic practice cost indices and conversion factor that determine the PFS payment for HCPCS code G9187 are included in the CY 2017 PFS Final Rule. We will annually update the RVUs for HCPCS code G9863 for post-discharge home visits for EPM beneficiaries by crosswalking the RVUs for HCPCS code G9863 to HCPCS code G9187 as part of the annual PFS update, and information on the update will be included in the PFS Final Rule each year.

TABLE 49—HCPCS CODE FOR POST-DISCHARGE HOME VISITS FOR EPM BENEFICIARIES

HCPCS code number	Long descriptor	Short descriptor	RVUs equal to those of this HCPCS code for same calendar year under the PFS
G9863	Episode Payment Model (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.	EPM in home visit	G9187

The waiver of direct supervision requirements for certain post-discharge home visits is set forth at § 512.600. The waiver of certain post-operative billing restrictions under the PFS global surgery rules is set forth at § 512.615.

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; [132]
- 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.[133] 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 proposed a waiver of this same provision as well as waiver of the requirement that the eligible telehealth individual be in an originating site when 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 proposed 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 final 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 proposed, 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

[132] For the list of approved Medicare telehealth services, see the CMS Web site at *http://www.cms.gov/Medicare/Medicare-General-information/telehealth/*.

[133] 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.

located at the time the service is furnished via a telecommunications system. Specifically, we proposed to waive the requirement only when telehealth services are being furnished in the 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–10–CM principal diagnosis code that is not excluded from the applicable EPM's episode definition (see section III.C. of this final 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 proposed 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 proposed to structure the new codes similarly to the office/outpatient E/M codes but adjusted to reflect the location as the beneficiary's residence and the virtual presence of the practitioner. Specifically, we proposed to create a parallel structure and set of descriptors currently used to report office or other outpatient E/M services, (CPT codes 99201–99205 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 did not propose 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 proposed to develop payment rates for these new telehealth G-codes for E/M services in the patient's home that are similar to the payment rates for the office/outpatient E/M services, since the codes will describe the work involved in furnishing similar services. Therefore, we proposed to include the resource costs typically incurred when services are furnished via telehealth. In terms of the relative resource costs involved in furnishing these services, 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 proposed 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 proposed to include final RVUs under the CY 2016 PFS when we finalize the rules for EPMs. Additionally, we proposed 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 stated that we do 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 did not proposed 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 final 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 did 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 proposed to require the physician to document in the medical record that auxiliary licensed clinical staff were available on site in the patient's home during the visit and if they were not, to document the reason that such a high-

level visit would not require such personnel.

We 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, we believe that 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(m) 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 did not propose that the waiver of the telehealth geographic site requirement for telehealth services and the originating site requirement for telehealth services furnished in the 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 did propose, 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.

The existing set of codes used to report evaluation and management (E/M) visits are extensively categorized and defined by the setting of the service, and the codes describe the services furnished when both the patient and the practitioner are located in that setting. Section 1834(m) of the Act provides for particular conditions under which Medicare can make payments for office visits when a patient is located in a health care setting (the originating sites authorized by statute) and the eligible practitioner is located elsewhere. However, in the proposed rule, we stated that we did not believe that the kinds of E/M services furnished to patients outside of health care settings via real-time, interactive communication technology are accurately described by any existing E/M codes. This would include circumstances when the patient is located in his or her home and the location of the practitioner is at another location. Therefore, in order to create a mechanism to report E/M services accurately under the EPMs, we proposed to create a specific set of HCPCS G-codes to describe the E/M services furnished to EPM beneficiaries in their homes via telehealth when the physician or practitioner is in another location.

Among the existing E/M visit services, we stated that we envision these services would be most similar to those described by the office and other outpatient E/M codes. Therefore, we proposed to structure the new codes similarly to the office/outpatient E/M codes but adjusted to reflect the location as the beneficiary's residence and the virtual presence of the practitioner. Specifically, we proposed to create a parallel structure and set of descriptors currently used to report office or other outpatient E/M services, (CPT codes 99201 through 99205 for new patient visits and CPT codes 99212 through 99215 for established patient visits). For example, in the proposed rule we discussed a HCPCS G-code for a level 3 E/M visit for an established patient would be a telehealth visit for the evaluation and management of an

established patient in the patient's home, which requires at least 2 of the following 3 key components:

- An expanded problem focused history.
- An expanded problem focused examination.
- Medical decision making of low complexity.

Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the patient's or family's needs or both. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent with the patient or family or both via real-time, audio and video intercommunications technology. The preceding text would be included in the code descriptor for the proposed level 3 established patient telehealth E/M visit HCPCS G-code, just as this information is currently included in the code descriptor for the corresponding level 3 established patient office/outpatient E/M CPT code.

In the proposed rule, we noted that we were not proposing a HCPCS G-code to parallel the level 1 office/outpatient visit for an established patient, since that service does not require the presence of the physician or other practitioner. We stated our belief that this would duplicate the home visits for non-homebound beneficiaries previously discussed in this section.

We proposed to develop payment rates for these new telehealth G-codes for E/M services in the patient's home that are similar to the payment rates for the office/outpatient E/M services, since the codes will describe the work involved in furnishing similar services. Therefore, we proposed to include the resource costs typically incurred when services are furnished via telehealth. In terms of the relative resource costs involved in furnishing these services, in the proposed rule we stated our belief that the efficiencies of virtual presentation generally limit resource costs other than those related to the professional time, intensity, and MP risk to marginal levels. Therefore, we proposed to adopt work and MP RVUs associated with the corresponding level of office/outpatient codes as the typical service because the practitioner's time and intensity and MP liabilities when conducting a visit via telehealth are comparable to the office visit. We stated that final RVUs under the CY 2016 PFS would be included in the EPM final rule. Additionally, we proposed 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 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 through 3 for new visits and 2 and 3 for established visits, we did not believe that the visit would necessarily require auxiliary clinical staff to be available in the patient's home. We anticipated these lower level visits would be the most commonly furnished and would serve as a mechanism for the patient to consult quickly with a practitioner for concerns that can be easily described and explained by the patient. We did not propose to include PE RVUs for these services, since we did not believe that virtual visits envisioned for this model typically incur the kinds of costs included in the PE RVUs under the 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 in order for the complete service to be furnished. We stated our belief that it would be rare for a practitioner to conduct as complex and detailed a service as a level 4 or 5 E/M home visit via telehealth for EPM beneficiaries in the EPM episodes without licensed clinical staff support in the home.

However, we also noted that the proposed model already includes several avenues for licensed clinical staff to be in the patient's home, either through a separately paid home visit as proposed for the model or through home health services as discussed earlier in this final rule. Therefore, although we considered support by auxiliary clinical staff to be typical for level 4 or 5 E/M visits furnished to EPM beneficiaries in the home via telehealth, we did not propose to incorporate these costs through PE RVUs. Given the anticipated complexity of these visits, we noted that we would expect to observe level 4 and 5 E/M visits to be reported on the same claim with the same date of service as a home visit or during a period of authorized home health care. If neither of these occurs, we proposed to require the physician to document in the medical record that auxiliary licensed clinical staff were available on site in the patient's home during the visit and if they were not, to document the reason that such a high-level visit would not require such personnel.

We noted that because the services described by the HCPCS G-codes for the proposed model, by definition, are furnished remotely using telecommunications technology, they therefore are paid under the same conditions as in-person physicians' services and they do not require a waiver to the requirements of section 1834(m) of the Act. We also noted that because these home telehealth services would be E/M services, all other coverage and payment rules regarding E/M services would continue to apply.

We additionally noted that under the 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.

We sought comments on the proposed waivers with respect to telehealth services, and the proposed creation of the home visit telehealth codes.

The following is a summary of the comments received and our responses.

Comment: Many commenters supported the waiver of originating site and geographic site requirements and allowing telehealth visits for the EPMs. One commenter urged CMS to clarify that EPM participants can provide telehealth services that are not covered by Medicare or not paid for when provided free of charge if that supports the goal of improving quality while reducing costs. Another commenter suggested that CMS waive the requirement that services furnished under this waiver be performed by physicians or nonphysician practitioners and to permit the provision of telehealth services by HHAs through licensed clinicians to individuals who are not receiving Medicare-covered home health services. Another commenter cautioned CMS against the use of wasteful telehealth services that increase costs without improving health care access or quality. One commenter recommended that CMS allow even greater flexibility for EPM episode services and proceed further by allowing a waiver for technological restrictions and to offer up-front payment for investment in telehealth services beyond those currently covered under the telehealth benefit. One commenter requested that this waiver, if implemented, be authorized for any provider types that are allowed to provide telehealth services per state laws. Another commenter urged CMS to engage with

patients and providers to determine the most effective ways to test telehealth in populations that need it most.

Response: We appreciate the information from commenters on alternative approaches to providing care other than in-person. In the CJR Final Rule, we responded to similar comments regarding the telehealth waivers (80 FR 73448). As with the CJR model, the EPM is not testing a telehealth model and, therefore, we do not intend to fundamentally change the scope of telehealth requirements for payment under Medicare. Rather, we proposed to waive certain existing telehealth requirements to provide participant hospitals with additional tools to improve episode quality and efficiency given the constraints on physician time for in-person visits at distant locations or in the beneficiary's home. The proposed waivers would allow greater physician engagement via telehealth in EPM beneficiary care coordination and management following an EPM anchor hospitalization, regardless of the beneficiary's geographic location or home location. We believe that under the EPM it is important for beneficiaries to receive telehealth services in a way that permits them to interact with treating health care professionals in real-time, including being able to both see and interact with those providers, and the treating health care professionals being able to see and listen to the beneficiaries. Beneficiaries recovering at home following an EPM anchor hospitalization benefit from meaningful engagement in care that is patient-centered in order to improve their understanding and adherence to treatment regimens. Therefore, we do not believe it would be appropriate to allow telehealth services to be furnished to EPM model beneficiaries that do not meet the existing Medicare telehealth requirements for communications technology.

As with CJR model, we continue to believe that it would not be appropriate to allow telehealth services to be furnished to EPM beneficiaries that do not meet the existing Medicare telehealth requirements for communications technology. Finally, in response to the commenter requesting that we clarify that EPM participants can provide telehealth services free-of-charge, when they are not covered and paid by Medicare, we refer to section III.I.9. of this final rule for discussion of the requirements for in-kind beneficiary engagement incentives that may be provided by EPM participants under the EPMs.

Comment: One commenter strongly objected to the proliferation of new telehealth-specific HCPCS G-codes when there is a suitable CPT code to describe the service and urged CMS to allow for telehealth coverage of any related CPT/HCPCS procedure codes for physical medicine and rehabilitation. Another commenter was concerned that new codes are without clinical merit or distinction and undermine parity of clinical standards of care between services provided by telehealth means and service provided in-person.

Response: As discussed in the CJR Final Rule (80 FR 73450), we continue to believe that specific HCPCS G-codes are the most appropriate way for telehealth visits furnished in a model beneficiary's home or place of residence to be reported and paid. The work and MP RVUs for these new HCPCS G-codes will be the same as those for the comparable office and other outpatient E/M visit codes under the CY 2017 PFS. The HCPCS G-codes, their descriptors, and the CPT codes upon which their RVUs are based are displayed in Table 50. While we acknowledge that telehealth services are likely to incur practice expenses, as discussed in the proposed rule, we do not believe that virtual visits envisioned for this model typically incur the kinds of costs included in the PE RVUs under the PFS; we believe that these are merely a subset of the expenses incurred for in-person visits. And while we would be interested in examining any publicly available data regarding these costs relative to the costs included in the RVUs for other PFS services, we are finalizing our proposal not to include PE RVUs in the payment rate for these unique EPM services. Accordingly, we are waiving section 1834(m)(4)(2)(B) to allow this deviation from the payment of office/outpatient visits for purposes of the EPM telehealth in-home visit services. Finally, we will consider new CPT codes as they are released according to our usual processes, and will specifically evaluate whether they may be used in the future to report home telehealth visits for CJR model and EPM beneficiaries.

Final Decision: After consideration of the public comments received, we are finalizing our proposal, without modification, to waive the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act that limit telehealth payment to services furnished within specific types of geographic areas or in an entity participating in a federal telemedicine demonstration project approved as of December 31, 2000. Any service on the list of Medicare-approved telehealth services and reported on a claim with an ICD–10–CM principal diagnosis code that is not excluded from the EPM episode definition (see section III.C.3.b. of this final rule) can be furnished to an EPM beneficiary, regardless of the beneficiary's geographic location. We also are finalizing our proposal to waive the originating site requirements of section 1834(m)(4)(C)(ii)(I) through (VIII) of the Act that specify the particular sites at which the eligible telehealth individual must be located at the time the service is furnished via a telecommunications system only when telehealth services are being furnished in the 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–10–CM principal diagnosis code that is not excluded from the EPM episode definition (see section III.C.3.b. of this final rule) can be furnished to a 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. We will continue to require that telehealth services furnished under the EPM telehealth waiver be furnished using an interactive telecommunications system, consistent with the current requirement for payment of telehealth services under the PFS. The waiver of certain telehealth requirements is set forth at § 512.605.

We are finalizing the proposal, without modification, to create 9 HCPCS G-codes to report home telehealth E/M visits furnished under the EPM waiver as displayed in Table 50. These codes will be payable for EPM beneficiaries beginning July 1, 2017, the start date of the EPM performance year as discussed in section III.D.2. of this final rule. Rather than finalizing the RVUs for the new HCPCS codes in this final rule, we are finalizing them through reference to the RVUs for other CPT codes paid under the PFS as equal to the work and MP RVUs established for the comparable office/outpatient visits.

The final CY 2017 RVUs, geographic practice cost indices and conversion factor that determine the payment rates for the CPT codes are included in the CY 2017 PFS Final Rule.

We will update the RVUs for the EPM HCPCS telehealth G-codes annually by crosswalking them to the corresponding CPT codes as part of the annual PFS update, and information on the updates will be included in the PFS final rule each year.

TABLE 50—HCPCS CODES FOR TELEHEALTH VISITS FOR EPM BENEFICIARIES IN HOME OR PLACE OF RESIDENCE

Code number	Long descriptor	Short descriptor	Work and MP RVUs equal to those of the corresponding office/outpatient E/M visit CPT code for same calendar year under the PFS
G9864	Remote in-home visit for the evaluation and management of a new patient for use only in the Medicare-approved Episode Payment Model—AMI, CABG, or SHFFT model, which requires these 3 key components: • A problem focused history; • A problem focused examination; and • Straightforward medical decision making, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are self limited or minor. Typically, 10 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology.	In home E/M new pt 10 mins.	99201
G9865	Remote in-home visit for the evaluation and management of a new patient for use only in the Medicare-approved Episode Payment Model—AMI, CABG, or SHFFT model, which requires these 3 key components: • An expanded problem focused history; • An expanded problem focused examination; • Straightforward medical decision making, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of low to moderate severity. Typically, 20 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology.	In home E/M new pt 20 mins.	99202
G9866	Remote in-home visit for the evaluation and management of a new patient for use only in the Medicare-approved Episode Payment Model—AMI, CABG, or SHFFT model, which requires these 3 key components: • A detailed history; • A detailed examination; • Medical decision making of low complexity, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology.	In home E/M new pt 30 mins.	99203
G9867	Remote in-home visit for the evaluation and management of a new patient for use only in the Medicare-approved Episode Payment Model—AMI, CABG, or SHFFT model, which requires these 3 key components: • A comprehensive history; • A comprehensive examination; • Medical decision making of moderate complexity, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of moderate to high severity. Typically, 45 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology.	In home E/M new pt 45 mins.	99204

TABLE 50—HCPCS CODES FOR TELEHEALTH VISITS FOR EPM BENEFICIARIES IN HOME OR PLACE OF RESIDENCE—Continued

Code number	Long descriptor	Short descriptor	Work and MP RVUs equal to those of the corresponding office/outpatient E/M visit CPT code for same calendar year under the PFS
G9868	Remote in-home visit for the evaluation and management of a new patient for use only in the Medicare-approved Episode Payment Model—AMI, CABG, or SHFFT model, which requires these 3 key components: • A comprehensive history; • A comprehensive examination; • Medical decision making of high complexity, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of moderate to high severity. Typically, 60 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology.	In home E/M new pt 60 mins.	99205
G9869	Remote in-home visit for the evaluation and management of an established patient for use only in the Medicare-approved Episode Payment Model—AMI, CABG, or SHFFT model, which requires at least 2 of the following 3 key components: • A problem focused history; • A problem focused examination; • Straightforward medical decision making, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are self limited or minor. Typically, 10 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology.	In home E/M est. pt 10 mins.	99212
G9870	Remote in-home visit for the evaluation and management of an established patient for use only in the Medicare-approved Episode Payment Model—AMI, CABG, or SHFFT model, which requires at least 2 of the following 3 key components: • An expanded problem focused history; • An expanded problem focused examination; • Medical decision making of low complexity, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology.	In home E/M est. pt 15 mins.	99213
G9871	Remote in-home visit for the evaluation and management of an established patient for use only in the Medicare-approved Episode Payment Model—AMI, CABG, or SHFFT model, which requires at least 2 of the following 3 key components: • A detailed history; • A detailed examination; • Medical decision making of moderate complexity, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of moderate to high severity. Typically, 25 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology.	In home E/M est. pt 25 mins.	99214

TABLE 50—HCPCS CODES FOR TELEHEALTH VISITS FOR EPM BENEFICIARIES IN HOME OR PLACE OF RESIDENCE—Continued

Code number	Long descriptor	Short descriptor	Work and MP RVUs equal to those of the corresponding office/outpatient E/M visit CPT code for same calendar year under the PFS
G9872	Remote in-home visit for the evaluation and management of an established patient for use only in the Medicare-approved Episode Payment Model—AMI, CABG, or SHFFT model, which requires at least 2 of the following 3 key components: • A comprehensive history; • A comprehensive examination; • Medical decision making of high complexity, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology.	In home E/M est. pt 40 mins.	99215

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, within a short period of time (generally 30 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 final rule, we are revising the effective date of the waiver of the SNF 3-day rule for the CJR model, and we are stating that participant hospitals may begin using the waiver for episodes that begin on or after January 1, 2017.

We proposed EPM payment policies, similar to CJR payment policies 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 finalized in this final 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 final rule.

Because of the potential benefits we see for participating EPM hospitals, their provider partners, and beneficiaries, we proposed 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 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 proposed to use our authority under section 1115A of the Act with respect to certain SNFs that furnish Medicare Part A post-hospital extended care services to beneficiaries included in an 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 did not propose 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 proposed 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 final 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 the EPMs being finalized in this final 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 proposed 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.[134] 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 we proposed as eligible for selection for the AMI and CABG models in the 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 proposed 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 proposed 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 final rule, we believe some program and patient outcome vulnerabilities may exist with adopting 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 47). Most AMI beneficiaries, regardless of AMI medical treatment or PCI treatment for AMI, are 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 proposed 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 proposed 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

[134] *www.medicare.gov/NursingHomeCompare/*

communication with the EPM participant to ensure that the beneficiary is in the model at the time the waiver is used. We proposed that where the beneficiary would be eligible for inclusion in 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 47), 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 did not propose 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 47), 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.[135] 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 proposed 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 sought 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.

The following is a summary of the comments received and our responses.

Comment: Commenters generally supported the proposal to allow EPM beneficiaries to be discharged to a SNF after less than a 3-day inpatient hospital stay, though one commenter recommended CMS not adopt its proposal to permit EPM participants under any condition to waive the SNF 3-Day Stay Rule when referring EPM beneficiaries to a SNF.

Commenters urged CMS to implement the waiver on July 1, 2017, rather than delaying until April 1, 2018 so that providers have an opportunity to use the waiver and redesign care pathways in ways that streamline and improve the quality of care before the measurement period begins for cost reconciliations.

One commenter was concerned that limiting the 3-day SNF waiver to discharges from the anchor hospitalization would be problematic if a patient is readmitted to a hospital during the 90-day post-discharge episode duration and subsequently needs SNF care. One commenter strongly suggested a broader waiver of the 3-day Rule for small and rural hospitals than CMS proposed.

A few commenters requested that CMS make the SNF waiver available regardless of the star rating of the admitting SNF. Some of these commenters acknowledged the rationale for a quality requirement for the admitting SNF but asserted that the proposed use of the star rating would not be appropriate for determining the quality requirement. A couple of commenters asserted that the overall star rating would not directly correlate to an AMI episode and would therefore not be predictive of which SNFs would be most capable of caring for AMI beneficiaries under the waiver. A few commenters recommended that CMS modify the proposed criteria of ''at least 3 stars'' to ''at least 3 stars overall OR at least 3 stars on both the staffing and quality measure components.'' Another commenter suggested the waiver apply only if the facility has a star-rating of four stars or above, while another commenter suggested the waiver apply to any SNF with a star rating of two stars or above. One commenter recommended that some allowance/methodology be developed to allow new SNFs that have not received a Star Rating to participate in the Waiver. Another commenter was concerned that the demand on SNFs with three or more stars will create capacity issues and limit the ability to discharge patients to those facilities, and a few commenters were concerned that the quality requirement would constrain beneficiary freedom of choice.

Response: In the CJR Final Rule, we responded to similar comments regarding the SNF waiver (80 FR 73456). As we discussed in the EPM proposed rule and the CJR Final Rule, an episode payment model like the CJR model or the EPM has the potential to mitigate the existing incentives under the Medicare program to overuse SNF benefits for beneficiaries, as well as to furnish many fragmented services that do not reflect significant coordinated attention to and management of complications following hospital discharge. The reduction of these incentives in an episode payment model lays the groundwork for offering participant hospitals greater flexibility around the parameters that determine SNF stay coverage. As discussed in the CJR Final Rule, we understand from many current BPCI Model 2 participants engaged in LEJR episodes that this waiver plays an important role in their care redesign efforts to streamline and improve the quality of care, as they work closely with their SNF partners.

Regarding the delay in availability of the 3-day rule waiver, we linked the proposed availability of the 3-day rule waiver to the downside risk of the EPM participant. Specifically, we stated in the proposed rule that since EPM participants had no downside risk during PY 1 (for discharges prior to April 1, 2018), we were concerned that participants may be more likely to discharge beneficiaries to SNFs early leading to increased episode spending for which the participant would bear no responsibility. Accordingly, we proposed to delay the availability of the 3-day rule waiver until PY 2 for discharges on or after April 1, 2018 and beyond.

In section III.D.2.c. of this final rule, based on comments requesting phased-in downside risk beginning later than we proposed for the EPM, we agreed that delaying the date by which participants would be required to assume downside risk would improve participants' ability to successfully achieve the goals of the models. Accordingly, we are finalizing the policy that EPM participants will not be required to assume downside risk until PY 3—that is, episodes ending on or after January 1, 2019, with anchor hospital discharges that occur on or after October 4, 2018 (90 days prior to January 1, 2019).

Consistent with linking the availability of the 3-day rule waiver to the participant's downside risk, for this final rule, we believe it is appropriate to delay the availability of the 3-day rule waiver until PY 3. For the purposes of implementing this waiver, we will allow the 3-day rule waiver for anchor hospital discharges that occur on or after October 4, 2018. We believe that implementing this waiver with an effective date for discharges that occur on or after October 4, 2018, rather than implementing this waiver with an effective date for episodes ending on or

[135] *http://www.ncbi.nlm.nih.gov/pubmed/19817664.*

after January 1, 2019, provides clarity to the anchor hospital and the recipient SNF whether the waiver applies to SNF services furnished to a particular beneficiary. We believe this clarity is important to help ensure compliance with the conditions of the waiver and also improves our ability to operationally monitor waivers for misuse.

Also, we are allowing participants to voluntarily elect downside risk for episodes ending on or after January 1, 2018 (PY 2). However, we will not provide the waiver for those participants who elect voluntary early downside risk in PY 2. It is operationally infeasible for us to first allow use of the waiver in different years for different EPM participants. We expect that most participants will not elect early downside risk, because we do not expect to have more robust risk-adjustment in place until performance year 3. Regarding responses to other 3-day rule comments, we believe that limiting the 3-day SNF waiver to discharges from the anchor hospitalization at an EPM participant is appropriate as the care redesign needed to support a clinically appropriate early discharge from an AMI anchor hospitalization would not necessarily support other types of hospital discharges that might occur during the course of an episode. We note that limiting use of the waiver to discharges from the anchor hospitalization does not preclude a beneficiary from receiving SNF care at other points during the 90-day episode. Medicare will continue to cover SNF stays for EPM beneficiaries who require SNF care and remain in the hospital 3 days or longer under all existing rules for Medicare coverage and payment of Part A-covered SNF services.

With respect to the use of the star rating as a quality requirement for the admitting SNF, we believe that our proposal to limit use of the SNF 3-day stay rule waiver to discharges of beneficiaries to SNFs with an overall rating of three stars or better provides sufficient and appropriate protection against premature hospital discharge, especially in the context of the financial and quality incentives under the model itself. As discussed in the CJR Final Rule (80 FR 73458) we believe it is appropriate to restrict access to the waiver in order to ensure SNF quality and, therefore, protect the beneficiary from potential harm that could arise from the financial incentives of an episode payment model. We continue to believe that SNF overall ratings reflect important differences in quality among SNFs that are applicable to care of EPM beneficiaries. With respect to beneficiary choice, we note that imposing conditions upon a waiver to limit its use is not the same as restricting access to certain SNFs that would continue to be available to beneficiaries after a qualifying 3-day inpatient stay. Medicare will continue to cover SNF stays for EPM beneficiaries who require SNF care and remain in the hospital 3 days or longer under all existing rules for Medicare coverage and payment of Part A-covered SNF services, and these rules do not include a star rating requirement. In this way, the EPM waiver of the SNF 3-day stay rule is an extension of existing coverage for a Part A-covered SNF stay, and is not a limit to it.

Comment: Some commenters believed that 3-day rule waiver should apply to the CABG and SHFFT models in addition to the AMI model. Some of these commenters asserted that the waiver should be available for all clinical episodes under the EPMs, with participant hospitals given the flexibility to evaluate on a case-by-cases basis when early discharge to a SNF is clinically appropriate and the SNF services are medically necessary, with some recommending that CMS also implement the SNF 3-day rule waiver for Medicare Advantage Organizations and all Shared Savings Program ACOs.

Response: As discussed in the proposed rule, to mitigate program and patient outcome vulnerabilities that may exist with adopting the waiver of the SNF 3-day rule, we believe it will be necessary to determine if this waiver applies to EPMs on a model-specific basis. Based on our analysis of data discussed in section III.J.3. of this final rule, we continue to believe the 3-day rule waiver should not be applied to CABG and SHFFT model beneficiaries, given the typical severity of their clinical conditions treated with surgery that is followed by relatively lengthy inpatient hospital care. We will continue to monitor this waiver during the EPM testing to determine if modification of this limited waiver is warranted. We note that recommendations regarding the waivers under Medicare programs other than the EPM or CJR model are out of scope of this rule.

Comment: One commenter recommended that instead of requiring SNF to insert a Treatment Authorization Code on the claim for a beneficiary in the model where the SNF seeks to the use the waiver, CMS should provide SNFs with reference numbers for EPM beneficiaries that are eligible to receive services under the waiver, similar to the list that CMS provides to ACOs under the Shared Savings Program.

Response: Under the Shared Savings Program, beneficiaries are attributed to an ACO and CMS can compile and provide ACOs with a beneficiary assignment list for the performance year. In contrast, EPM episodes are triggered by admission to an EPM participant that results in discharge from an anchor hospitalization for a specified surgery or clinical condition, and it would not be practical or timely for CMS to compile and disseminate a prospective list of EPM beneficiaries that would be available to SNFs upon SNF admission.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, with modification to waive the SNF 3-day rule for AMI episodes for discharges from anchor hospitalizations that occur on or after October 4, 2018, without modification of the SNF quality requirements. We will waive the SNF 3-day rule for a beneficiary who is an AMI model beneficiary on the date of discharge from the anchor hospitalization only if the SNF is qualified at the time of the AMI model beneficiary's SNF admission. We define a qualified SNF as one that has an overall rating of three stars or better in the Five-Star Quality Rating System for SNFs on the Nursing Home Compare Web site for at least 7 of the 12 preceding months, as determined by CMS based on the most recent rolling 12 months of SNF star rating data available for the calendar quarter that includes the date of the beneficiary's admission to the SNF. We will post the list of qualified SNFs quarterly to the CMS Web site. If a SNF is on this list, the other requirements for the waiver as listed previously are met, and other existing Medicare coverage requirements are met, the SNF stay for the AMI model beneficiary will be covered under Part A under the AMI model SNF 3-day rule waiver.

The SNF would insert a Treatment Authorization Code on the claim for a beneficiary in the AMI 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 AMI model participant to ensure that the beneficiary is in the model at the time the waiver is used. Where the beneficiary is an AMI model beneficiary on the date of discharge from an anchor hospitalization, 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.

All other Medicare rules for coverage and payment of Part A-covered SNF services continue to apply. The waiver of the SNF 3-day rule is set forth at § 512.610.

b. Additional Beneficiary Protections Under the SNF 3-Day Stay Rule Waiver

For those specific proposed EPMs, where we proposed to allow the SNF 3-day rule waiver, we proposed beneficiary protections against financial liability in addition to the beneficiary protections discussed elsewhere in this final 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 noted 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.

As discussed in section V.N. of this final rule, for the CJR model we proposed to cover services furnished under the SNF waiver at § 510.610 when the information available to the provider at the time the services under the SNF waiver were furnished indicated that the beneficiary was included in the CJR model (see 81 FR 50968 through 50971). Similarly for EPM, we proposed to cover services furnished under the SNF waiver at proposed § 512.61 when the information available to the provider at the time the services furnished under the SNF waiver were furnished indicated that the beneficiary was included in the CJR model (see 81 FR 50941 through 50943).

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.

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 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 the beneficiary is not provided a discharge planning notice, as described in proposed § 512.450(b). Another scenario would be where the EPM participant applies the SNF 3-day rule waiver for episodes that begin prior to April 1, 2018, when this waiver is not applicable (as proposed), and payment to the qualified SNF for furnishing Medicare covered SNF services is denied. A third scenario would be if an EPM participant applies the SNF 3-day rule waiver for a specific proposed EPM where the waiver is not allowed, such as under the CABG and SHFFT episodes in this final rule. In any of these circumstances, we assume the EPM participant'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. In the proposed rule, we stated our belief that it is appropriate to adopt a similar

policy under the EPMs. In contrast to the Next Generation ACO Model, however, we stated our belief that it was most appropriate to hold the EPM participants financially responsible for misusing the waiver in situations where waiver requirements are not met, because EPM participants are required to be aware of the 3-day waiver requirements. EPM participants 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.

We proposed that EPM participants 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. We proposed that EPM participants are required to ensure the waiver requirements of proposed § 512.610 (a) and (b) are met. Therefore, in the proposed rule we stated our belief that it is reasonable that the ultimate responsibility and liability for a non-covered SNF stay should rest with the EPM participant. 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 proposed 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 proposed if, subsequent to an EPM participant applying the SNF 3-day rule waiver, we determine that the following waiver requirements were not met then the EPM participant will be financially liable for the SNF stay:

- The EPM participant discharges a beneficiary that is in a specific EPM where the SNF 3-day rule waiver does not apply.
- The EPM participant discharges a beneficiary prior to April 1, 2018 (as proposed), where the SNF 3-day rule waiver does not apply.
- The EPM participant 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 proposed 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 non-covered SNF services furnished during the SNF stay.

In addition, if the EPM participant discharges an EPM 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 EPM 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 EPM participant of liability. However, we are requiring EPM participants to keep a record of discharge planning notice distribution to EPM beneficiaries. We will monitor EPM participants' 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 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. We will communicate with hospitals and SNFs about how a hospital would pay SNFs for non-qualifying services provided.

We sought comment on these proposals. Specifically, we sought comment on whether it is reasonable to: (a) Cover services furnished under the SNF waiver based on the EPM participant'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 financially responsible for rejected SNF claims as a result of lack of a qualifying inpatient hospital stay in cases where the EPM participant discharges a beneficiary to a SNF that did not qualify for waiver use and did not provide the beneficiary with a discharge planning notice. We sought comment on whether SNFs instead of, or in addition to, the EPM participant should be held liable for such claims and under what circumstances. Finally, we sought comment on any other related issues that we should consider in connection with these proposals 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.

The following is a summary of the comments received and our responses.

Comment: Many commenters expressed support for CMS' proposal to cover services furnished under the SNF waiver based on an EPM participant's knowledge of beneficiary eligibility for the EPM at the time the services under the waiver were furnished. A few commenters sought clarification whether CMS was proposing this policy for both the CJR model and the EPM, though these same commenters expressed their support and asserted that the same protection should be extended to both CJR and EPM beneficiaries.

Response: We appreciate commenters' support for this proposed policy. We will finalize our proposal to cover services furnished under the SNF waiver based on the EPM participant'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. We refer readers to section V.N. of this final rule for a discussion of the additional beneficiary protections under the SNF 3-day stay rule waiver for CJR beneficiaries.

Comment: Commenters agreed that beneficiaries should not be charged for non-covered SNF charges in instances where the EPM participant discharges a beneficiary to a SNF that did not qualify for waiver use and did not provide the beneficiary with a discharge planning notice. Some commenters asserted that hospitals should not be solely responsible for non-covered SNF services resulting from discharging a beneficiary to a SNF that does not meet the quality requirement as it is challenging for hospitals to keep track of changes in SNF ratings or to identify EPM beneficiaries in a timely manner. A few of these commenters recommended that CMS provide EPM participants with a list of eligible SNFs on a quarterly or periodic basis.

A couple of commenters expressed concern that independent physicians could refer and admit a beneficiary to a SNF that does not meet the quality

requirement without including the hospital, yet the hospital would be financially liable for the non-covered SNF stay under the proposed policy. Some commenters suggested that the SNF should share in financial liability for non-covered SNF services related to misuse of the waiver as the SNF is providing and billing for these non-covered services, and CMS should consider ways in which it could ensure the SNFs take steps to ensure that patients discharged to the SNF with less than a 3-day inpatient stay qualify to receive services under the waiver.

Response: We appreciate commenters' support for our proposal that beneficiaries should not be charged for non-covered SNF charges in instances where the EPM participant discharges a beneficiary to a SNF that did not qualify for waiver use and did not provide the beneficiary with a discharge planning notice.

As discussed in the previous section, we proposed that to be qualified under the SNF 3-day rule waiver a 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, and we proposed to post on the CMS Web site the list of qualified SNFs in advance of the calendar quarter.

As discussed in the previous section, the waiver of the SNF 3-day rule only applies to circumstances where the beneficiary is medically appropriate for discharge and requires a SNF stay after less than a 3-day inpatient hospital stay. Medicare will continue to cover SNF stays for EPM beneficiaries who require SNF care and remain in the hospital 3 days or longer under all existing rules for Medicare coverage and payment of Part A-covered SNF services, and these rules do not include a star rating requirement. In this way, the EPM waiver of the SNF 3-day stay rule is an extension of existing coverage for a Part A-covered SNF stay, and is not a limit to it. An EPM participant that believes it is incapable of identifying qualifying SNFs or EPM beneficiaries is not required to use the waiver.

As discussed in the previous section, the waiver provides EPM participants with additional flexibilities to redesign care in order to maximize quality and efficiency, as well as reduce episode spending and generate hospital internal cost savings. Therefore, we believe that it is appropriate to hold the EPM participants financially responsible for misusing the waiver in situations where waiver requirements are not met.

We acknowledge that an independent physician might refer a beneficiary to a SNF that does not qualify under the waiver. However, we believe that the established process for discharge planning would typically involve the hospital. EPM participants are required to be aware of the 3-day waiver requirements, and the EPM participants will make the decision as to whether it is appropriate to discharge a beneficiary without a 3-day stay. We note that if the beneficiary chooses a SNF that does not qualify under the waiver based on a physician's recommendation and the hospital provides proper notification of non-coverage, the beneficiary would be financially liable for the SNF stay, while the EPM participant would not be financially liable for the SNF stay.

We considered the suggestions of commenters that SNFs share in financial liability for non-covered SNF services related to the waiver of the SNF 3-day rule under the proposed EPMs. EPM participants are required to be aware of the 3-day waiver requirements. SNFs are not EPM participants, and we believe that SNFs will rely upon the hospital, as the EPM participant, to determine whether use of the waiver is appropriate. As we gain experience with the EPM, we may revisit this issue in future rulemaking.

Comment: One commenter suggested that CMS assume responsibility for providing the beneficiary notice as an objective, informed and trusted voice in this process. Another commenter requested that CMS provide clarification as to what an EPM participant needs to maintain as documentation showing the hospital has provided the proper discharge notice to the patient prior to discharge, which would absolve the EPM participant of financial liability if the SNF waiver is not appropriate. One commenter recommended that CMS require EPM participant to inform beneficiaries of their options, including (1) waiving the 3-day hospital stay and going to a 3-star or higher rated SNF with no additional financial consequences for the beneficiary; (2) beneficiary can opt to stay in the hospital the full 3 days and then select a SNF of their choosing regardless of star status; or (3) beneficiary can accept the 3-day stay waiver and choose any SNF understanding that they are liable for the full cost of that care, as it would not be a Medicare eligible expense. One commenter urged CMS to modify its proposal so that beneficiaries are held harmless for non-covered SNF services for which they are referred by the originating hospital, regardless of whether a discharge planning notice is provided.

Response: As discussed in section III.G. of this final rule, hospitals are required to provide beneficiaries with written notification of their post-acute care options upon discharge. Given the existing relationship between the hospital and the patient, and the hospital's established role in discharge planning, we believe that it is appropriate to require the EPM participant to provide beneficiaries with written notification if the EPM participant makes any referrals for non-covered services as part of the discharge planning process. We do not believe that it would be practical or consistent with existing Medicare policy for CMS to provide the beneficiary with notice at time of discharge if the SNF waiver is not appropriate and the services would not be covered. With respect to the commenter's suggested approach for notifying the beneficiary of the range of options available post-discharge, we refer to section III.G. of this final rule for discussion of discharge planning requirements for EPM participants and the essential elements that are required for proper beneficiary notification.

Comment: One commenter was concerned that the proposal does not address cases in which Medicare accepts a beneficiary's appeal of Medicare Provider Non-Coverage after the discharging physician determined not to certify that patient for Skilled Nursing Facility (''SNF'') care. The commenter believes that CMS should not penalize EPM participant for cases where Medicare allowed an appeal.

Response: Under this proposal, if the EPM participant provides the beneficiary with proper notification that the SNF stay would not be covered, the hospital would not be financially liable for the non-covered SNF stay regardless of the results of a beneficiary's appeal of Medicare Provider Non-Coverage.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to cover services furnished under the SNF waiver based on the EPM participant'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. We are also finalizing the proposal, without modification, to hold the EPM participant financially responsible for rejected SNF claims if an EPM 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 EPM participant has failed to provide a discharge planning notice as specified in § 512.450(b)(3). Specifically, if subsequent to an EPM participant applying the SNF 3-day rule waiver, we determine that the following

waiver requirements were not met then the EPM participant will be financially liable for the SNF stay:

- The EPM participant discharges a beneficiary that is in a specific EPM where the SNF 3-day rule waiver does not apply.
- The EPM anchor hospital discharges a beneficiary prior to October 4, 2018 (as finalized in section III.J.6.a. of this final rule), where the SNF 3-day rule waiver does not apply.
- The EPM participant 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)(3), to the beneficiary alerting them of potential financial liability.

In these preceding instances, we proposed 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 non-covered SNF services furnished during the SNF stay.

The final policies for financial liability for non-covered SNF services provided due to incorrect application of the SNF 3-day rule waiver are set forth in § 512.610(c).

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 final 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 proposed to waive requirements of the Act for all Medicare Part A and Part B payment systems only to the extent necessary to make reconciliation payments or receive repayments based on the NPRA that reflect the episode payment methodology under 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 sought comment on our proposed waivers related to repayment and recoupment actions as a result of the NPRA calculated.

We did not receive any comments suggesting changes to this waiver thus, we are finalizing the proposal, without modification, to waive requirements of the Act for all Medicare Part A and Part B payment systems only to the extent necessary to make reconciliation payments or receive repayments based on the NPRA that reflect the episode payment methodology under this proposed payment model for EPM participants selected in accordance with CMS's proposed selection methodology. In addition, 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 EPM beneficiaries and aggregated to determine actual episode spending in the calculation of the NPRA. We therefore are waiving 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. The waiver of deductible and coinsurance that otherwise apply to reconciliation payments or repayments is set forth at § 512.620.

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 final rule, we are making 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 proposed 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 proposed to specifically exclude the medical director function from this waiver. In addition, we proposed that all other definitions and requirements related to a physician or supervising physician under § 410.49 continue to apply. We proposed to codify this waiver at § 512.630.

For an EPM beneficiary in an AMI or CABG episode, we proposed that this 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 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 model beneficiaries and providers or suppliers of CR and ICR services. We solicited 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 propose any additional waivers to the CR/ICR program requirements in this final rule. We solicited 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 waivers.

The following is a summary of the comments received and our responses.

Comment: Many commenters expressed appreciation and support for the proposed waiver, though a number of commenters stated that implementing this kind of regulatory flexibility for only a subset of CR/ICR patients that are AMI and CABG beneficiaries in the CR/ICR program would have limited impact on increasing the availability of CR/ICR services. The commenters observed that providers and suppliers of CR/ICR services still would have to comply with physician supervision requirements for patients other than AMI and CABG beneficiaries. As a result, the added flexibility will not occur in practice, limiting its intended effect. Thus, the commenters recommend implementation of a site-specific rather than a condition-specific physician supervision waiver which should be extended to all Medicare beneficiaries receiving CR/ICR services at designated institutions.

Some commenters recommended that CMS consider applying this waiver to all CR and ICR programs, including those in the control groups, as it would benefit the entire Medicare patient population. Some of these commenters asserted that the effects of the waiver and the incentive payment will be confounded in the EPMs and CR incentive payment model as proposed, while extending the waiver to all CR/ICR programs would allow CMS to isolate the impact of the EPMs and CR incentive payment on model participants.

Response: We appreciate the commenters' interest in ensuring the availability of CR/ICR services for AMI and CABG model beneficiaries, including those beneficiaries who would also be in the CR incentive payment model. We proposed a waiver that 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 a provider or supplier of CR and ICR services furnished to an AMI or CABG beneficiary during an AMI or CABG episode. We appreciate that as proposed for AMI and CABG beneficiaries alone, the physician functions of prescribing exercise and establishing, reviewing, and signing an individualized treatment plan for a provider or supplier of CR and ICR services are individual beneficiary-specific actions. In other words, a nonphysician practitioner can prescribe the exercise and sign an individualized CR/ICR treatment plan for an AMI or CABG beneficiary as part of that beneficiary's care, with no relationship to the other Medicare beneficiaries not in the AMI or CABG model but receiving CR/ICR services for whom these two individual activities would continue to be required to be performed by a physician. Therefore, the waiver to allow a nonphysician practitioner to perform these two physician functions should be useful for AMI and CABG beneficiaries to facilitate timely referral and initiation of CR/ICR services.

We acknowledge that the third physician function that we proposed to waive, specifically that of physician supervision for CR/ICR services, to allow a nonphysician practitioner to supervise CR/ICR services for AMI and CABG beneficiaries is a different circumstance. Our understanding is that most CR/ICR programs operate during hours where multiple patients receive treatment in the CR/ICR program during the same period of time, all supervised by one physician while the beneficiaries' care is being furnished by clinical staff of the program. Therefore, it may be challenging for providers and suppliers of CR/ICR services to actually make meaningful use of the waiver of the physician supervision requirement for CR/ICR services furnished to AMI and CABG beneficiaries during operating hours of a CR/ICR program where other patients are also being seen who still require physician supervision.

As the commenters pointed out, we also appreciate that providing a site-specific waiver of physician supervision for CR/ICR services to allow a nonphysician practitioner to supervise these services in a CR/ICR program at that site could provide more meaningful flexibilities that could expand the availability of CR/ICR services for AMI and CABG beneficiaries, consistent with our rationale for proposing this waiver. However, while some commenters arguing in favor of CR/ICR site-specific waivers of the physician supervision function, rather than the proposed limitation of the waiver only to AMI and CABG beneficiaries, recommended that we provide the waiver for CR/ICR services at specific institutions, AMI and CABG beneficiaries have complete freedom of choice to obtain care from

any provider or supplier throughout AMI and CABG episodes, as discussed in section III.G.2. of this final rule. Therefore, we are not confident that we could identify specific institutions for a site-specific CR/ICR physician supervision waiver and still preserve AMI and CABG beneficiary freedom of choice of providers and suppliers, if certain institutions were afforded the opportunity under the AMI and CABG models to furnish CR/ICR services with more flexibility to AMI and CABG beneficiaries and others were not.

The other possibility we considered in response to commenters' concerns was providing the waiver of physician supervision to any CR/ICR site where an AMI or CABG beneficiary was being treated, an approach that would provide the same flexibilities regarding CR/ICR services to any CR/ICR provider or supplier chosen by the AMI or CABG beneficiary, thereby not interfering with beneficiary freedom of choice. However, this latter scenario would greatly expand the CR/ICR physician supervision waiver by potentially applying it to the CR/ICR services furnished to a large number of Medicare beneficiaries who are not in the AMI or CABG model just because they are being treated in the same CR/ICR program as even a single AMI or CABG beneficiary. While some commenters urged us to apply the proposed CR/ICR physician supervision waiver to all CR/ICR programs, including those in the AMI and CABG model control groups, based on their rationale that it would benefit the entire Medicare patient population, we may only provide waivers that are necessary to test the AMI and CABG models with regard to the cost and quality of care for AMI and CABG beneficiaries, not those that we believe would benefit all Medicare beneficiaries. Therefore, we do not believe such an expansion is necessary to test the AMI and CABG models.

We continue to believe that the proposed waiver that 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 a provider or supplier of CR and ICR services furnished to an AMI or CABG beneficiary during an AMI or CABG episode is a waiver that is necessary to test the AMI and CABG models. At this time, we will not modify the proposed waiver to expand the waiver of the CR/ICR physician supervision requirement to any beneficiaries that are not in AMI or CABG episodes. We will continue to seek input from AMI and CABG model participants, including those who are also EPM–CR participants, throughout implementation of the models and may consider making future proposals if we observe that limited availability of CR/ICR services is affecting beneficiaries' access to CR/ICR services under the models.

Comment: Some commenters expressed their support for a current legislative bill that would expand access to cardiac rehabilitation by allowing physicians assistants, nurse practitioners and clinical nurse specialists to supervise cardiac, intensive cardiac and pulmonary rehabilitation programs. The commenters requested that CMS provide Congress with data from the AMI and CABG models that support the value of cardiac rehabilitation.

Response: Upon receiving a specific request from Congress, the Secretary will provide the necessary technical assistance.

Comment: Some commenters sought clarification whether the proposed waiver would allow nonphysician practitioners to independently refer, that is, sign the order for CR/ICR services, per state scope of practice laws, therefore directly addressing the delay between hospital discharge, referral, and enrollment into CR/ICR services.

Response: The waiver of physician definition for prescribing exercise would allow nonphysician practitioners to independently sign the order for CR/ICR services, subject to state scope of practice laws.

Comment: A few commenters recommended that CMS extend the waiver to allow qualified nonphysician practitioners to perform the functions of a Medical Director for a provider or supplier of CR or ICR services.

Response: We do not believe that extending the waiver to cover the functions of the Medical Director is medically appropriate for testing the AMI and CABG models.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, 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. The waiver of physician definition for furnishing cardiac rehabilitation and intensive cardiac rehabilitation services to an EPM beneficiary is set forth at § 512.630.

K. Data Sharing

1. Overview

In section III.D.2. (81 FR 50843 through 50845) of the proposed rule, we proposed 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 models during the inpatient hospitalization and 90 days post-discharge. Consistent with the CJR model, we proposed retrospective bundled payment models that would 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 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 were given the ability to request historical claims data of beneficiaries aligned with the particular Pioneer ACO entity. (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, in the proposed rule, we proposed 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 (81 FR 50944 through 50946). Given that we also proposed to incorporate regional pricing in the calculation of benchmark and quality-adjusted target prices, we also proposed to provide EPM participants with aggregate regional data (81 FR 50945). Our proposal to make these data available to EPM participants was included in § 512.350. We note that, consistent with CJR, the EPM participant with which 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 proposed in section III.B.1. of the proposed rule (81 FR 50813) that some of the hospitals participating in CJR would also participate in the proposed EPMs. We requested 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.

The following is a summary of the comments received and our responses.

Comment: Some commenters requested that CMS explicitly encourage the use of health IT to allow clinicians to communicate across settings of care. A commenter further suggested that CMS encourage post-acute care adoption of health information technology through incentives. The commenter stated that to date, there has not been a focus on post-acute care health information technology adoption or any standardization of data sharing platforms for clinical, financial or patient experience data between acute and post-acute care providers.

Response: While we do not explicitly require the use of health information exchange mechanisms in this final rule for all proposed EPM tracks, we do encourage EPM participants to collaborate with their post-acute care providers in their care redesign and to the extent that health information technology (health IT) is useful to that end we would encourage its use. Providing incentives for such use is beyond the scope of this final rule but in the evaluation of the EPMs we will certainly look to see the impact that health IT has on care coordination to the extent that participants use health IT to communicate with their preferred post-acute care providers.

2. Beneficiary Claims Data

As we stated in the proposed rule, 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 proposed 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 (81 FR 50944–50945).

First, for EPM participants that lack the capacity to analyze raw claims data, we proposed to provide summary beneficiary claims data reports on beneficiaries' use of health care services during the baseline and performance periods 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 reflected that, relative to their peers, a certain provider was 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 proposed 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 proposed 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 proposed 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 information 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 proposed 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 was included in § 512.350. Further, CMS would 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 requested comments on this proposal.

The following is a summary of the comments received and our responses.

Comment: Commenters overwhelmingly supported our proposal to make data, in the form of raw claims and summary format, available upon request. Multiple commenters stated that meaningful and accurate data is a necessity for success under the CJR model and will be critical to success under the proposed EPMs. However, some commenters had suggestions on how to improve the data that we proposed to provide based on their experiences with other CMS models such as CJR and BPCI. These commenters stated that they have heard from multiple BPCI and CJR participants that there is a need for more sophisticated data in order to better understand performance and opportunities for improvement. They also stated that the data shared to date in CJR is resource-intensive to interpret and is not always actionable and that improved claims data quality would help EPM participants. Another commenter agreed that CMS should improve the quality of reports it provides hospitals. They noted that many hospitals do not have the capability to manipulate claims level data in house nor can they afford to purchase that capability. The commenters stated that CMS has clearly indicated it is moving toward longitudinal payment models and that CMS contractors therefore need to develop standardized reporting capabilities (and reports) that will fully support providers.

Response: Based on our experience on other CMS models like BPCI and CJR and feedback we have received through learning events, affinity groups, and collaboration site discussion boards, we generally believe we have proposed to make available the relevant data needed to succeed in the EPMs. However, we will take these comments into consideration when creating the data feeds for the new models. We will also work with our contractors to standardize, refine, and improve the data we disseminate to better inform providers.

Comment: Multiple commenters stressed the importance of data reliability and accuracy. A few commenters currently participating in CJR stated that the data files they receive are unwieldy to work with, contain errors, and are not delivered in a timely manner, further delaying analysis and results calculation. Another commenter stated that some of the files were difficult for some smaller hospitals to analyze and that the hospitals that could analyze the data found the data to be incomplete in many cases and inconsistent with the hospital's own data. A commenter further suggested that for the EPMs, CMS should institute and enforce service level agreements (SLA) with its contractors that dictate acceptable time frames in which to provide EPM participants with accurate, complete data files. In addition, they suggested that CMS needs to create an EPM ombudsman who will serve as the conduit for complaints from providers regarding data and that the ombudsman should be responsible for determining whether the contractor is in violation of the SLA and subject to penalty.

Response: We appreciate the need for accurate, complete, and timely data and intend, to the extent feasible and appropriate, to build quality assurance tasks into the statement(s) of work for the payment contractor(s) we engage to perform the payment analysis, reporting and data file preparation. We will also work to enhance the underlying IT structure and systems to assist in resolving file load and transfer times. We will work with our contractors to ensure they are delivering accurate and complete data in a timely manner according to the terms of their contracts and to ensure that they have quality assurance protocols in place to run on the data in advance of the file releases. Likewise, consistent with the terms of their contracts, we will take appropriate corrective actions with contractors where performance falls short of expectations. While the models have not yet been implemented, we have no

reason to expect that contractor performance should fall short of expectations and thus do not anticipate a need for a special ombudsman to address data complaints and assess penalties. We will establish an open communication system with EPM participants so that they can immediately bring any issues surrounding file or data quality to our attention so that we can investigate and resolve problems quickly should they arise.

Comment: Another commenter encouraged CMS to use master data management technology to ensure correct patient-provider alignment across programs to ensure quality, timeliness, and proper assigning of data.

Response: We appreciate this comment and will explore options for incorporating this technology with our contractors.

Comment: A commenter requested that CMS consider adding hierarchical condition category (HCC) risk scores to the data files, citing that they may help EPM participants identify outliers and patients requiring more intense services.

Response: At this time, we do not plan to add HCC risk scores to the data files we will provide because we do not believe they are necessary data elements for EPM participants to conduct day-to-day operations in the EPMs given the current structure of the EPM models and payment calculations. Therefore, those data elements would not meet the HIPAA Privacy Rule's ''minimum necessary'' standard, which applies to ''health care operations'' disclosures.

Comment: A commenter, who stated that they are a current CJR participant, noted the difficulties in mining the data they received to exclude BPCI episodes and other cancelled episodes. They added that participants need to ensure they are identifying every patient whose care is included in the bundle and to confirm those patients were moved into cost-effective care coordination pathways.

Response: We appreciate this comment and we plan to explore adding indicators to the beneficiary-identifiable claims data supplied to EPM participants that will provide information about circumstances that could result in EPM episode cancellation, such as admission of a beneficiary to a hospital that initiates episodes under BPCI for care that could potentially cancel an EPM episode. To the extent that adding such indicators to the claims data is feasible, providing this information through the claims data to EPM participants would ensure that EPM participants are informed as frequently as quarterly about circumstances that could result in EPM episode cancellation. We also note that at reconciliation, complete information would be provided to EPM participants about those episodes that were ultimately included in the participant's reconciliation report as discussed in section III.D.5. of this final rule. Additional discussion on this can be found in sections III.C.4. (EPM Episodes) and III.D.6. (Adjustments for Overlaps) of this final rule.

Comment: We received some comments expressing concerns with the logistics of receiving EPM data from some participants with past experience in CJR. A few of these commenters recommended that CMS ensure appropriate processes are in place for the proposed EPMs to ensure that providers will actually be able to access data when needed. Another commenter also provided some specific examples of improvements that could be made to the data delivery process to improve efficiency for users that may work with multiple EPM hospitals and models. Some examples include a mechanism to download multiple sets of files simultaneously, delivering the data through a secure FTP site, and providing accurate file layouts before data is released. In addition, they requested specific points of contact for hospital systems participating in EPM for issues related to data dissemination.

Response: We appreciate these comments and will take them into consideration when developing the data dissemination process and creating the data portal for the EPMs. We will provide EPM participants with specific points of contact for data issues at the time they register for their portal account access.

Comment: Some commenters also expressed that they are sensitive to the increasing volume of requests that CMS is likely experiencing in parallel with expanding care and payment redesign models, and they encouraged CMS to carefully consider how potential backlogs and delays in data availability may impact the target implementation date.

Response: We appreciate this comment and understand this concern. We realize that timely access to data prior to model implementation is important to model participants and will work with our contractors and other CMS components to disseminate data as soon as feasible once the final rule is published.

Comment: A commenter cited CMS' interpretation of Section 105(b) of MACRA (Pub. L. 114–10—see 81 FR 44471 for CMS interpretation) and requested that CMS provide qualified clinical data registries (QCDRs) with access to Medicare data for purposes of linking such data with clinical outcomes data and performing scientifically valid analysis or research to support quality improvement or patient safety. In addition, they encouraged CMS to indicate ''fact of death'' by matching Medicare claims data with Social Security Death Masterfile (SSDMF) death data (or another source of vital statistics) before providing it to QCDRs.

Response: We believe these comments are outside the scope of this final rule, but we would encourage QCDRs to contact ResDAC for more information on requesting the files they desire at: *http://www.resdac.org/cms-data/request/cms-data-request-center*.

Comment: A few commenters also remarked on CMS' proposal to exclude individually identifiable data related to substance abuse from claims files as it currently does in other programs. Commenters noted that this information is key for hospitals to understand the full risk associated with patients and identify appropriate care management. Some comments suggested that CMS should provide cost and claim data for these services since hospitals will be forced to bear risk for these patients. A few commenters also requested that CMS provide the de-identified cost and claims data for these services and stated that if this is not possible CMS should, at a minimum, provide the aggregate payment amount for these services. Another commenter encouraged the Innovation Center to use its waiver authority to make beneficiary-specific claims-level substance abuse information available to hospitals. In addition, they recommended that CMS work with the Congress to create an exception to 42 CFR part 2 to provide beneficiary-specific claims level substance abuse information.

Response: Section 1115A of the Act does not authorize the waiver of the requirements under 42 CFR part 2. Moreover, our proposal to exclude this information is consistent with our treatment of these data in other similar CMS programs and models where providers must take on risk in managing the care of their beneficiaries, such as the Shared Savings Program and the BPCI initiative. We would note that, based on our experience to date, we are unaware of this policy being a significant impediment to the operations of these efforts. We also appreciate the suggestions to make these data available in a de-identified manner. We have considered this option and are not currently aware of a means to make de-identified beneficiary-specific data

available in a way that would provide useful information to participating hospitals without potentially making it possible to identify beneficiaries. Similarly, we have also not identified a way in which to make meaningful aggregate data available on a limited basis without potentially compromising beneficiary confidentiality. However, we will continue to consider these comments and the feasibility of making such data available in a way that is both meaningful to participating hospitals and in compliance with 42 CFR part 2.

Final Decision: After consideration of the public comments received, we are finalizing our proposals at § 512.350 (a) to make available to EPM participants, through the most appropriate means and in the manner described previously, summary and beneficiary-level claims data that CMS determines may be useful to EPM participants for purposes of the EPMs. We are also finalizing our proposal to exclude information that is subject to the regulations governing the confidentiality of alcohol and drug abuse patient records (42 CFR part 2) from any summary or beneficiary-level claims data shared with an EPM participant. CMS will make beneficiary-identifiable data available to an EPM participant in accordance with applicable privacy and security laws and established privacy and security protections 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.

3. Aggregate Regional Data

As discussed in section III.D.4.b.(6) (81 FR 50855 and 50856) of the proposed rule, we proposed 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 proposed EPMs, particularly our proposal to incorporate regional pricing data when establishing target prices under the model, we proposed 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 proposed 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 the proposed rule (81 FR 50829). This data would be provided at the regional level; that is, we proposed 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. We sought comments on our proposal to provide these data to EPM participants.

The following is a summary of the comments received and our responses.

Coment: We received comments supporting our proposal to provide the opportunity to request aggregate regional data that includes information about average episode spending. However, commenters also included several suggestions for how this data could be improved. A commenter stated that they believe this data can be made more actionable by including key utilization metrics such as—

- Percent of episodes with at least one readmission
- Percent of episodes that include skilled nursing facility (SNF) care
- Percent of episodes that include home health care
- Percent of episodes that include an inpatient rehabilitation (IP rehab) stay
- Index hospitalization average length of stay (ALOS)
- SNF ALOS for episodes that include SNF
- IP rehab ALOS for episodes that include IP rehab

They stated that these metrics would serve as benchmarks for EPM participants, and help identify opportunities for improvement and inform care intervention strategies.

Response: We appreciate the comments supporting our proposal to provide the opportunity to request aggregate regional data. In addition, we will continually work to improve the data we provide to EPM participants and we will explore the feasibility of including the additional utilization metrics suggested by the commenter in the aggregate regional data files.

Final Decision: After consideration of the public comments received, we are finalizing our proposal 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 for potential episode payment model AMI, CABG, and/or SHFFT episodes initiated in the U.S. Census Division where the EPM participant is located.

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.4.b.(3) of the proposed rule (81 FR 50854), episode benchmark prices would 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 proposed 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 believed 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 final rule. As we stated in the 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 proposed 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. of this final rule. Specifically, we proposed 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 requested comments on these proposals.

The following is a summary of the comments received and our responses.

Comment: We received many comments about the importance of providing timely data prior to the start of the model. Many commenters requested that CMS make historical and program design data available to EPM participants as soon as CMS is able to do so after the publication of the final rule. The commenters stated that they would need the data as early as possible in order to allow for enough time to review the data, to understand the needs and utilization patterns of the population, and to tailor interventions based on findings. They also stated that the data would help identify the facilities and provider types most frequently used by patients after discharge. In addition, commenters pointed out that early data would be essential for EPM participants to understand how their episodes compare to others in the region and where they stand at the start of the EPMs. A commenter recommended that CMS provide historical claims data a minimum of 6 months prior to the commencement of the models so as to allow providers the opportunity to analyze the data for care coordination opportunities, evaluate post-acute care providers for partnership opportunities, and negotiate risk-sharing arrangements. Another commenter further requested all the historical data used to set the target prices be provided to EPM participants by December 31, 2016 for a July 1, 2017 start date and that we also provide guidance and technical support to assist participants once this data is shared.

Response: We appreciate comments and understand the usefulness of these data to EPM participants' ability to understand and adjust their performance and partner with collaborators. We will make every effort to make this data available for request as soon as possible after the final rule is published while complying with applicable privacy and security laws. Additionally, we will provide guidance and technical support during the process to request, retrieve, and evaluate the data received.

Comment: A few commenters cited that data challenges, including the significant financial investment, time and complexities involved in developing and using the necessary infrastructure, along with substantial transaction fees for sharing health information necessitate a delay in the start of the EPMs. They went on to state that EPM participants should be provided data with at least as much preparatory time as BPCI participants.

Response: We appreciate these comments and again acknowledge the importance of providing timely access to data. As previously noted, we will work to make this data available for request as soon as feasible while complying with applicable privacy and security laws. To the extent that it may be relevant, we note that we have revised our proposal to begin downside risk across the board as of April 1, 2018. As discussed in detail in section III.D.2.c. of this final rule, we are finalizing an option to allow the voluntary selection of downside risk for performance year 2 and to extend our proposed date for required downside risk to performance year 3, which should provide participants with more lead time to understand their data prior to taking on 2 sided risk under the EPMs.

Final Decision: After consideration of the public comments received, we are finalizing our proposal, without modification to make 3 years of baseline data available to EPM participants and intend to make these data available to participants upon request prior to the start of the first episode payment model performance year (July 1, 2017) and in accordance with applicable privacy and security laws and established privacy and security protections. The 3-year period utilized for the baseline period matches the baseline data used to create EPM participants' episode benchmark prices. Specifically, the baseline beneficiary-level and summary data (both EPM participant-level and regional summary data) will be available for episodes that began January 1, 2013 through December 31, 2015.

5. Frequency and Period of Claims Data Updates for Sharing Beneficiary-Identifiable Claims Data During the Performance Period

As we stated in the proposed rule (81 FR 50946), 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.

As stated in the proposed rule, 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 proposed 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 (81 FR 50946). For each quarter and extending through June 30, 2018, we proposed that participants during that first year would receive data for up to the current quarter and all of the previous quarters going back to 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 noted 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 proposed 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' requirements to ensure the applicable HIPAA conditions for disclosure have been met. Also, consistent with our procedures for CJR, we proposed 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 proposed to eventually make these data available on as frequently as a monthly basis if practicable. In addition, we proposed that for an EPM participant to receive data on episode spending, they would 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 sought comments on this proposal.

The following is a summary of the comments received and our responses.

Comment: Many commenters were supportive of CMS' proposal to make data available as frequently as monthly if practical, but strongly encouraged the monthly release of the data to the EPM participants as soon as the EPMs are implemented, as opposed to quarterly. A commenter stated that a quarterly timeline would significantly delay EPM participants in identifying inefficiencies arising with regard to beneficiary utilization and noted that issues could occur in the continuum of care delivery and coordination. Another commenter indicated that monthly data is essential, especially at the beginning of the EPMs, and that the quarterly data has a lag so the initial file will contain mostly incomplete episodes. Other commenters referenced the BPCI initiative which currently provides monthly data to its Awardees.

Response: We appreciate these comments and realize that frequent data will assist many EPM participants that are selected for the EPMs. As proposed, we will work with our contractors to provide data monthly as opposed to quarterly as soon as it is feasible for us to do so.

Comment: We received some comments on providing reconciliation data and results more frequently than annually. Commenters referenced the quarterly reconciliation timelines in BPCI and one commenter stated that the quarterly results would allow providers to assess their performance and understand if care interventions are working, or need to be altered. Another commenter strongly encouraged CMS to provide EPM participants with quarterly updates for completed episodes through a mechanism similar to other Innovation Center initiatives.

Response: Based on our experience in BPCI, quarterly reconciliation can lead to large variation in NPRA and uncertainty for providers, in addition to being a very resource-intensive process for providers and CMS. While we understand that quarterly reconciliation results and data could be helpful for providers to assess their performance, we believe that the beneficiary claims data we plan to disseminate will allow providers to do this. Additionally we note that we will be working with our contractors to explore the feasibility of providing a high-level interim report on reconciliation status during the payment year which should help EPM participants assess how they are doing under the model. Therefore, as stated in section III.D.5. of this final rule, we plan to finalize our policy for annual reconciliation data and results in the same way we have done this for CJR. Additional discussion on this topic can be found in section III.D.5. of this final rule.

Comment: Commenters requested that data be made available automatically without a specific request for the data. These commenters noted the potential for additional administrative burden associated with requesting the data. A commenter recommended that an EPM participant should only need to register to receive data and provide the appropriate contact.

Response: We want to limit administrative burden for EPM participants participating in these models and wish to clarify that while we will make data available to EPM participants only upon request, participants would be able to make a single request for these data for each model prior to the start of the performance period and the data would be available to them for the duration of their participation or until they notify CMS that they no longer wish to receive these data. To be consistent with the HIPAA Privacy Rule's ''minimum necessary'' standard, we will continue to make data available only in response to a request.

Comment: Other commenters appreciated our proposal that EPM participants only need to make an initial single request rather than multiple periodic requests for data as this will impose less of an administrative burden on hospitals.

Response: We appreciate these comments.

Final Decision: After consideration of the public comments received, we are finalizing our proposal at § 512.350(b)(1) to provide up to 6 quarters of claims data (both summary and beneficiary-level) to EPM participants upon request and in accordance with applicable privacy and security laws. We are also finalizing our proposal that for an EPM participant to receive data on episode spending, they need only make a single initial request rather than multiple periodic requests. Additionally, we are finalizing our proposal to make these data available on a quarterly basis and as frequently as a monthly basis if practicable. Consistent with our proposal to make these data available as frequently as monthly if practicable, we are updating our proposal at § 512.350(b)(2) to provide that updated claims data will be made available not ''as frequently as on a quarterly basis throughout the EPM participant's participation,'' but instead ''no less frequently than on a quarterly basis.''

6. Legal Permission To Share Beneficiary-Identifiable Data

As we have stated previously (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 the disclosure. Here, the HIPAA Privacy Rule allows for the proposed disclosure of individually identifiable health information by CMS.

In the proposed rule, we proposed to make EPM participants financially responsible for services that may have occurred outside of the hospital during the 90-day post-discharge period (81 FR 50946). 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 the ''minimum necessary'' to accomplish the intended purpose of the use, disclosure or request (45 CFR 164.502(b)). We believe that the provision of the proposed data elements listed previously would constitute the minimum data necessary to accomplish the 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 final 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 the proposed rule, we proposed 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 (81 FR 50947). 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 sought comments on our proposals regarding the authority to share beneficiary-identifiable data.

The following is a summary of the comments received and our responses.

Comment: Multiple commenters agreed with our proposals to provide EPM participants with the opportunity to request 3 years of historical or baseline data prior to the start of the first EPM performance year. However, some commenters requested that CMS make this data available to all hospitals regardless of whether they located in a randomly selected MSA or not. A commenter pointed out that because there is not a voluntary avenue for participation in these proposed models by hospitals that are not included in the selected MSAs, such hospitals could face a competitive disadvantage by not being provided the same kinds of financial and performance data as hospitals that are included in these EPMs. Other commenters requested that CMS begin providing data to all hospitals so that they may begin to understand their patients clinical care paths, episode spending, and compare themselves to their peers.

Response: We appreciate the comments supporting our proposal to make 3 years of historical or baseline data available to EPM participants. For hospitals that are not in selected MSAs, we understand that this data would assist in identifying opportunities for improving efficiency and care coordination, but we do not have the authority to expand the availability of these data beyond what we proposed. We proposed to make EPM data available under the HIPAA Privacy Rule provision that permits the disclosure of this information for ''health care operations'' purposes and in accordance with the ''minimum necessary'' standard.

We thank commenters for their input on our proposals to provide beneficiary-level data to EPM participants, upon request, under the HIPAA Privacy Rule provisions that permit disclosures of PHI for ''health care operations'' purposes. We are not modifying our proposals to provide hospitals that are not located in the randomly selected EPM MSAs with the opportunity to request EPM 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 proposed 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 believed 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 CJR, however, we understood that some CJR collaborators under that model believed 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 believed that it would be 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 final 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 were 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 sought 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. We note that the number of simulated episodes with chained anchor admissions by the price MS–DRG on which we solicited comments for AMI model anchor MS–DRGs is no longer relevant due to the fact that we are not finalizing the AMI transfer policy we proposed, as discussed in detail in section III.C. of this final rule.

The following is a summary of the comments received and our responses.

Comment: Several commenters supported our consideration of options to potentially provide some publicly available data to assist EPM and CJR collaborators. However, commenters specified that claims data should be made available for all EPM collaborators and providers affected by the implementation of EPMs. In particular, they stated that post-acute care providers find it difficult to access the data needed (for example, claims data on readmissions) to support care coordination capabilities. Another commenter requested that any provider who treats an EPM beneficiary during the episode should also have access to the claims data so that providers would be able to analyze the data and develop approaches to care redesign, especially when the hospital has not expended the resources to do such analytics. They also commented that this analysis would allow post-acute care providers to demonstrate their value to a hospital and would also allow post-acute care providers to better position themselves when entering into gainsharing arrangements with a participating hospital. Other comments suggested that CMS should require that EPM data be shared equitably among the participating entities, regardless of which entity is charged with coordinating the fiscal arrangement according to CMS.

Response: We appreciate the suggestions commenters offered. While we understand the commenters' desire for us to provide beneficiary-identifiable claims data to collaborating post-acute care providers, we note that we are unable to do this as we do not have the authority to expand the availability of these data beyond what we proposed. As with CJR, and as indicated earlier, there are significant sensitivities and constraints on our ability to make beneficiary-identifiable data available. We proposed to make these data available to hospitals participating in the model in recognition of and in compliance with the HIPAA Privacy Rule provision that permits the disclosure of this information for ''health care operations'' purposes and in accordance with the minimum necessary standard. Requests for EPM data from entities that are not officially participating in the model would not meet the required standards to receive

these data. Although providers and suppliers (physicians, post-acute care providers, etc.) that are collaborators with hospitals participating in the EPMs might be eligible to receive data under HIPAA, provided that they had a ''business associate'' relationship with the beneficiary, we do not believe it is appropriate for CMS to provide collaborators these data directly because hospitals are the entities designated under the model to assume risk and responsibility for a beneficiary's episode of care under the model. Accordingly, as the responsible entity (and as a covered entity under HIPAA), we believe that hospitals should decide what data they need to manage care and care processes with their collaborators and, in consultation with their own legal counsel, what data they may or may not wish to make available to those collaborators provided they are in compliance with the HIPAA Privacy Rule.

Comment: Other commenters made suggestions regarding the types of data we considered to provide publicly to EPM collaborators. They stated that the data should include information included in the Quality and Resource Use Reports (QRUR) so that collaborators will be able to understand their own costs as well as those for downstream providers in order to effectively enter into these financial and clinical arrangements.

Response: We appreciate the suggestions, but do not plan to provide QRUR data in our publicly available files. We note that information and instructions on obtaining QRURs can be found at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Obtain-2013-QRUR.html*.

Comment: We received several comments supporting the sharing of beneficiary identifiable data by EPM participants with entities with which the hospital has a business associate agreement (BAA). Commenters noted that data sharing is an excellent strategy for engaging providers and that data can be a catalyst for change. Based on experience in BPCI, commenters pointed out that data sharing also inspires collaboration as hospitals and post-acute care providers are more likely to come together to conduct root cause analyses of adverse patient care events so that both entities learn from the bundled payment program data. A commenter added that the BPCI model recognized the need for a facilitator convener—an entity that serves an administrative and technical assistance function for one or more designated awardees/awardee conveners, and who would not have an agreement with CMS, bear financial risk, or receive any payment from CMS. Another commenter requested that CMS consider distributing the data to EPMs or their designees under a data use agreement (DUA) process similar to how beneficiary-identifiable claims data are currently distributed under the BPCI program. They stated that this would allow third-party entities to provide data analysis services to EPM participants who lack the capabilities and infrastructure to do so.

Response: We appreciate the support offered by these commenters. In addition, we will require a data request and attestation form and will have a mechanism in place for business associates, as defined under HIPAA, to receive data directly from CMS on an EPM participant's behalf (if approved by that EPM participant). This form would also allow business associates of selected hospitals to provide administrative or technical assistance to multiple hospitals.

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

As stated in the proposed rule, the EPMs are intended to enable CMS to better understand the effects of episode payment approaches on a broader range of Medicare providers and suppliers than would choose to participate in a 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 CR incentive model is intended to enable CMS to assess whether the incentive improves patient quality and access to this covered benefit without increasing overall payments. All CMS models, which would include the 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 EPMs as well as our response to comments received and our final decisions.

B. Design and Evaluation Methods

As stated in the proposed rule, our evaluation methodology for the EPMs and CR incentive model is consistent with the standard Innovation Center evaluation approaches we have taken in other projects such as the BPCI initiative, the CJR model, the Acute Care Episode (ACE) Demonstration, the Pioneer ACO model, and other Innovation Center models. Specifically, the evaluation design and methodology we proposed is designed to allow for a comparison of historic patterns of care among the participants to any changes made in these patterns in response to the 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 an alternative payment model.

As stated in the proposed rule, 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, as we stated in the proposed rule, we plan to take into account the impact of the models at the geographic unit level, the hospital level, and at the patient level. We will also

consider 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 models while also taking into account the effects of other ongoing interventions such as BPCI and the Shared Savings Program. For example, we will consider 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 will consider multiple sources of data to evaluate the effects of the EPMs and CR Incentive models. We expect to base much of our analysis on secondary data sources such as Medicare FFS claims. The beneficiary claims data will 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 will consider a CMS-administered survey of beneficiaries who received a qualifying procedure during the performance period in the EPMs' evaluation. This survey would be administered to beneficiaries who were in the EPMs 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 will consider 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 models. These surveys would provide insight on providers' experience under the model and further information on the care redesign strategies undertaken.

In addition, we will consider CMS evaluation contractor administered site visits and focus groups with selected hospitals, physicians, and post-acute care providers in EPMs and CR evaluation efforts. We believe that these qualitative methods will 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 anticipated 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 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 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? Is 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 planned interventions;

++ 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

The models have a 5-year performance period and the evaluation periods would encompass the entire 5-year period and up to 2 years after. We plan to evaluate the EPMs on an annual basis. However, we recognize, that interim results are subject to issues such as sample size and random fluctuations in practice patterns. Hence, while 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 sought comments on our design, evaluation, data collection methods, and research questions.

The following is a summary of the comments received and our responses.

Comment: Several commenters expressed concerns with the manner in which quality is examined under the EPMs. Specifically, there was concern that the understanding of the impact on quality for these models should include a more comprehensive approach beyond just those quality measures used in the reconciliation methodology. Commenters expressed the belief that the quality measures used in reconciliation were not adequate for the purpose of determining if access and clinical quality were adversely affected. A commenter suggested that CMS examine quality related to the performance of providers aside from the model participant hospitals and that CMS should incorporate measures that reflect the totality of care received in the episode.

Response: We thank the commenters for their thoughts and acknowledge the importance of examining the impact of the EPMs on measures of quality of care beyond what is used in the reconciliation methodology. Our intention in the evaluation is to conduct a multifaceted and multi-pronged examination of issues of quality, access, and unintended consequences. The final evaluation design plan for the evaluation of the EPMs will be developed at a future date and will include quality as a key area of research focus. CMS intends to examine issues of quality of care using a variety of metrics and for a variety of patient and provider subgroups.

Comment: A few commenters expressed concern with the possible impact of the EPMs on reducing access to new or to more expensive but higher quality technology and devices. A commenter requested that CMS conduct a formal evaluation of the impact of the EPMs on patient access to newer technology and that CMS make adjustments to care if patient access is compromised. Similarly, another commenter expressed concern that the focus of the model on short-term costs might cause a shift away from new technologies such as angiography with use of Fractional Flow Reserve (FFR). The commenter encouraged CMS to use incentives for newer technologies shown to improve patient outcomes. In addition, a commenter expressed concern that the EPMs would induce undue pressure to use device choices based on considerations other than quality in the treatment of SHFFT.

Response: We appreciate the commenters' concerns and will be evaluating treatment patterns and shifts in the evaluation of this mode. We address the issue of new technology and payment in section III.C.3.(b). of this final rule. We note that we do not anticipate data collection related to device use or new technology beyond what is currently available in claims data. The issue of physician or other providers' perception of stinting of care or unintended consequences is an issue that may arise in qualitative data collection efforts such as interviews and focus groups. As with all evaluation topics, CMS will strive to balance the amount of burden placed on the sites with regards to primary data collection in choosing its areas of focus.

Comment: Two commenters recommended that CMS increase the frequency with which monitoring and evaluation reports are made public. Quarterly reporting was suggested as commenters believed quarterly public reports would be useful to both the public and the provider community and would help to provide feedback to providers as to what is occurring under the model with respect to unintended consequences so as to allow for adjustments as needed.

Response: We appreciate the need for frequent data updates for these models and strive to provide at least quarterly data feeds to model participants. We refer readers to section III.K. of this final rule for a detailed discussion on the provision of data and claims to participants under the EPMs. One of the purposes for the distribution of this quarterly claims information is to allow for participants to conduct self-assessments of their performance under the model. CMS will be conducting regular interim assessments of the results between the annual reports which will be made publically available. These interim reports examine key metrics which are subject to issues such as sample size and random fluctuations in practice patterns that may be more confusing than illuminative to distribute. Their primary purpose is to highlight possible trends to examine and explore in the annual reports. CMS will consider public release of interim data points on a case by case basis depending on the nature of the findings and the degree of certainty in the results but cannot commit to providing publically available reports on a quarterly basis.

Comment: A variety of commenters expressed interest in the evaluation of the impact of the EPMs on quality and outcomes. Commenters suggested that the CMS evaluation should incorporate an assessment of whether EPMs had an impact on issues such as:

- Overall procedure volume,
- Shifting of care beyond the 90-day episode,
- Stinting of care and reduction in the quality of devices used in SHFFT procedures,
- Patient shared-decision making related to device selection,
- Hospital to hospital transfers in the Cardiac EPMs. The commenter was particularly interested in the extent to which transfers patterns between participating and non-participating hospitals were altered under the model,
- Process measures of quality such as statin use or cardiac rehab referrals, and
- Over or inappropriate use of home health services.

Response: The topic areas mentioned by commenters are in alignment with CMS' intended research questions in the evaluation. We appreciate the contribution and insight behind these comments and the focus they offer towards refining the evaluation's areas

of emphasis in understanding the impact of the EPM on the delivery of care.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification.

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 almost 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 will 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 noted 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 § 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 proposed to replace the term ''target price'' with the term ''quality-adjusted target price,'' as described further in section V.C. of this final rule.) 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 proposed 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 stated our belief that 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 proposed 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. We stated that, 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 final rule for further discussion of our rationale for this approach.

We proposed to amend our regulations to add a new subsection § 510.300(b)(8) to reflect this proposal. We sought comment on our proposal. The following is a summary of the comments received and our responses.

Comment: A few commenters expressed support for our proposal to

include reconciliation payment and repayment amounts in our calculations for updating quality adjusted target prices. One commenter stated that we should apply this policy for calculating quality adjusted target prices earlier than performance year 3.

Response: We appreciate the commenters' support for our proposal. We disagree with the comment suggesting that we implement this change prior to performance year 3. We note that, because reconciliation takes place 2 months after the completion of a performance year, we will not have calculated reconciliation and repayment amount totals from performance year 1 in adequate time to incorporate them into baseline spending totals used to construct quality-adjusted target prices for performance year 2, even if we were to shift the historical baseline period forward. Since we will not be re-calculating historical baseline episode spending until we set quality-adjusted target prices for performance year 3 based on data from 2014 through 2016, we will not implement this change prior to performance year 3.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to include CJR reconciliation payment and repayment amounts, as well as BPCI LEJR reconciliation payment and repayment amounts from regional hospitals, in the historical episode spending amounts used to calculate quality adjusted target prices for Performance Years 3, 4, and 5 for CJR model participants.

C. Quality-Adjusted Target Price

We proposed 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 will 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 clarified 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 proposed to implement these terminology changes in all communications with participant hospitals 60 days after the change is finalized. We proposed 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.'' We received no comments regarding our proposed payment terminology changes.

Final Decision: We are finalizing the proposal, without modification, to use the term ''quality-adjusted target price'' in lieu of ''episode target price,'' and to use the term ''applicable discount factor'' to refer to the discount used to determine repayment amounts in performance years 2 and 3. We are making one technical change to our proposed regulations text to avoid inadvertently deleting existing § 510.300(a)(5), by renumbering it to (a)(6).

D. Reconciliation

In this final rule, in addition to the changes we proposed, detailed later in this section, we also want to correct an example of a reconciliation calculation that we included in the preamble to the CJR final rule (80 FR 73399). This example incorrectly suggested that stop-loss and stop-gain limits would be applied separately for each MS–DRG/fracture level. In actuality, we will apply stop-loss and stop-gain limits after aggregating quality-adjusted target prices at reconciliation and episode spending across all MS–DRG/fracture levels for a given hospital participant. This methodology is correctly described in the regulatory text of the CJR final rule 42 CFR 510.305(e).

In addition, we are correcting the definition of HCPCS in § 510.2 to read Healthcare Common Procedure Coding System.

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 proposed to modify our policy to hold hospitals responsible for post-episode payments that exceed 3 standard deviations from the regional mean. First, we proposed 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 proposed that this modified timeline would be applied to our reconciliation of the first CJR performance year and all performance years thereafter. We stated that 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 proposed 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 proposed 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 proposed 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 sought comment on our proposals. We received no comments on our proposal to calculate post-episode spending at the time of the subsequent reconciliation and to exempt post-episode spending from stop-loss limits.

Final Decision: We are finalizing the proposal, without modification, to calculate post-episode spending for each performance year at the time of the subsequent reconciliation for that performance year, and to exempt post-episode spending from stop-loss limits.

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 proposed 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 proposed 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 believed this change was 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 the proposed modification will impact the steps involved in the reconciliation

process are provided further in this section.

We proposed to implement the 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 believed this timeframe was 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 proposed to add a new paragraph to our regulations at § 510.305(i). We sought comment on our proposal. We received no comments on our proposal to calculate ACO overlap amounts separately from the subsequent reconciliation, so that ACO overlap amounts will not be subject to stop-loss limits.

Final Decision: We are finalizing the proposal, without modification, to perform ACO overlap calculations separately from the subsequent reconciliation, so that ACO overlap amounts will not be subject to stop-loss limits.

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 proposed 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 final 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 proposed to implement these changes to our reconciliation process beginning with the reconciliation for performance year 1.

We proposed to amend our regulations at § 510.305(e), § 510.305(f), and add a new paragraph (j) to reflect these proposals. We also proposed to streamline § 510.305(i)(2) for clarity.

We sought comment on our proposal. The following is a summary of the comments received and our responses.

Comment: One commenter requested that stop-loss be capped at 10 percent for all years of the model.

Response: While we appreciate the commenter's thoughts on capping stop loss, we note that we did not propose to change the stop-loss and stop-gain limits. As we noted in the CJR final rule (80 FR 73401), we believe that we have taken sufficient steps to limit downside risk by capping high cost episodes and phasing in downside risk more gradually than originally proposed over performance years 2 and 3. Our proposal here was limited to the manner

in which the stop-loss and stop-gain limits are applied and therefore we decline to adopt the commenter's suggested approach.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification to apply the stop-loss or stop-gain amount calculated in the first reconciliation to the NPRA of both the first reconciliation and the subsequent reconciliation NPRA, but not to post-episode spending or ACO overlap adjustments.

4. Modifications to Reconciliation Process

As previously discussed in this section, we proposed several modifications to how we conduct the reconciliation process for participant hospitals in the CJR model for all performance years. We proposed 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. 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 proposed for the AMI, CABG, and SHFFT models at III.D.5. of this final rule. We refer readers to that section for additional discussion of our approach. The following is a summary of the comments received and our responses.

Comment: One commenter requested that reconciliation be performed on a quarterly basis, in order to provide faster feedback to help hospitals improve their overall quality and cost performance.

Response: As we did not propose to change the frequency of reconciliation, we decline to adopt this change. As we noted in the CJR final rule (80 FR 73385), our experience with the BPCI quarterly reconciliation process has shown that, because providers and suppliers have a calendar year to submit FFS claims for payment, many claims are incomplete at the time of an initial quarterly reconciliation, leading to significant fluctuation between initial and subsequent reconciliation calculations. Time spent in such frequent reconciliation and appeals processes can detract from participants' efforts focusing on care redesign and coordination with providers and suppliers engaged in furnishing care for beneficiaries under the model. While quarterly data feeds are subject to similar limitations with respect to the completeness of claims, we believe the quarterly data feeds that hospitals receive, which include both line-level and summary claims data, provide sufficiently detailed and timely feedback to guide quality improvement efforts.

Final Decision: After consideration of the public comments received, we are finalizing the proposals to the CJR pricing and reconciliation process without modification.

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 proposed 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 proposed to amend the regulations at § 510.315(c) to reflect this change. We also proposed a technical change to the regulations to renumber

certain subparagraphs. We sought comment on our proposals.

Final Decision: We did not receive any comments on this section. Therefore, we are finalizing the proposal without modification.

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 proposed 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 proposed 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 proposed 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 final 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 proposed for the proposed EPMs as discussed in section III.E.3.c. of this final rule.

We proposed to amend our regulations at § 510.315(d) to reflect these changes. We sought comment on our proposal.

Final Decision: We did not receive any comments on this section. Therefore, we are finalizing the proposal without modification.

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 FR 73363–73381). We described a technical correction to our composite quality scores that will determine reconciliation payment eligibility and the effective discount percentage at reconciliation. We noted 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 in this section.

As we stated in the proposed rule, 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).

The following is a summary of the comments received and our responses.

Comment: Several commenters expressed concern that this technical correction would penalize hospitals because fewer hospitals would fall into the ''Acceptable'' category and, as a result, fewer hospitals would be eligible for a reconciliation payment. Commenters stated that CJR participant hospitals have been modeling savings based on the composite quality scores and corresponding quality categories published in the CJR final rule, and, thus, changing these values would result in a funding shortfall for hospitals that have budgeted for savings based on the original values. Some of these commenters suggested that CMS ensure that all the hospitals that fell into the ''Acceptable'' category based on composite quality scores and corresponding quality categories in the final rule would also fall in the ''Acceptable'' category using the proposed corrected values.

Response: We appreciate the commenters' concern that the proposed technical correction to the composite quality scores and corresponding quality categories would penalize CJR participant hospitals. In the CJR final rule, we described calculating the quality improvement points separately from the quality performance points for each measure. For example, as finalized in the CJR final rule, hospitals could earn a maximum of 8.0 quality performance points (80 FR 73376) and a maximum of 0.8 quality improvement points (80 FR 73380) for the HCAHPS Survey measure. Instead, we should have calculated improvement points as part of the total composite quality score points for a measure. For example, assigning a maximum of 7.2 quality performance points for the HCAHPS Survey measure would have allowed for the addition of a maximum of 0.8 quality improvement points, for a total of 8.0 maximum composite quality score points for the HCAHPS Survey measure. This correct method—calculating improvement points as part of the total composite quality score points for a measure—was the method used to estimate savings for the CJR model.

To correct this error, we are finalizing our proposal to change the composite quality scores and corresponding quality categories. We appreciate that this could present a challenge for some hospitals that were expecting to fall into a certain category based on modeling their own composite quality score values. Similar to the method used to estimate savings for the CJR model, the composite quality scores and corresponding quality categories we are

finalizing in this rule will place over 90 percent of participant hospitals in the ''Acceptable'' category or better. In addition, the changes made to the quality performance distribution and quality improvement points in sections V.E.1. and V.E.2. of this final rule, respectively, will also affect estimations of a hospital's composite quality score. As stated in section V.E.2. of this final rule, 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, thus, provide more opportunities for hospitals to earn a higher composite quality score.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to correct the composite quality scores that will determine reconciliation payment eligibility and the effective discount percentage at reconciliation. We also are making conforming changes to the other provisions in § 510.305 to reflect the new composite quality score ranges for the quality categories.

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 proposed to award up to 10 percent of the maximum measure performance score on the THA/TKA Complications and HCAHPS Survey measures, and to impose a cap on the CJR model composite quality score at 20 points. This change would bring the 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 proposed to amend our regulations at § 510.315(d) to reflect this change. We sought comment on our proposal.

Final Decision: CMS did not receive any comments on this section. Therefore, we are finalizing the proposal without modification.

5. Acknowledgement of Voluntary Data Submission

Our regulations at § 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 proposed 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 sought comment on our proposal.

Final Decision: CMS did not receive any comments on this section. Therefore, we are finalizing the proposal without modification.

6. Calculation of the HCAHPS Linear Mean Roll-Up (HLMR) Score

We proposed 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 proposed this change because removal of Pain Management from the HVBP Program was proposed in the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (81 FR 45603).

This mirrors the approach we proposed for the proposed EPMs as discussed in section III.E.4.d.(1)(f) of this final rule. Our regulations do not include the methods to calculate the HLMR, so we refer readers to section III.E.4.d.(1)(f) of this final rule for additional discussion of our approach.

We proposed 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 the 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.

Final Decision: CMS did not receive any comments on this section. Therefore, we are finalizing the proposal without modification.

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 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 proposed 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 proposed 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 proposed the same exclusion of

beneficiaries aligned to Next Generation ACOs and ESCOs in downside risk tracks. We proposed 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 model 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 proposed elsewhere in this final 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 did not propose to exclude beneficiaries assigned to Shared Savings Program Track 3 ACOs, however, because we intended 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 did not seek to disrupt the operations of our large, permanent ACO program to test this novel approach for accounting for overlap. The Shared Savings Program is a national program; we did not believe that testing a new approach to addressing overlap in a national program would be appropriate prior to testing such an approach with a smaller population. However, we sought comment on whether we should extend this proposed policy—that is, excluding from the CJR model 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 final rule for further discussion of our proposed approach and rationale, including details on how we would operationalize the 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 proposed elsewhere in this final rule to allow certain ACOs to be CJR collaborators. Our proposal, which is discussed in detail in section V.J.1.a. of this final rule, would allow for gainsharing arrangements between ACOs (as defined in the CJR rule) and CJR participant hospitals. The 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 final rule for additional detail on the proposed and final 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 sought 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. The following is a summary of the comments received and our responses.

Comment: Several commenters expressed support for the proposed exclusion of beneficiaries attributed to ACOs in either the Next Generation ACO or Comprehensive ESRD Care models. A substantial number of these commenters also supported extending the exclusion to beneficiaries attributed to Medicare Shared Savings Program Track 3 ACOs, as Medicare Shared Savings Program Track 3 ACOs include downside risk as well. A number of these commenters recommended extending the exclusion even further to include more ACO related exclusions from the CJR model and expressed concern that the current approach to model overlaps undermines ACOs. One commenter noted that ACOs have invested significant resources in managing acute and post-acute care already and overlap with the CJR model deprives them of a key source of savings and of a return on their investment. In support of this perspective, several commenters recommended the ACO exclusions from CJR should be extended to include beneficiaries attributed to any ACO unless a collaborative agreement is in place. If there is no collaborative agreement in place between a CJR model participant and an ACO that it is not part of, then beneficiaries attributed to that ACO should be excluded from the CJR model episodes.

Response: We acknowledge the range of perspectives expressed by commenters and appreciate the many specific suggestions for handling these overlaps. We also acknowledge the operational challenge both ACOs and CJR hospital participants face and the financial implications for both when there are overlaps. We believe the level and range of comments reflect the challenge in balancing multiple perspectives that we discussed in the proposed rule. The predominance of commenters supported our proposal to exclude from the CJR model those beneficiaries attributed to Next Generation ACOs and the downside risk track of Comprehensive ESRD Care models, and a significant number of commenters made compelling arguments for extending it to Shared Savings Program Track 3 ACOs. These comments have convinced us that the best way to balance the interests of both ACOs and CJR participant hospitals, as well as CMS's interest in maximizing population health and lowering total costs of care, is to finalize our original proposal with the addition of Shared Savings Program Track 3 ACO beneficiaries.

As we describe more fully in section III.D.6.c of this final rule, we believe that existing ACO models that assume downside risk and prospectively commit to coordinating a beneficiary's overall care for the entire year should not be deprived of the opportunity to benefit from cost savings achieved during an LEJR episode of care. Post-acute care, in particular, is an area in which ACOs have made significant investments, and existing ACOs that assume both downside risk and prospective responsibility for a beneficiary's care should have the opportunity to share in the cost savings achieved in the post-acute phase of an LEJR episode. However, we continue to be concerned about depleting the eligible population of CJR participants, which would not only diminish the power of the model test and potentially

exclude patients who would not ultimately be assigned to an ACO, but would also deprive CJR participant hospitals of opportunities to save under the model.

For these reasons, we are finalizing our proposal with the one modification; that is, we are excluding from the CJR model those beneficiaries that are assigned to a Shared Savings Program ACO participating in Track 3. In order to accurately reflect these changes and align beneficiary inclusion criteria with EPMs, we are also incorporating these changes into the CJR model beneficiary inclusion criteria, which will apply to CJR episodes that begin on or after July 1, 2017.

Comment: Many commenters expressed concern about the challenge of having accurate and timely information on patient attribution with multiple models. They believed it was unrealistic to expect hospital staff and others to be able to accurately identify patients in excluded ACO models and questioned how CJR participants and their partners would be able verify a patient's status.

Response: We appreciate the operational challenges that CJR participants and their collaborating partners face in an environment where there are many, potentially overlapping models in place. We are actively looking for opportunities to reduce operational barriers where we can practically and effectively do so. To this end, we are in the process of developing a web portal where CJR participant hospitals can, at the point of care, look up and identify beneficiaries prospectively assigned to ACOs who will be excluded from the CJR model. This system, which is being developed consistent with the requirements of the Privacy Act and is currently in testing, is expected to be operational when EPMs are implemented in July of 2017. Model participants will be provided with more specific information on this portal project as it is rolled out.

Final Decision: After consideration of the public comments received, we are finalizing our proposal with the one modification; that is, we are excluding from the CJR model those beneficiaries that are assigned to a Medicare Shared Savings Program ACO participating in Track 3. As discussed in the proposed rule (81 FR 50955), these exclusions would apply for episodes that begin on or after July 1, 2017. We also note that CMS will implement an on-line system for verification of attribution to support CJR participant hospitals in their ability to identify such excluded beneficiaries.

We are also finalizing modifications to the beneficiary inclusion criteria at § 510.205 to indicate that, for episodes beginning on or after July 1, 2017, the CJR model will include Medicare beneficiaries not prospectively assigned to—

- An ACO in the Next Generation ACO model;
- An ACO in a track of the Comprehensive ESRD Care Model incorporating downside risk for financial losses; or
- A Shared Savings Program ACO in Track 3.

G. Appeals Process

Currently, the CJR model 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 proposed 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 proposed 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 the 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 proposed 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 proposed to amend the regulations at § 510.310 to reflect the proposals, and to correct a technical error in paragraph (d)(6) (which would be renumbered (e)(6)). We also proposed to delete § 510.310(a)(3) in the current regulations as it is duplicative with § 510.310(a)(1). We sought comment on our proposal.

Comment: No comments unique to the CJR model were submitted in response to our proposed amendments to the appeals process in the CJR model.

Response: We appreciate the comments surrounding the appeals processes for the CJR model and EPMs. We refer to section III.C.8 of this final rule for a detailed discussion of comments and responses in regards to the appeal processes for these models.

Final Decision: In current CJR regulations at § 510.310(a), a participant hospital may dispute a calculation that involves a matter related to 'determinations associated with quality measures affecting payment.' We explain in the preamble of the CJR final rule that determinations associated with quality measures affecting payment may include the calculation of the percentiles of quality measure performance to determine eligibility to receive a reconciliation payment (80 FR. 73411). For consistency with the final EPM regulation text in § 512.310(a) that was modified in response to comments in order to more fully identify those determinations associated with quality measures affecting payment that may be disputed under this provision, we are making a technical change in this final rule to the regulation text at § 510.310(a), that a participant hospital may dispute a calculation that involves a matter related to the use of quality measure results in determining the composite quality score, or the application of the composite quality score during reconciliation. This does not change the substantive standard that we proposed and finalized in the CJR final rule, but rather refines the regulatory text to better reflect our final policy. Therefore, § 510.310(a) is finalized as follows:

- Notice of calculation error (first level of appeal). Subject to the limitations on review in subpart D of Part 510, if a participant hospital wishes to dispute calculations involving a matter related to payment, reconciliation amounts, repayment amounts, the use of quality measure results in determining the composite quality score, or the application of the

composite quality score during reconciliation, the participant hospital is required to provide written notice of the calculation error, in a form and manner specified by CMS.

H. Beneficiary Notification

As stated in the proposed rule, CMS currently requires participant hospitals and CJR collaborators to provide written notice to any Medicare beneficiary that meets certain criteria in § 510.205 of his or her inclusion in the CJR model. The notification must detail the structure of the model, the existence of providers and suppliers with whom the participant hospital has a sharing arrangement, and the fact that the beneficiary retains the freedom of choice. We refer readers to the CJR final rule (80 FR 73516–73521) for further discussion of these requirements, which are codified under § 510.405. Although we did not propose specific changes to § 510.405(a)(1), which requires that participant hospitals provide CJR beneficiaries with lists of all post-acute care providers in an area, we did proposed a parallel beneficiary notification provision for the EPMs. As discussed in detail in section III.G.2 of this final rule, we received comments on both the EPM beneficiary notification proposals and the existing CJR provision and we are making changes to the EPM beneficiary notification regulations in response to these comments. Since we proposed to maintain alignment between the CJR model and the EPMs to the extent possible as referenced in sections V.C; V.I.1; V.J.1 through V.J.4; and V.K. of the proposed rule, we are also making conforming changes to § 510.405(a)(1) for the CJR model to match the modifications we are finalizing for the EPMs in § 512.450(a)(1). Specifically, we are revising § 510.405(a)(1) to state that as part of discharge planning and referral, participant hospitals must provide a complete list of HHAs, SNFs, IRFs, or LTCHs that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of the SNF, IRF, or LTCH, the geographic area requested by the patient. This list must be presented to CJR beneficiaries for whom home health care, SNF, IRF, or LTCH services are medically necessary. In addition, we are adding the definition of area to the CJR model definitions under § 510.2. The definition we are adding is the same definition that is used in the Conditions of Participation (CoP) for discharge planning. Area means ''as defined in § 400.200 of this chapter, the geographical area within the boundaries of a State, or a State or other jurisdiction, designated as constituting an area with respect to which a Professional Standards Review Organization or a Utilization and Quality Control Peer Review Organization has been or may be designated.'' We note that we expect the SNF list provided to a CJR beneficiary would also include all rural hospital providers of SNF-level care in swing beds in the geographic area requested by the patient. We believe that these changes will clarify and streamline the requirements for the provision of the list of post-acute care providers, as well as reduce the burden on participant hospitals.

In the proposed rule, we proposed to amend § 510.405 to include all CJR collaborators in the requirements for delivery of beneficiary notices and to streamline our current regulations. We also proposed to require participant hospitals and CJR collaborators to be able to generate and provide to CMS upon request a list of all beneficiaries who received a notice, including the type of notice and the date it was delivered. We sought comments on all aspects of this proposal. We also note that we proposed, but did not summarize in the preamble, new language for § 510.405(b) that would permit delivery of the hospital detailed beneficiary notice as soon as reasonably practicable after admission, but during the stay and prior to discharge, when a beneficiary's medical condition makes notice on admission infeasible.

The following is a summary of the comments received and our responses.

Comment: Commenters expressed concern that the multiple beneficiary notifications required under CMS' proposal would create an overload for CJR beneficiaries, would result in administrative burden on providers, and would be infeasible in some cases. Several commenters also expressed concern about the times at which beneficiaries must receive beneficiary notifications from participant hospitals or CJR collaborators, the requirement that beneficiary notifications must be in writing, and a participant hospital's ability to generate lists of all beneficiaries that received beneficiary notifications.

Response: We appreciate the commenters' feedback on our proposals. We received similar comments for the proposed EPM regulations for beneficiary notification and refer readers to III.G.3. for a detailed summary of comments we received and our responses on beneficiary notification as applicable to the CJR model. In response to these comments, we are modifying the notice provisions to, among other things, permit flexibility in the timing of notice delivery as a result of a beneficiary's condition and delay until July 1, 2017 implementation of the requirement that participant hospitals and CJR collaborators be able to generate a list of beneficiaries to whom the notices have been delivered.

Comment: Several commenters expressed concern with the current beneficiary notification form provided by CMS on the CJR model's Web site. Commenters requested that we simplify the wording of our current forms as they believe the notifications as written are more sophisticated than a sixth grade reading level, and that beneficiaries find the policy terms discussed throughout the beneficiary notifications confusing.

Response: We appreciate the commenters' feedback on the beneficiary notification forms we have made available for use by participant hospitals to assist in compliance with the regulations under § 510.405. We will work to find ways to revise and simplify the language in the beneficiary notification template so that beneficiaries can more easily understand the model. Revised versions of the template will be made available on the CMS Web site soon after the publication of this final rule.

Comment: Commenters recommended the hospital beneficiary notification clarify for beneficiaries that all hospitals within the metropolitan area are required to participate in the CJR model, as they believe the current beneficiary notification template implies that CJR beneficiaries who do not want to participate in the CJR model are able to seek care at another provider not participating in the CJR model.

Response: We appreciate the commenter's feedback. We disagree with the commenter's suggestion to require that the notification state that all hospitals within the applicable metropolitan area are required to participate in the CJR model, because some hospitals in the MSA are not required to participate in light of the exception in § 510.100(b). Moreover, other than participant hospitals, no providers or suppliers are required to participate in the CJR model or enter into a sharing arrangement; therefore, the CJR model does not restrict Medicare beneficiaries' ability to choose any other Medicare enrolled provider or supplier. However, to address the commenter's concern about what the notice template implies, as part of our update to the templates we will explore making changes to provide further information about the scope of the

model and the hospitals that are required to participate.

Comment: One commenter voiced concern that the current beneficiary notification omits outpatient therapy providers in the list of post-acute care options, noting that this omission could influence a Medicare beneficiary to believe certain treatments or services, such as outpatient physical therapy, are not an option for them in this model. The commenter recommended that at a minimum, beneficiaries should be provided a written list of all of the local providers from whom they can choose to receive their rehabilitation therapy.

Response: Under current CJR regulation in § 510.405(a)(1) which complement the discharge planning CoP, 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. By post-acute care providers we do not mean providers of outpatient therapy services, which are unlikely to be the initial provider/supplier that furnishes rehabilitation services to a CJR beneficiary immediately following discharge from the anchor hospitalization. We mean HHAs, SNFs, IRFs, and LTCHs where post-acute care services may be covered under Part A following hospital discharge. Similar to the discharge planning CoP, we believe the lists provided to CJR beneficiaries at discharge should be of those institutional post-acute providers that provide Part A-covered services if institutional post-acute care is medically necessary for the beneficiary immediately following hospital discharge in order to specifically safeguard beneficiary freedom of choice of post-acute care providers under the CJR model and establish transparency about financial relationships between post-acute care providers and CJR hospital participants. Under the CJR model, we do not require complete lists of other providers or suppliers of outpatient therapy or any other Part B services that a beneficiary might need during the 90-day post-discharge episode duration to be provided by the CJR participant hospital to the beneficiary, just as the discharge planning CoP does not require lists of other providers or suppliers for follow up Part B-covered services to be provided to a patient.

However, as discussed in this section, in response to comments, we are modifying the requirements of § 510.405(a)(1) to provide greater clarity about the complete list of post-acute care providers to be provided to a CJR beneficiary. Under revised § 510.405(a)(1), participant hospitals will be required to provide, to beneficiaries for whom home health care, SNF, IRF, or LTCH services are medically necessary, a complete list of participating HHAs, SNFs, IRFs, or LTCHs that serve the geographic area in which the patient resides (as defined by the HHA) or in the case of SNFs, IRFs, or LTCS, the area requested by the patient. This revised provision makes clear that CJR participant hospitals need only provide a complete list of HHAs, SNFs, IRFs, or LTCHs to a CJR beneficiary if one of these types of post-acute care services is medically necessary and, in that case, only a list of those post-acute care providers that furnish the medically necessary level of services. In situations where home health care, SNF, IRF, or LTCH services are not medically necessary immediately following discharge, CJR participant hospitals may provide recommendations to CJR beneficiaries about follow up services immediately following discharge and thereafter during the CJR episode, including outpatient therapy services, consistent with all existing laws and regulations. However, we believe it is unlikely that outpatient therapy services immediately following hospital discharge would be a medically appropriate option for most CJR beneficiaries, who would likely be homebound for a period of time and require more comprehensive post-acute care services rather than outpatient therapy services.

Comment: A commenter currently participating in the CJR model stated that in cases of emergent fracture, the requirement to provide the beneficiary notification at the time of admission has presented significant operational hurdles, in that these patients upon admission are unable to comprehend the notification and that providing the notification to accompanying family members has resulted in confusion. This commenter recommended that in cases of emergent fracture, the notification should be provided to patients after the surgery, to avoid causing additional confusion and distress for patients experiencing a traumatic event.

Response: We appreciate the commenter's feedback. We note that in the case of an emergent patient immediate notification of model participation is not always appropriate, and we note that the first priority of the participant hospital should be providing medical care to the beneficiary. For this reason, we proposed to modify the regulation at § 510.405(b) to permit the notification to 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 CJR episode, in cases where the patient's condition makes it infeasible to deliver the notice at admission. We believe that providing the participant hospital this flexibility will avoid causing additional confusion for the beneficiaries and his or her family members. For the same reasons, we are modifying the proposed requirements for CJR collaborator delivery of notices to permit similar flexibility in consideration of a patient's condition.

Final Decision: After consideration of the public comments received on EPM and CJR beneficiary notification policies, we are finalizing our proposal to modify § 510.405, with additional modifications. Specifically, we are finalizing changes to § 510.405(a)(1) to specify when a complete list of certain post-acute care providers must be provided to the CJR beneficiary as part of discharge planning and referral. We are also finalizing changes to § 510.405(b) to streamline the requirements for required beneficiary notification and to reduce provider burden and provide additional flexibilities. These changes are effective as of the effective date of this final rule.

Since we are adding to the list of CJR collaborators, as discussed in section V.J.1.a. of the proposed rule and in this final rule, we proposed to amend the beneficiary notifications requirements at § 510.405(b) to account for these additional types of CJR collaborators. We are finalizing these proposals with modifications to clarify when beneficiary notifications must be provided to beneficiaries, and to address specific requirements for PGPs, NPPGPs, TGPs, members of the PGP, members of the NPPGP, members of the TGP, ACOs, ACO participants, and ACO providers/suppliers. These modifications are made in response to comments on the proposed changes to § 510.405(b) and the corresponding proposals for the EPMs that are discussed in section III.G.3. However, because elsewhere in this final rule we are finalizing our proposals to permit these new types of CJR collaborators effective July 1, 2017, we are similarly delaying the effective date of the beneficiary notice requirements that would apply to these types of CJR collaborators. We believe this approach will reduce confusion that could result from imposing requirements with respect to entities that cannot be CJR collaborators until July 1, 2017.

We proposed to amend § 510.405(b)(4) to reflect changes to the SNF waiver. We did not receive any comments on this

proposal, so we are finalizing the text as proposed, but renumbering to § 510.410(b)(3). We note that we are making conforming changes for related cross-references in § 510.610. These changes are effective as of the effective date of this final rule.

To provide CJR hospitals and their collaborators with more time to come into compliance and to provide consistency with the EPMs, we are delaying until July 1, 2017 the effective date of the requirement proposed as § 510.405(b)(5) to generate a list of beneficiaries who have received notifications upon request until July 1, 2017 and are renumbering to § 510.410(b)(4). Effective July 1, 2017 we also will make certain conforming changes to other provisions of § 510.405(b) to reflect this requirement.

Please refer to the Regulations Text section at the end of this final rule for the final regulation text language.

I. Compliance Enforcement

We proposed numerous amendments to the regulations in § 510.410. The amendments are largely to address the revisions to the CJR model to allow for additional financial relationships and 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. Although our proposed changes reflect an intent that compliance enforcement under the CJR model would stay mostly the same, we proposed changes in § 510.410 to adapt it to our proposal to amend the regulations at § 510.500 and § 510.505, as well as to reflect the addition of § 510.506. For example, we proposed to remove the term 'collaborator agreement' from § 510.410 in keeping with the proposed deletion of this concept from § 510.500.

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 in any of the ways listed in § 510.410(b)(1). We proposed that CMS may also take remedial action against a participant hospital if any of hospital's related collaboration agents and downstream collaboration agents were noncompliant in order for CMS to have the ability to address any noncompliance of these collaboration agents or downstream collaboration agents. As discussed in section V.J.1.a. of this final rule, the proposed addition of ACOs as CJR collaborators, combined with the proposed modifications of the financial arrangements available under the CJR model, would allow for many additional entities and individuals to have financial arrangements under the CJR model as collaborators, collaboration agents, or downstream collaboration agent. We believe our compliance enforcement must give us the authority to ensure that all such entities and individuals are advancing the goals of the CJR model, such as maintaining access to care. We believe that CJR participant hospitals should ensure that their sharing arrangements, the distribution arrangements of their collaborators, and the downstream distribution arrangements of their collaboration agents comply with the model requirements and safeguard program integrity. Therefore, we proposed 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 § 510.410(b)(1). Further, we proposed 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 proposed to amend the regulations at § 510.410 to include these requirements. We sought comment on our proposal. The following is a summary of the comments received and our response.

Comments: Commenters generally supported the amendments to the regulations concerning compliance enforcement. However, some commenters expressed concerns regarding the proposal that participant hospitals are responsible for compliance of CJR collaborators' collaboration agents, and collaboration agents' downstream collaboration agents, and believe these requirements are burdensome for the participant hospital, in that participant hospitals do not have direct contractual relationships with collaboration agents or downstream collaboration agents. Additionally, one commenter expressed concern about the proposal in § 510.410(b)(1)(ix) that CMS may take remedial action when the participant hospital or its related CJR collaborator, collaboration agent, or downstream collaboration is subject to action involving violations of the physician self-referral law, civil monetary penalties law, Federal anti-kickback statute, antitrust laws, or any other applicable Medicare laws, rules, or regulations that are relevant to the CJR model. The commenter stated that violations of any other applicable Medicare laws, rules, or regulations that are relevant to CJR model is overly broad and instead, CMS should apply a reasonable knowledge standard to the participant hospital's awareness of a collaborator's involvement in such matters. Commenters also requested that CMS provide in the final rule examples of actions that are not clear violations of existing health care fraud and abuse statutes.

Response: We received similar comments and recommendations from commenters for the proposed EPMs compliance enforcement section. Given the proposed amendments to the CJR model regulations for compliance enforcement at § 510.410 mirror the proposed EPM regulations at § 512.460, we refer readers to section III.F.2. for a detailed explanation of our responses as they relate to the CJR model as well as the EPMs.

Final Decision: After consideration of the public comments received, we are finalizing the proposals in § 510.410 for compliance enforcement, with modifications to delete as redundant the proposal to amend § 510.410(b)(vi) to separately authorize CMS to take remedial action based on non-compliance with requirements specified in § 510.120(b). We are also clarifying that the 25 percent that CMS may add to the repayment amount under certain conditions as set forth in existing § 510.410(b)(3) is a penalty. Additionally, since changes to the financial arrangement provisions discussed in V.J. will not be effective until July 1, 2017, we are also making the amendments to related sections effective July 1, 2017 to avoid confusion and preserve the existing CJR regulations until these changes take effect.

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. We proposed a full replacement for the prior CJR regulations for financial arrangements §§ 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 proposals reflected changes from the current CJR model regulations that generally fell 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 available under the model.

Many of our proposed changes were largely organizational in nature, not changes to policy or requirements; however, in several cases we proposed new financial arrangements policies and/or requirements for the CJR model. We discuss these policies in detail later in this section and we also refer readers to section III.I. of this final rule for further discussion and rationale behind our proposed approach.

We proposed that all amendments to regulations discussed in this section V.J. would be effective beginning July 1, 2017, in order to align with the beginning of the first performance year of the proposed EPMs. We sought comment on all proposals discussed further in this section.

The following is a summary of the comments received and our responses.

Comment: We received several comments for both the CJR model and EPM in regards to the immediate need for waivers of existing fraud and abuse laws as well as the need for revisions to fraud and abuse.

Response: We appreciate the commenters' perspectives on fraud and abuse law reform and specific suggestions about fraud and abuse law waivers for CMS-led bundled payment models, including the CJR model and the EPM. As we explain in section III.I.2, these issues are beyond the scope of this rulemaking.

Comment: One commenter requested that CMS provide a mechanism for EPM participants and CJR participant hospitals to ask questions about fraud and abuse law waivers.

Response: As we noted, section III.I.2, waivers of fraud and abuse laws are outside the scope of this rulemaking. We note that the public may contact CMS with programmatic questions related to the EPM and CJR model by emailing *epm@cms.hhs.gov* and *cjr@cms.hhs.gov,* respectively.

We did not receive any comments on our proposal that all amendments to regulations discussed in this section V.J. would be effective beginning July 1, 2017, in order to align with the beginning of the first performance year of the proposed EPMs. Therefore, we are finalizing this proposal without modification. In addition, we note that the July 1, 2017 effective date provides CJR participants with additional time to come into compliance with the revised requirements and preserves the existing CJR regulations until these changes take effect. We refer readers to § 510.2 for effective dates of definitions discussed in section V.J.

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 proposed to allow the following entities to be CJR collaborators: ACOs (with the limitations discussed later in this section), hospitals, and CAHs. We believe the proposal would allow for increased care coordination opportunities across the spectrum of care for beneficiaries in CJR episodes. Given that the proposals in this section mirror those proposed for the EPMs in section III.I.3. of this final 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 final rule.

We proposed that ''ACOs,'' meaning accountable care organizations, as defined at § 425.20, that participate in the Medicare Shared Savings Program and is not in Track 3, be permitted to be CJR collaborators. The 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. Like providers and suppliers, ACOs are regulated by CMS. We can verify that these ACOs meet current Shared Savings Program requirements such that they are suitable for a role as CJR collaborators.

We also proposed 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 proposed that the following providers, suppliers, and other entities be added to the list of permissible CJR collaborators: ACOs, hospitals, and CAHs.

We sought comment on our proposal to include ACOs, hospitals, and CAHs in the definition of CJR collaborators.

The following is a summary of the comments received and our responses.

Comment: Several commenters requested clarification about whether certain groups of health care professionals that do not include physicians could be CJR collaborators. The commenters requested that, in addition to PGPs, groups of certified registered nurse anesthetists (CRNAs), advanced practice registered nurses (APRNs), outpatient speech-language pathologists, physical therapists, and other qualified licensed healthcare professionals who are not physicians, be permitted to be CJR collaborators. One commenter explained that these groups are identified by a TIN.

A number of commenters pointed out that while the proposed rule specifically listed PGPs as eligible to be CJR collaborators, CMS' proposal did not separately list groups of physical therapists or other therapists as eligible to be CJR collaborators. One commenter asserted that allowing only individual therapists to be CJR collaborators and excluding therapy practice groups from entering into sharing arrangements with EPM participants is shortsighted because rehabilitation therapy practices and independent therapists are likely to be significant contributors to SHFFT episodes. The commenters requested that CMS clarify the regulations to explicitly permit groups of therapists to enter into sharing arrangements with participant hospitals. One commenter further proposed that once a therapy practice group contracts with a hospital as a collaborator, it should be up to the practice group to ensure that financial exchanges with the participant hospital were attributed to the physical therapists who directly furnished services to CJR beneficiaries.

Response: We appreciate the interest of the commenters in ensuring groups of nonphysician practitioners and groups of therapists have the same opportunities to be CJR collaborators that we proposed for PGPs, as well as their interest in allowing financial exchanges with their members who furnished services to CJR beneficiaries.

Under our current regulation, individual nonphysician practitioners are permitted to be CJR collaborators. Individual therapists are also permitted to be collaborators to the extent that they fall within the collaborator category in the current CJR regulations for provider or supplier of outpatient therapy services. As collaborators, these individuals would be eligible to receive gainsharing payments from participant hospitals. Moreover, our existing definition of proposal defined a PGP member includes a physician, nonphysician practitioner or therapist who is an owner or employee of a PGP who has reassigned to the PGP his or her right to receive Medicare payments. Accordingly, as PGP members, these nonphysician practitioners and therapists would be eligible for distribution payments and downstream distribution payments from a PGP. We agree with the commenters that because the CJR regulations and our proposed revisions to these regulations addressed the role of PGPs without reference to other types of groups, we left some uncertainty about whether groups without a physician owner or employee are eligible to be CJR collaborators and whether under our proposals such groups would be permitted to enter into distribution arrangements or downstream distribution arrangements with their members. We also agree with the commenters that our provision allowing providers and suppliers of outpatient therapy services to be CJR collaborators is potentially unclear, because this term does separately identify therapists in private practice or groups of therapists in private practice on the list of CJR collaborators, as does our regulatory provision regarding physicians and PGPs. We also appreciate the commenters' uncertainty associated with the fact that we did not address whether a collaborator that was a therapy group practice would be permitted to enter into distribution arrangements or downstream distribution arrangements with their members, given that we did specify this in the language that we proposed for PGPs.

We do not believe it would be appropriate to allow a group of licensed health care professionals to be CJR collaborators if that group consists solely of individuals who are not among the categories of individuals that may be CJR collaborators. However, we believe that if a category of individuals is eligible to be CJR collaborators, then Medicare-enrolled groups that include such individuals should also be permitted to be collaborators. Further, we believe that such groups should also be permitted to enter into distribution arrangements or downstream distribution arrangements with their members. We clarify these policies through this final rule.

Groups of nonphysician practitioners that do not include a physician are not included in the category of PGPs that are on the current list of CJR collaborators. However, we believe these groups of nonphysician practitioners should be permitted to be CJR collaborators, just as we allow both individual physicians and nonphysician practitioners to be CJR collaborators. We also believe these groups of nonphysician practitioners should be treated similarly to PGPs with regard to their ability to engage in distribution arrangements and downstream distribution arrangements with their members, consistent with our treatment of nonphysician practitioners who are PGP members. Therefore, we are adding to the list of entities that are eligible to be CJR collaborators a nonphysician practitioner group practice (NPPGP), defined as ''an entity that is enrolled in Medicare as a group practice, includes at least one owner or employee who is a nonphysician practitioner, does not include a physician owner or employee, and has a valid and active TIN.'' The requirements for sharing arrangements, distribution arrangements, and downstream distribution arrangements for NPPGPs and NPPGP members are discussed in the sections of this final rule that address our policies for these arrangements.

We further believe that our provisions allowing a provider or supplier of outpatient therapy services to be a CJR collaborator should be modified to provide greater clarity about the providers and suppliers of outpatient therapy services that can be CJR collaborators. The Medicare Claims Processing Manual, Chapter 5, Part B Outpatient Rehabilitation and CORF/OPT Services, Section 10 lists the following Medicare-enrolled providers and suppliers that can submit claims for outpatient therapy services: SNF; outpatient hospital; CAH; HHA; outpatient physical therapy provider (OPT), otherwise known as rehabilitation agency; comprehensive outpatient rehabilitation facility (CORF); physician; nonphysician practitioner; and physical or occupational therapist or speech-language pathologist in private practice.[136] We note that the list of CJR collaborators in the current regulations already includes, SNFs, HHAs, physicians, and nonphysician practitioners so their inclusion as collaborators under the definition of provider or supplier of outpatient therapy services is duplicative. Therefore, rather than maintaining a definition of provider of outpatient therapy services which would have included all providers and suppliers of outpatient therapy services, we believe it is clearer to specify individually on the list of CJR collaborators all the types of Medicare-enrolled providers and suppliers that can bill Medicare for

[136] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c05.pdf.*

outpatient therapy services. Thus, we are defining a new term therapist in private practice as ''a therapist that either: complies with the special provisions for services furnished by physical therapists in private practice in § 410.60(c) of this chapter; or complies with the special provisions for services furnished by occupational therapists in private practice in § 410.59(c) of this chapter; or complies with the special provisions for services furnished by speech-language pathologists in private practice in § 410.62(c) of this chapter.'' We are adding therapist in private practice to the list of CJR collaborators, which ensures that all individual suppliers of outpatient therapy services are on the CJR collaborator list. In addition, we are revising our definition of provider of outpatient therapy services to mean ''an entity that is enrolled in Medicare as a provider of therapy services and furnishes one or more of the following: outpatient physical therapy services as defined in § 410.60 of this chapter; outpatient occupational therapy services as defined in § 410.59 of this chapter; outpatient speech-language pathology services as defined in § 410.62 of this chapter.'' Under this revised definition, provider of outpatient therapy services now includes only those entities that enroll in Medicare specifically as a provider of outpatient physical therapy/occupational therapy/speech-language pathology services, and we are revising the list of CJR collaborators to use this defined term in place of ''provider or supplier of outpatient therapy services.'' Finally, in addition to finalizing our proposal to add hospitals and CAHs to the list of CJR collaborators, we are adding CORFs to the list of CJR collaborators because it is the only other type of provider that can furnish outpatient therapy services that is not included on the CJR collaborator list under our new and revised terms. Thus, with the addition of therapy group practices as discussed specifically below, in total, these changes to the definitions and supplements to the list of CJR collaborators clarify which individuals and entities may be CJR collaborators by separately specifying each type of supplier and provider of outpatient therapy services that is eligible to be a CJR collaborator.

With respect to the specific interest of commenters in therapy practice groups being eligible to be CJR collaborators that can share payments under CJR financial arrangements with their members, we agree with the commenters that such groups should be permitted to be CJR collaborators and to enter into distribution arrangements and downstream distribution arrangements with their members, consistent with our treatment of PGPs and NPPGPs. Thus, we are defining therapy group practice (TGP) as ''an entity that is enrolled in Medicare as a therapy group in private practice, includes at least one owner or employee that is a therapist in private practice, does not include an owner or employee who is a physician or nonphysician practitioner, and has a valid and active TIN'' and adding TGP to the list of CJR collaborators. The requirements for sharing arrangements, distribution arrangements, and downstream distribution arrangements for TGPs and TGP members are discussed in the sections of this final rule that address our policies for these arrangements.

We are finalizing, with the modifications discussed, the definition of CJR collaborator in § 512.2 to mean 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) Therapist in private practice.
(8) CORF.
(9) Provider of outpatient therapy services.
(10) PGP.
(11) Hospital.
(12) CAH.
(13) NPPGP.
(14) TGP.

Comment: A number of commenters expressed support for CMS' proposed definition of ''CJR collaborators,'' including the proposed addition of ACOs, hospitals, and CAHs to the types of collaborators that were previously adopted for the CJR model. The commenters claimed that allowing additional health care providers, suppliers, and ACOs to be CJR collaborators would further encourage robust care coordination across the CJR episode. Several commenters asserted that by recognizing the expertise that ACOs may offer participant hospitals as CJR collaborators with regard to managing the cost and quality of care that Medicare beneficiaries receive, ACOs will be able to use their substantial expertise and resources to contribute to the CJR model's dual goals of limiting spending and increasing quality. One commenter further commended CMS for making the list of CJR collaborators exhaustive and not including third party conveners, who the commenter believes lack a commitment to patients, local providers, or their community.

In contrast, some commenters expressed disappointment that the list of CJR collaborators did not include entities such as pharmaceutical companies; medical device companies; medical technology companies; social services aging networks; and other third parties, such as the types of convening organizations participating in other CMMI models. Several commenters believe that were medical device and pharmaceutical manufacturers allowed to be CJR collaborators, those manufacturers may make meaningful contributions to the success of the CJR model by ensuring their products are used appropriately; aligning financial and other incentives to improve patient outcomes; demonstrating the value of their products; and reducing costs. Other commenters who favored adding medical technology companies as CJR collaborators asserted that medical technology companies can make a significant, positive impact on care redesign and cost containment as well as provide integrated data analytic infrastructure and services to optimize care and to achieve quality goals. A few commenters suggested that CMS should expand the list of potential CJR collaborators to include non-provider or non-supplier entities that have a track record of providing Medicare providers and suppliers participating in other models with support services such as care redesign, data analytics, and general program support, as well as community-based organizations that are well-equipped and efficient in providing social and supportive services that help beneficiaries stay out of the hospital. Several commenters also encouraged CMS to include all APM entities as CJR collaborators, reasoning that APM entities are similar to ACOs in that they are a legal entity that is separate from its participants.

Additionally, one commenter recommended that Next Generation ACOs be included in the definition of ACOs that are on list on CJR collaborators, so the Next Generation ACO may act on behalf of its providers to enter into financial arrangements with participant hospitals for beneficiaries not assigned to the ACO. The commenter explained that not including Next Generation ACOs in the definition of ACOs that CMS proposed could be CJR collaborators will require ACO participants and ACO providers/suppliers of the Next Generation ACO to enter in CJR sharing arrangements on their own without the Next Generation ACO to represent them.

Finally, one commenter shared its perspective that CMS should not restrict the definition of CJR collaborators because such an approach discourages the introduction of new entities and individuals in the healthcare market. The commenter requested that CMS allow market forces to shape the innovation of CJR participants and their community partners in order to determine the financial partnerships that would be most beneficial to achieving the overarching goals of the CJR model. The commenter asserted that being too prescriptive regarding the individuals and entities that can and cannot enter into financial arrangements under the CJR model would not allow for new organizations to develop in the market that may have the potential to generate substantial cost savings for participant hospitals.

Response: We appreciate the support of the commenters for our proposed list of the types of individuals and entities that can be CJR collaborators, including our proposal to include hospitals, CAHs, and ACOs that would expand the list beyond current CJR collaborators adopted in the CJR Final Rule (80 FR 73418).

We note that some of the potential contributions, such as integrating the data analytic infrastructure and services to optimize care to achieve quality goals, that were suggested by commenters as reasons to allow third parties, such as pharmaceutical, medical device, and medical technology companies as well as other types of convening organizations participating in other CMMI models, to be CJR collaborators can be achieved outside of the context of sharing arrangements through other relationships between the participant hospital and those entities. In response to the specific requests that we include APM entities on the list of CJR collaborators, given that an APM entity, as defined in § 414.1305, means an entity that participates in an APM or payment arrangement with a non-Medicare payer through a direct agreement or through Federal or State law or regulation, we believe that adding all APM entities to the list of CJR collaborators would be overly expansive and risk loosening the clinical link between the CJR collaborator, participant hospital, and beneficiary that we believe is important for improving the quality and reducing the cost of care under the model. With the exception of ACOs, PGPs, NPPGPs, and TGPs, we continue to believe that any CJR collaborator that receives a gainsharing payment must have furnished a billable service included in the episode to a CJR beneficiary and that the payment arrangements for gainsharing payments must be substantially based on the quality of care and the provision of CJR activities. In the case of ACOs, PGP, NPPGPs, and TGPs that are CJR collaborators, we require that the entity itself must have contributed to CJR activities and been clinically involved in the care of beneficiaries in order to be eligible to receive a gainsharing payment or be required to make an alignment payment. At this point we are not convinced any APM entities could meet these eligibility criteria, other than ACOs. We also do not agree with the commenter who recommended that we not restrict the definition of CJR collaborators to any specific individuals or entities. We believe it is important for participant hospitals to engage CJR collaborators that have a commitment to their local communities, local providers, and Medicare beneficiaries in order to create the greatest potential for sustained improvements in quality and reductions in cost under the CJR.

We appreciate the commenter's suggestion that Next Generation ACOs be included in the definition of ACOs that are on the list of CJR collaborators, so the Next Generation ACO may act on behalf of its ACO participants and ACO providers/suppliers to establish sharing arrangements with participant hospitals for beneficiaries not assigned to the ACO. While we understand that the Next Generation ACO would like to enter into a CJR sharing arrangement as a CJR collaborator on behalf of its providers and suppliers, to be eligible to receive a gainsharing payment or be required to make an alignment payment under the sharing arrangement the Next Generation ACO itself must have contributed to CJR activities and been clinically involved in the care of beneficiaries through activities such as 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 and reduce spending for the 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 beneficiaries. We are unclear of the role the Next Generation ACO itself would play in the care of beneficiaries that are not assigned to the ACO, beyond serving as a contracting agent for its ACO participants and ACO providers/suppliers. We further believe that such an arrangement would require distinguishing activities on behalf of beneficiaries assigned to the ACO who are excluded from CJR episodes and beneficiaries not assigned to the ACO who are included in CJR episodes, and such distinctions could create confusion for beneficiaries, providers, and suppliers, as well as administrative complexity for the Next Generation ACO. Therefore, we do not believe it would be appropriate to include Next Generation ACOs in the definition of ACOs that may be CJR collaborators.

Finally, we note that as discussed in section III.D.6.c.(3) of this final rule, we are additionally finalizing the exclusion of beneficiaries from CJR episodes who are prospectively assigned to a Shared Savings Program ACO in Track 3. Therefore, for consistency with our policy for Next Generation ACOs whose assigned beneficiaries are also excluded from CJR episodes, we are excluding Shared Savings Program ACOs in Track 3 from the definition of ACOs that may be CJR collaborators. Thus, we are modifying our definition of ACO to read ''ACO means an accountable care organization, as defined at § 425.20 of this chapter, that participates in the Shared Savings Program and is not in Track 3.'' We emphasize that no CJR policy precludes providers or suppliers who are ACO participants or ACO providers/suppliers in a Next Generation ACO from entering into a sharing arrangement with a participant hospital on their own, provided they are on the list of CJR collaborators.

In summary, at this time we will not adopt a final policy that includes additional entities or individuals that are not providers or suppliers beyond those we proposed to be CJR collaborators. We selected acute care hospitals as the financially responsible entity for the CJR model because we are interested in evaluating the impact of bundled payment and care redesign across a broad spectrum of hospitals with varying levels of infrastructure and experience in entering into risk-based payment arrangements. We believe that it is most appropriate to identify a single type of provider to bear financial responsibility for making repayment to CMS under the CJR model. Given that hospitals perform a central role in coordinating episode-related care and ensuring smooth transitions for beneficiaries, this role factored in our decision to select IPPS hospitals as the financially responsible entity for this model. Under this structure, we believe that limiting the testing of gainsharing relationships to solely those between participant hospitals, certain Shared

Savings Program ACOs, and providers and suppliers enrolled in Medicare is most appropriate because we expect enrolled providers and suppliers to be most directly and specifically engaged with the participant hospitals in care redesign and CJR episode care for beneficiaries. While we recognize that Shared Savings Program ACOs are not providers or suppliers, 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 make them suitable for a role as CJR collaborators. Further, by including such ACOs on the list of CJR collaborators, we are permitting locally variable financial arrangements that could account for the way care in CJR episodes is coordinated and managed in communities, and ensure that entities with appropriate skills and experience are permitted to share the CJR's risks and rewards with participant hospitals.

We are finalizing in § 510.2 the definition of ACO, with modification to mean an accountable care organization, as defined at § 425.20 of this chapter, that participates in the Shared Savings Program and is not in Track 3.

Comment: One commenter requested clarification about whether outpatient speech-language pathologists are considered providers of outpatient therapy services and, therefore, eligible to be CJR collaborators.

Response: We appreciate the opportunity to clarify that speech-language pathologists are eligible to be CJR collaborators under the existing CJR regulations if they meet the definition of provider of outpatient therapy. Moreover, as discussed previously in this section, speech-language pathologists in private practice are included under the new definition of therapist in private practice when they are therapists that comply with the special provisions for services furnished by speech-language pathologists in private practice in § 410.62(c). In addition, a group of speech-language pathologists in private practice is included under the new definition of TGP when the group is entity that is enrolled in Medicare as a therapy group in private practice, includes at least one owner or employee that is a therapist in private practice, does not include an owner or employee who is a physician or nonphysician practitioner, and has a valid and active TIN. Therefore, under the revisions that will take effect on July 1, 2017, we will clarify that both therapists in private practice and TGPs may be CJR collaborators and therefore make clearer that individual speech-language pathologists in private practice, as well as speech-language pathology groups in private practice, are eligible to be CJR collaborators.

Final Decision: After consideration of the public comments received, we are finalizing the proposals in § 510.2 for the definition of CJR collaborator and other terms used in that definition, with modification to revise the definitions of provider of outpatient therapy services; and ACO; create new definitions for CORF, therapist in private practice, NPPGP, and TGP; and include these additional individuals and entities on the list of CJR collaborators. With the exception of the new definition of therapist in private practice, these revised definitions will be effective July 1, 2017. CJR collaborator means an ACO (as defined in § 510.2) 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) Therapist in private practice.
(8) CORF.
(9) Provider of outpatient therapy services.
(10) PGP.
(11) Hospital.
(12) CAH.
(13) NPPGP.
(14) TGP.

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 proposed to delete the term ''collaborator agreement'' in § 510.2 and transition the requirements of collaborator agreements to requirements of sharing arrangements. Overall, the proposal would simplify and streamline the requirements for sharing arrangements under CJR, 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 proposed to change several terms, the proposed sharing arrangements policies are largely similar to the current policies regarding collaborator agreements.

We sought to amend the regulations at § 510.2 by deleting the term collaborator agreement in Part 510. We sought comment on our proposals.

The following is a summary of the comments received and our responses.

Comment: Several commenters requested clarification as to whether the proposed changes to financial arrangements in the CJR model would require CJR participant hospitals to review their current financial arrangements and modify the terminology to reflect the changes if they are finalized. One commenter acknowledged CMS' efforts to providing consistency between the CJR model and the EPM, but claimed that requiring CJR participant hospitals to review their financial arrangements would constitute a significant burden on CJR participant hospitals.

Response: The proposed changes to CJR financial arrangements in §§ 510.500 and 510.505 would require CJR participant hospitals, and any other individual or entity involved in a financial arrangement under these regulations, to review the changes to the requirements of the CJR model, and to revise their financial arrangements and applicable terminology if necessary. While we acknowledge that the amendments to the financial arrangements requirements in the CJR model will create some short-term administrative burden on CJR participants and other parties involved in these arrangements, we believe that the revised CJR model regulations streamline and clarify the requirements for all parties and will help facilitate compliance with the requirements of the CJR model. In addition, the major policy changes, such as allowing ACOs to be collaborators and adopting the term CJR activities as the comprehensive framework for capturing both direct patient care and care redesign for CJR episodes, received widespread support from commenters. We recognize the time that CJR participant hospitals and CJR collaborators with financial arrangements under the existing requirements will need to review the amended requirements finalized in this final rule and revise their existing financial arrangements in order to be compliant. As such, the amended requirements for financial arrangements in the CJR model will be effective on July 1, 2017, the same date when the first performance year for the EPM begins. Therefore, CJR participant hospitals and CJR collaborators will have knowledge of the federal requirements for CJR financial arrangements approximately 6 months prior to their effective date in the CJR model, which we believe is sufficient to

review and revise their existing financial arrangements if necessary.

Final Decision: After consideration of the public comments received, we are finalizing the proposal without modification to delete the term collaborator agreement effective July 1, 2017.

c. Addition of CJR Activities

We proposed 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 proposed 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 final rule provide more detail as to how the addition of CJR activities affect other proposals in this part.

We proposed to amend § 510.2 by adding the term 'CJR activities.' We sought 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. We received comments regarding both CJR activities and EPM activities and refer readers to section III.I.4.b. of this final rule for a detailed explanation of the comments and our responses.

Final Decision: After consideration of the public comments received, we are finalizing the proposal to add the term CJR activities, without modifications, effective July 1, 2017.

2. Sharing Arrangements

We believe the proposed amendments to this section will provide participant hospitals and CJR collaborators with more 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. In the proposed rule, we discussed the proposed requirements for sharing arrangements, including both our continuation of policies we finalized in the CJR final rule, and several new proposals. We proposed that participant hospitals must develop, maintain, and use a set of written policies for selecting individuals and entities to be CJR collaborators, and that such policies 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. Our proposed addition of ''past or anticipated'' does not effect a substantive change, but merely conforms the way the volume or value standard is articulated in this provision with the way that the volume or value standard is articulated in other provisions at § 510.500. However, by adding ''past or anticipated,'' we make clear that 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 proposed 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 sought comment on our proposal. We received a number of comments on our proposal. Because the comments and responses to our proposal for CJR were not substantively different from the comments and responses on proposed § 512.500(a), we refer readers to section III.I.4.a for a discussion of the comments and our responses to them

Additionally, we note that the CJR model and the EPMs' policies surrounding the various requirements of financial arrangements mirror one another. We provided in Table 46 in section III.I.4.a. of this final rule to list the standards related to ''volume and value'' for EPM financial arrangements, and here provide Table 51 below with

the parallel information for the CJR model.

TABLE 51—STANDARDS RELATED TO "VOLUME OR VALUE" FOR CJR FINANCIAL ARRANGEMENTS

	Volume/value prohibition?	Scope of volume/value prohibition	Citation
Collaborator selection criteria.	Yes	Cannot be based *directly or indirectly* on past or anticipated referrals or business otherwise generated by, between or among: vi. Participant hospital vii. Collaborator viii. Collaboration agent ix. Downstream collaboration agent x. Any individual or entity affiliated with (i)–(iv)	§ 510.500(a)(3).
Opportunity to make or receive a payment.	Yes	Same as for collaborator selection criteria	§ 510.500(c)(7) (gainsharing or alignment payments). § 510.505(b)(4) (distribution payment). § 510.510(b)(4) (downstream distribution payment).
Alignment payment methodology.	Yes	Cannot *directly* account for volume or value of past or anticipated referrals or business otherwise generated by, between or among (i)–(v) above.	§ 510.500(c)(14).
Gainsharing payment methodology.	No	N/A—methodology must be substantially based on quality of care and the provision of CJR activities; may consider relative amount of CJR activities provided.	§ 510.500(c)(5) (gainsharing payments).
Distribution and downstream distribution payment methodologies.	No	N/A—same methodology standard as for gainsharing payments, except that amounts distributed by a PGP to a PGP member can also be determined in a manner that complies with § 411.352(g) of the physician self–referral regulations.	§ 510.505(b)(5), (6) (distribution payments). § 510.510(b)(5), (6) (downstream distribution payments).

Final Decision: After consideration of the public comments received, we are finalizing effective July 1, 2017, the proposals in § 510.500(a) for the general requirements for CJR sharing arrangements, with modification to clarify that a CJR collaborator selection criterion that considers whether a potential collaborator has performed a reasonable minimum number of services that would qualify as CJR activities will be deemed not to violate the volume or value standard if the purpose of the requirement is to ensure the quality of care furnished to CJR beneficiaries. CJR sharing arrangements must comply with the following general provisions:

- 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.
- The participant hospital 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. A selection criterion that considers whether a potential CJR collaborator has performed a reasonable minimum number of services that would qualify as CJR activities will be deemed not to violate the volume or value standard if the purpose of the criterion is to ensure the quality of care furnished to CJR beneficiaries.
- 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

Currently, there are a number of specific requirements for sharing arrangements under the CJR model. We proposed to delete the term ''collaborator agreements'' and to incorporate many of the requirements from the existing CJR provision at § 510.500(c) into a streamlined provision regarding the requirements for ''sharing arrangements.'' We discuss the proposal in detail further in this section in order to ensure current and future participant hospitals and CJR collaborators are aware of all requirements that would apply under these proposed revisions.

We proposed 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 proposed 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 noted 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 proposed 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 proposed 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 noted 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 proposed 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 proposed 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 proposed 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.

We proposed the requirements for sharing arrangements at § 510.500(b). We sought comment on our proposals. Because this proposal mirrors what we proposed for the EPM and the comments on these proposals and our responses are substantially the same, we refer readers to section III.I.4.b for a detailed explanation of the comments and our responses to them.

Final Decision: After consideration of the public comments received, we are finalizing effective July 1, 2017, the proposals in § 510.500(b) for the requirements for CJR sharing arrangements, with modifications. We are modifying our proposal at § 510.500(b)(4) to specify that the CJR collaborator must have or be covered by a compliance program which must include oversight of the sharing arrangement and compliance with the requirements of the CJR model that apply to its role as a CJR collaborator, including any distribution arrangements. We are also modifying our proposal to remove the requirement that the written agreement memorializing a sharing arrangement include management and staffing information, a change which results in renumbering proposed § 510.500(b)(7)(v) (requiring the financial or economic terms for payment be specified in the written agreement about the sharing arrangement) to § 510.500(b)(7)(iv). CJR sharing arrangements must meet the following requirements:

- 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; and

++ All other applicable laws and regulations.

- The sharing arrangement must require the CJR collaborator to have or be covered by a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the CJR model that apply to its role as a CJR collaborator, including any distribution arrangements.
- 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;

++ The date of the sharing arrangement.

++ 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 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.

c. Gainsharing Payment, Alignment Payment, and Internal Cost Savings Conditions and Restrictions

Under the CJR model, we placed a number of conditions and limitations on gainsharing payments, alignment payments, and internal cost savings. Our proposal to amend the 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 proposed to change.

We proposed 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 a CJR beneficiary during a 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 proposed 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 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. Further, we proposed 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 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. 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 proposed 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 proposed that the internal cost savings reflect care redesign under the CJR in order to be eligible to be shared through gainsharing payments. We also proposed that 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 proposed a revised policy to not require in the CJR model that the calculation of internal cost savings be tied to the activities of a specific CJR collaborator. We believe the proposed change recognizes 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 proposed 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 proposed the methodology may take into account the amount of such CJR activities provided by a CJR collaborator relative to other CJR collaborators. While we emphasized that financial arrangements may not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or other 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, the proposed requirement recognizes that the relative amount of CJR activities (including direct care) furnished by a CJR collaborator to CJR beneficiaries during CJR episodes may contribute relatively more or less 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 final rule for additional discussion of our rationale. We sought 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 invited comment on whether additional safeguards or a different standard was 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 proposed 50 percent of the participant hospital's repayment amount for a CJR collaborator that is an ACO. We proposed 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 sought comment on the proposed limitation that would apply to ACOs that are CJR collaborators.

Additionally, we proposed 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. We proposed to revise 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 sought 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 proposed 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 proposed to amend the regulations at § 510.500(c) as described previously. We sought 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 were reasonable, necessary or appropriate to ensure the goals of program integrity, protecting against abuse and ensuring the goals of the model are met.

Because this proposal mirrors what was proposed for the EPM and the comments on these proposals and our responses are substantially the same, we refer readers to section III.I.4.c for a detailed explanation of the comments and our responses to them.

Final Decision: After consideration of the public comments received, we are finalizing the proposals, with modifications, for gainsharing payments, alignment payments, and internal cost savings conditions and restrictions, in § 510.500(c). In addition to the modifications discussed in our responses in section III.I.4.c, we are specifying that to be eligible to receive a gainsharing payment or to be required to make an alignment payment, an NPPGP or TGP (like PGPs) must have billed for an item or service that was rendered by one or more NPPGP members or TGP members respectively to a CJR beneficiary during a CJR episode 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 or was assessed a repayment amount. In addition, like PGPs, the NPPGP or TGP 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.

As finalized, effective July 1, 2017 gainsharing payments, alignment payments, and internal cost savings must meet the following conditions and restrictions:

• 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 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 CJR episodes.

++ To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a CJR collaborator other than an ACO, PGP, NPPGP, or TGP 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.

++ To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a CJR collaborator that is a PGP, NPPGP, or TGP must meet the following criteria:

—The PGP, NPPGP, or TGP must have billed for an item or service that was rendered by one or more PGP member, NPPGP member, or TGP member respectively 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

—The PGP, NPPGP, or TGP 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, NPPGP, or TGP 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 other providers and suppliers (such as PGP members, NPPGP members, or TGP members; 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 accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount; and

++ 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 a repayment amount. 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 CJR 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 CJR 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 for 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 or NPPGP, 50 percent of the Medicare-approved amounts under the PFS for items and services billed by that PGP or NPPGP and furnished to the participant hospital's CJR beneficiaries by the PGP members or NPPGP members respectively 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.

• 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 the participant hospital receives from CMS must not exceed the amount of that reconciliation payment.

• 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 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.

• A participant hospital must not make a gainsharing payment to a CJR collaborator if CMS has notified the participant hospital that such collaborator is subject to any action for noncompliance with this part or the fraud and abuse laws, or for the provision of substandard care to CJR beneficiaries 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 CJR participant hospital must not receive any amounts under a sharing arrangement from a CJR collaborator that are not alignment payments.

• For a performance year, the aggregate amount of all alignment payments received by the CJR 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; or

++ With respect to a CJR collaborator that is an ACO, 50 percent of the participant hospital's repayment amount.

• The amount of any alignment payments must be determined in accordance with a methodology that does 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 (GAAP) and Government Auditing Standards (The Yellow Book).

• All gainsharing payments and alignment payments must be made by check, electronic funds transfer, or another traceable cash transaction.

d. Documentation

We proposed 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, these revisions would not change any policies under the current documentation section of the CJR model.

In summary we proposed 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; 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 proposed 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 proposed 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 proposed to consolidate all records access and retention requirements in one place in the regulations, we proposed to delete § 510.500(e) from the current CJR regulations. We discussed 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 final rule. We refer readers to that section for further discussion of our proposed policies and rationale.

We proposed to amend the regulations at § 510.500(d). We sought comment on our proposals. We received no specific comments on the proposed documentation requirements for CJR sharing arrangements other than the comment discussed in section III.I.4.d. previously requesting further documentation related to the criteria for selection of CJR collaborators.

Final Decision: We are finalizing the proposals in § 510.500(d) for CJR documentation requirements, with the modification previously discussed to require the participant hospital to publicly post the written policies for selecting CJR collaborators on a Web page on the participant hospital's Web site and the reorganization to consolidate and streamline the documentation requirements related to public posting. CJR sharing arrangements must meet the following documentation requirements:

• The participant hospital must do all of the following:

++ Document the sharing arrangement contemporaneously with the establishment of the arrangement.

++ Publicly post (and update on at least a quarterly basis) on a Web page on the CJR participant hospital's Web site:

++ Accurate current and historical lists of all CJR collaborators, including CJR collaborator names and addresses.

++ Written policies for selecting individuals and entities to be CJR collaborators required by § 510.500(a)(3).

++ 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 all of the following:

—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 a CJR collaborator's gainsharing payment.
—Explanation for each recoupment, such as whether the CJR 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.

• 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 EPM collaborator to retain and provide access to, the required documentation in accordance with § 510.110.

3. Distribution Arrangements

Though we proposed 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,' remove the term 'collaborator agreement,' move the requirements for such agreements to appear as requirements for 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 proposed 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 proposed to define that payment as a ''distribution payment.'' A collaboration agent may make a distribution payment only 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 solicited comment on whether requirements for distribution payments by ACOs under the proposal were reasonable, necessary and appropriate to

promote program integrity, prevent fraud and abuse, and achieve the goals of the model. In addition, we solicited comment on how the regulation of the financial arrangements the proposal may interact with and on how these or similar financial arrangements are regulated under the Medicare Shared Savings Program.

We received no specific comments on the proposed general provisions for distribution arrangements under the CJR model. However, as discussed previously, we are finalizing revisions to allow NPPGP to be eligible to be CJR collaborators and we are modifying our general provisions for distribution arrangements to allow NPPGPs to enter into distribution arrangements with NPPGP members. Similarly, we are modifying our general provisions for distribution arrangements to allow TGPs to enter into distribution arrangements with TGP members. In addition, we are modifying the EPM proposals in response to the comments that we received, and therefore, consistent with our proposal to amend the CJR regulations to streamline and simply requirements for CJR and to align them with the EPMs, we are making corresponding changes to the CJR regulations. We believe these modifications also will reduce any burden that could arise from having to comply with different requirements for each model for hospitals participating in both CJR and EPMs. We refer readers to the discussion at III.I.5. for further information.

Final Decision: We are finalizing effective July 1, 2017 the proposals in § 510.505(a) for the general requirements for CJR distribution arrangements, with modification to allow NPPGPs or TGPs to enter into distribution arrangements with NPPGP members or TGP members respectively. Similar to PGPs when they are CJR collaborators, we believe it is appropriate to allow NPPGPs or TGPs to enter into distribution arrangements with NPPGP members or TGP members respectively for the sole purpose of sharing a gainsharing payment received by the NPPGP or TGP. Distribution arrangements under the CJR model must comply with the following general provisions:

- An ACO, PGP, NPPGP, or TGP that has entered into a sharing arrangement with a CJR 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.
- 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

We proposed to amend the requirements for distribution payments in § 510.505 as discussed in this section.

We proposed 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. The proposed requirement is substantively the same as the existing requirement in the CJR model. By adding the word ''past or anticipated,'' the proposed provision makes clear that 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 proposed to change the requirement as follows.

Like our proposal for gainsharing payments discussed previously, we proposed 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 proposed 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 noted 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 proposed 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). The 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. The 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. The approach mirrors our proposed policies for distribution arrangements for the EPMs, which are discussed in detail in section III.I.5. of this final rule.

We proposed to amend the regulations at § 510.505(b)(4) and (b)(5). We sought comment on the proposal and specifically whether additional safeguards or a different standard was 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 solicited 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 proposed to continue the limits in the current CJR regulations on the total amount of distribution payments to physicians, nonphysician practitioners, and PGPs as we proposed 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 proposed that all distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction. The 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.

Finally, we proposed at § 510.505(b)(15) 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 discussed 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. The approach mirrors our proposed records retention policies for the EPMs, which are discussed in detail in section III.H. of this final rule. We refer readers to that section for further discussion of our proposed policies and rationale.

We sought comment on our proposals regarding distribution arrangements

The following is a summary of the comments received and our responses.

Comment: We received comments on the requirements of a distribution arrangement under the CJR model and EPM, including the proposed cap on distribution and downstream distribution payments, which are discussed in section III.I.5.b.

Response: We appreciate the comments on the requirements of a distribution arrangement under the CJR model and the EPM. We refer to section III.I.5.b for a detailed discussion of comments and responses in regards to distribution arrangements under these models.

We are finalizing in §§ 510.505(6) and 510.510(6) that the amount of any distribution payments or downstream distribution payments from a PGP to a PGP 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 CJR activities.

Comment: One commenter requested clarification about whether outpatient therapy providers can receive distribution or downstream distribution payments as either a member of a PGP who is a CJR collaborator or as a member of a PGP that is an ACO participant in an ACO that has a distribution arrangement with a CJR collaborator.

Response: Certain outpatient therapy providers are included in the definition of a member of a PGP or PGP member which means ''a physician, nonphysician practitioner, or therapist who is an owner or employer of a PGP and who has reassigned to the PGP his or her right to receive Medicare payment.'' Thus, therapists who are PGP members may be eligible to receive distribution payments or downstream distribution payments when those PGPs enter into financial arrangements under the CJR model in accordance with all the requirements in this final rule.

Final Decision: After consideration of the public comments received, we are finalizing the proposals in § 510.505(b) for the requirements for CJR distribution arrangements, with modification to include policies for NPPGPs or TGPs that enter into distribution arrangements with NPPGP members or TGP members respectively. Like a PGP, an NPPGP that is an ACO participant in an ACO that is a CJR collaborator may enter into distribution arrangement with the ACO. The distribution payments to the NPPGP are subject to the same requirements as distribution payments to PGPs that are collaboration agents. The NPPGP is eligible to receive a distribution payment only if the collaboration agent 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 CJR participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed. The distribution payment to the NPPGP is capped at 50 percent of the total Medicare-approved amounts under the PFS for items and services billed by the NPPGP for items and services furnished by NPPGP members 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.

If an NPPGP is a CJR collaborator, it may enter into a distribution arrangement with an NPPGP member, which is defined as a nonphysician

practitioner or therapist who is an owner or employee of an NPPGP and who has reassigned to the NPPGP his or her right to receive Medicare payment. The requirements for NPPGP distribution payments under those distribution arrangements are the same as those for PGPs, except that we allow the amount of any distribution payments from a PGP to a PGP member to be determined in a manner that complies with § 411.352(g). While 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, NPPGPs do not fall under this definition of group practice. Therefore, the amount of any distribution payments from an NPPGP to an NPPGP member must always be determined in accordance with a methodology that is substantially based on quality of care and the provision CJR activities, the same standard that applies to PGP distribution payments that are not determined in a manner that complies with § 411.352(g). Like the requirement for PGP members when a distribution payment does not comply with § 411.352(g), an NPPGP member is eligible to receive a distribution payment only if the collaboration agent furnished an item or service to a CJR beneficiary during a CJR episode 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. Finally, the total amount of distribution payments paid for a performance year to the NPPG member may not exceed 50 percent of the total Medicare-approved amounts under the PFS for items and services furnished by the NPPGP member 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.

In addition, with respect to the distribution of any gainsharing payment received by an NPPGP, the total amount of all distribution payments must not exceed the amount of the gainsharing payment received by the CJR collaborator from the CJR participant hospital.

Like a PGP and NPPGP, a TGP that is an ACO participant in an ACO that is a CJR collaborator may enter into distribution arrangement with the ACO. The distribution payments to the TGP are not subject to the cap that applies to PGPs and NPPGPs. While we cap distribution payments to physicians and nonphysician practitioners, we will not cap such payments to therapists in private practice for the same reasons discussed for gainsharing payments to these individuals and, therefore, we will not cap distribution payments to TGPs. Like PGPs and NPPGPs, the TGP is eligible to receive a distribution payment only if the collaboration agent 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 CJR participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed.

If a TGP is a CJR collaborator, it may enter into a distribution arrangement with a TGP member, who is a therapist who is an owner or employee of a TGP and who has reassigned to the TGP his or her right to receive Medicare payment. Like distribution payments from an NPPGP to an NPPGP member, the amount of any distribution payments from a TGP to a TGP member must be determined in accordance with a methodology that is substantially based on quality of care and the provision CJR activities, the same standard that applies to PGP distribution payments that are not determined in a manner that complies with § 411.352(g). Like the requirement for PGP members when a distribution payment does not comply with § 411.352(g) and for NPPG members, a TGP member is eligible to receive a distribution payment only if the collaboration agent furnished an item or service to CJR beneficiary during a CJR episode 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 will not cap the total amount of distribution payments paid for a performance year to a TGP member for the reasons discussed previously for not applying caps on gainsharing payments to therapists in private practice. Finally, with respect to the distribution of any gainsharing payment received by a TGP, the total amount of all distribution payments must not exceed the amount of the gainsharing payment received by the CJR collaborator from the CJR participant hospital.

We are finalizing that distribution arrangements under the CJR model must comply with the following requirements:

- 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 CJR beneficiaries under the distribution arrangement.
- Participation in a distribution arrangement must be voluntary and without penalty for nonparticipation.
- The distribution arrangement must require the collaboration agent to comply with all applicable laws and regulations.
- 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.
- The amount of any distribution payments from an ACO, from an NPPGP to an NPPGP member, or from a TGP to a TGP member must be determined in accordance with a methodology that is substantially based on quality of care and the provision CJR activities and that may take into account the amount of such CJR activities provided by a collaboration agent relative to other collaboration agents.
- The amount of any distribution payments from a PGP 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 CJR activities and that may take into account the amount of such CJR activities provided by a collaboration agent relative to other collaboration agents.
- 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.
- 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:

++ In the case of a collaboration agent that is a 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.

++ In the case of a collaboration agent that is a PGP or NPPGP, 50 percent of the total Medicare-approved amounts under the PFS for items and services billed by that PGP or NPPGP for items and services furnished by PGP members or NPPGP members 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.

• With respect to the distribution of any gainsharing payment received by an ACO, PGP, NPPGP, or TGP, the total amount of all distribution payments must not exceed the amount of the gainsharing payment received by the CJR collaborator from the CJR participant hospital.

• 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.

• 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.

• The CJR collaborator must maintain contemporaneous documentation regarding distribution arrangements in accordance with § 512.110, including the following:

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.

• The CJR collaborator may not enter into a distribution arrangement with any individual or entity that has a sharing arrangement with the same CJR participant hospital.

• 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 § 512.110.

4. Downstream Distribution Arrangements Under the CJR Model

a. General

We proposed that the CJR model allow for certain financial arrangements within an ACO between a PGP and its members. We discussed our proposals for downstream distribution arrangements, which mirror our proposals for the proposed EPMs described in section III.I.6. of this final rule. Specifically, we proposed 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 defined 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 sought comment on our proposals for these general provisions, as well as any alternatives to this structure.

We received no specific comments on the proposed general provisions for downstream distribution arrangements under the CJR model. However, we are modifying the EPM proposals in response to the comments that we received, and therefore, consistent with our proposal to amend the CJR regulations to align them with the EPMs, we are making corresponding changes to the CJR regulations. We believe these modifications also will reduce any burden on hospitals participating in both CJR and an EPM that could arise from having to comply with different requirements for each model. We refer readers to the discussion at III.I.6. for further information.

Final Decision: We are finalizing effective July 1, 2017 the proposals in § 510.510(a) for the general requirements for CJR downstream distribution arrangements with modification to allow NPPGPs or TGPs to enter into downstream distribution arrangements with NPPGP members or TGP members respectively. Downstream distribution arrangements under the CJR model must comply with the following general provisions:

• An ACO participant that is a PGP, NPPGP, or TGP 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 a downstream distribution arrangement.

• 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

We proposed 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 final 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 final rule, we proposed 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 proposed 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 proposed 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 proposed 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 proposed a more flexible approach, as we did with the proposed EPMs. Consistent with our proposal for distribution payments, we proposed 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. We also proposed 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) or in a manner that is substantially based on quality of care and the provision of CJR activities.

Similar to our proposed requirements for distribution arrangements for those EPM collaborators that are PGPs, we proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 sought comment on our proposals.

We received no specific comments on the proposed requirements for downstream distribution arrangements under the CJR model.

Final Decision: We are finalizing effective July 1, 2017 the proposals in § 510.510(b) for the requirements for CJR downstream distribution arrangements, with modification to include policies for NPPGPs or TGPs that enter into downstream distribution arrangements with NPPGP members or TGP members respectively. Consistent with commenters' overall request that we streamline the regulations, we are also modifying proposed § 510.510(b)(6), which is final § 510.510(b)(7), to eliminate one of the two proposed requirements for eligibility of a downstream collaboration agent to receive a downstream distribution payment, specifically the requirement that the PGP bill for the item or service furnished by the downstream collaboration agent. Instead, we base downstream collaboration agent eligibility only on whether the downstream collaboration agent furnished an item or service 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 from which the ACO made the distribution payment to the PGP,

NPPGP, or TGP that is an ACO participant. This approach is parallel to § 510.505(b)(7), which applies to distribution payments from ACOs to ACO participants or ACO providers/suppliers and certain distribution payments from PGPs to PGP members, and ensures that the member of the PGP, NPPGP, or TGP receiving the downstream distribution payment furnished items and services to a CJR beneficiary during a CJR episode, without explicitly requiring that the PGP, NPPGP, or TGP to which the member of the PGP, NPPGP, or TGP would have reassigned his or her benefits also billed for the item or service. This latter additional requirement adds complexity that is unnecessary when our objective of the requirement is only to ensure that the recipient of the downstream distribution payment furnished an item or service to a CJR beneficiary during a CJR episode in order to link the payment to actual care. Finally, as discussed previously, in order to achieve consistency in the parameters for gainsharing payments and distribution payments to therapists and to streamline programmatic requirements, we are revising proposed § 510.510(b)(7), which is final in § 510.510(b)(8), by removing the cap on downstream distribution payments to PGP members as applied to therapists who are PGP members.

An NPPGP that is an ACO participant that has entered into a distribution arrangement with a CJR collaborator that is an ACO may enter into a downstream distribution arrangement with an NPPGP member, who is a nonphysician practitioner or therapist who is an owner or employee of an NPPGP and who has reassigned to the NPPGP his or her right to receive Medicare payment. The requirements for NPPGP downstream distribution payments under those downstream distribution arrangements are the same as those for PGPs, except that we allow the amount of any downstream distribution payments from a PGP to be determined in a manner that complies with § 411.352(g). The amount of any downstream distribution payments from an NPPGP to an NPPGP member must be determined in accordance with a methodology that is substantially based on quality of care and the provision CJR activities, the same standard that applies to PGP downstream distribution payments that are not determined in a manner that complies with § 411.352(g). Like the requirement for PGP members when a downstream distribution payment does not comply with § 411.352(g), an NPPGP member is eligible to receive a downstream distribution payment only if the downstream collaboration agent furnished an item or service to a CJR beneficiary during a CJR episode 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 from which the ACO made the distribution payment to the NPPGP that is an ACO participant. Finally, the total amount of downstream distribution payments paid for a performance year to the NPPGP member who is a nonphysician practitioner may not exceed 50 percent of the total Medicare-approved amounts under the PFS for items and services furnished by the NPPGP member 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 from which the ACO made the distribution payment to the NPPGP that is an ACO participant. In addition, 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 NPPGP from the ACO.

A TGP that is an ACO participant that has entered into a distribution arrangement with a CJR collaborator that is an ACO may enter into a downstream distribution arrangement with a TGP member, who is a therapist who is an owner or employee of an NPPGP and who has reassigned to the TGP his or her right to receive Medicare payment. Like downstream distribution payments from an NPPGP to an NPPGP member, the amount of any downstream distribution payments from a TGP to a TGP member must be determined in accordance with a methodology that is substantially based on quality of care and the provision CJR activities, the same standard that applies to PGP distribution payments that are not determined in a manner that complies with § 411.352(g). Like the requirement for PGP members when a distribution payment does not comply with § 411.352(g) and for NPPG members, a TGP member is eligible to receive a distribution payment only if the downstream collaboration agent furnished an item or service to a CJR beneficiary during a CJR episode 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 from which the ACO made the distribution payment to the NPPGP that is an ACO participant. We will not cap the total amount of downstream distribution payments paid for a performance year to a TGP member. Finally, 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 TGP from the ACO.

Like PGPs, NPPGPs and TGPs must maintain contemporaneous documentation regarding downstream distribution arrangements. Similarly, the NPPG or TGP may not enter into a downstream distribution arrangement with any NPPG member or TGP member respectively who has a sharing arrangement with a CJR participant hospital or a distribution arrangement with the ACO the NPPG or TGP is a participant in.

Downstream distribution arrangements under the CJR model must comply with the following requirements:

- 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.
- Participation in a downstream distribution arrangement must be voluntary and without penalty for nonparticipation.

The downstream distribution arrangement must require the downstream collaboration agent to comply with all applicable laws and regulations.

- 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 CJR participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a CJR participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent.
- The amount of any downstream distribution payments from an NPPGP to an NPPGP member or from a TGP to a TGP member must be determined in accordance with a methodology that is substantially based on quality of care and the provision 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.

• The amount of any downstream distribution payments from a PGP to a PGP 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 CJR activities, and the methodology may take into account the amount of such CJR activities by a downstream collaboration agent relative to other downstream collaboration agents.

• Except for a downstream distribution payment from a PGP to a PGP member that complies with § 411.352(g), a downstream collaboration agent is eligible to receive a downstream distribution payment only if the downstream collaboration agent furnished an item or service 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, NPPGP, or TGP that is an ACO participant.

• Except for a downstream distribution payment from a PGP to a PGP member that complies with § 411.352(g), the total amount of downstream distribution payments for a performance year paid to a downstream collaboration agent who is a physician or nonphysician practitioner and is either a PGP member or NPPGP member must not exceed 50 percent of the total Medicare-approved amounts under the PFS for items and services 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 distribution payment being distributed.

• 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, NPPGP, or TGP from the ACO.

• All downstream distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction.

• 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.

• The downstream distribution arrangement must not—

++ Induce the downstream collaboration agent to reduce or limit medically necessary services to any Medicare beneficiary; or

++ Reward the provision of items and services that are medically unnecessary.

• The PGP, NPPG, or TGP must maintain contemporaneous documentation regarding downstream distribution arrangements in accordance with § 510.110, including the following:

++ The relevant written agreements.

The date and amount of any downstream distribution payment.

++ 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.

• The PGP, NPPGP, or TGP may not enter into a downstream distribution arrangement with any PGP member, NPPGP member, or TGP member who has—

++ A sharing arrangement with a CJR participant hospital; or

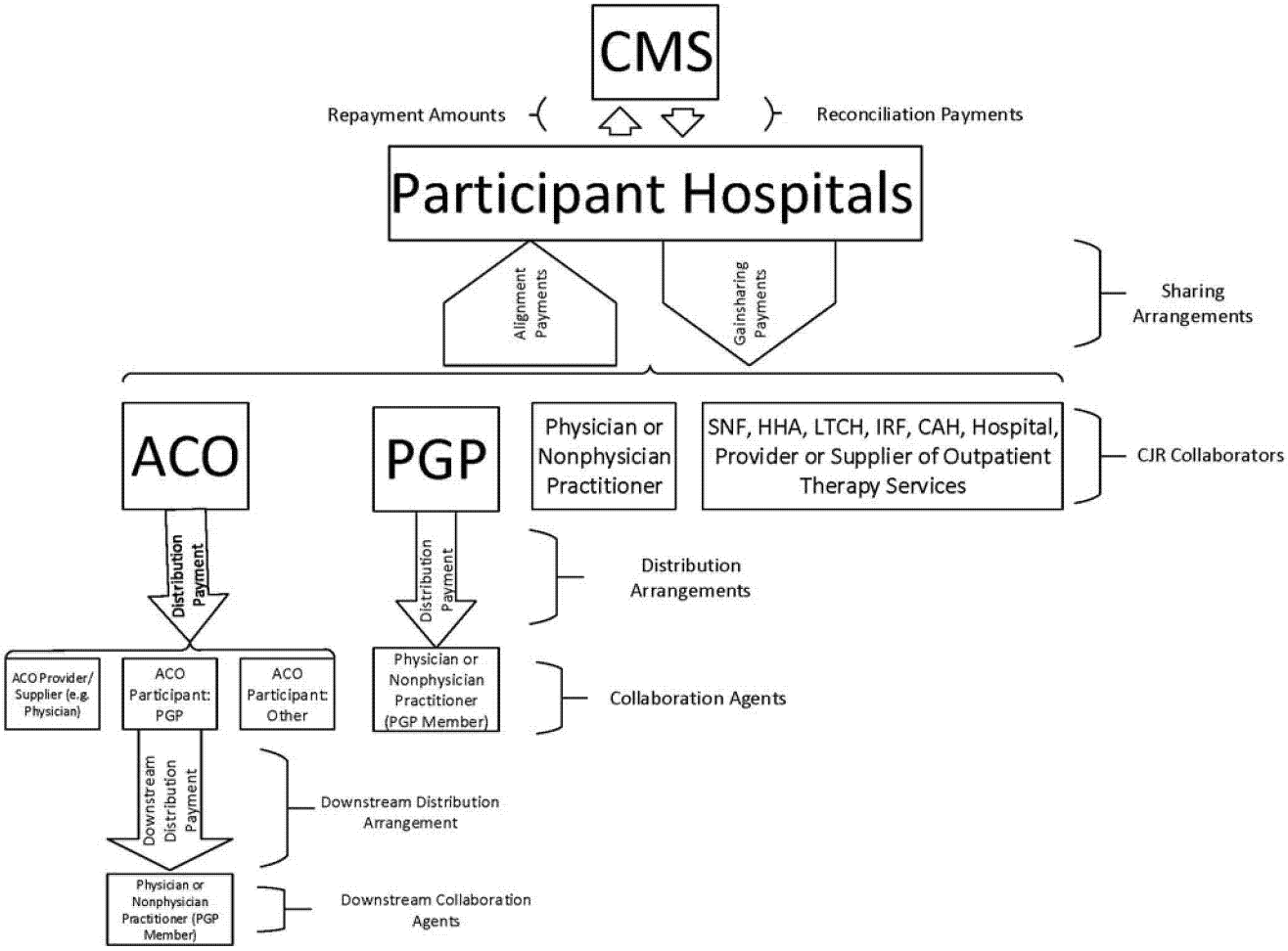
++ A distribution arrangement with the ACO that the PGP, NPPGP, or TGP is a participant in.

The PGP, NPPGP, or TGP 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.

5. Summary of Proposals for Sharing, Distribution, and Downstream Distribution Arrangements Under the CJR Model.

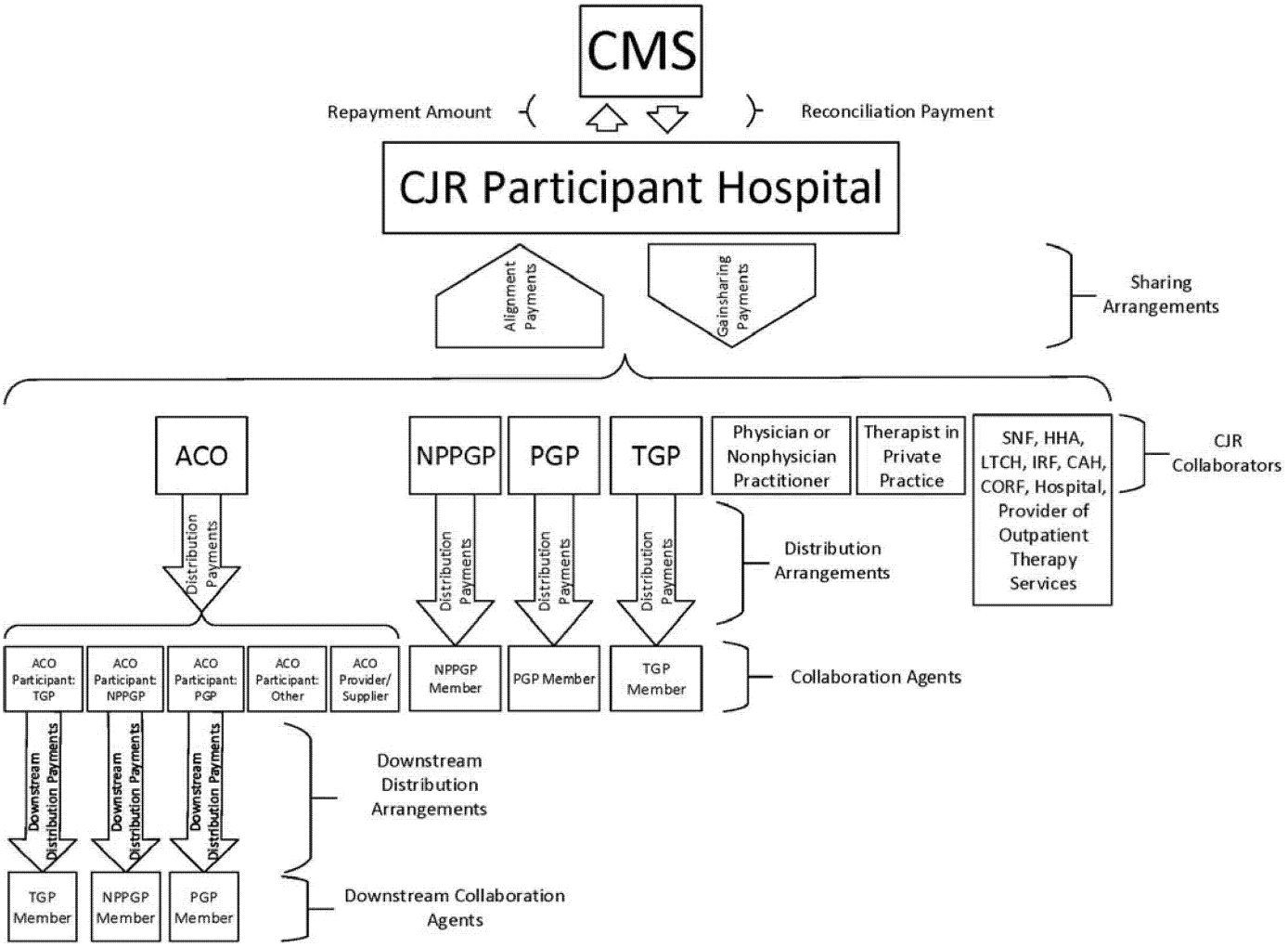
Figure 4 summarizes the proposals for the defined terms and financial arrangements discussed in section V.J. of this final rule.

Figure 4: PROPOSED CJR FINANCIAL ARRANGEMENTS



Our final policies for financial arrangements reflect a number of changes to the proposals for the CJR model financial arrangements in response to comments on the proposed rule. Figure 4. summarizes the policies for financial arrangements we proposed for CJR, whereas Figure 5 summarizes the policies we are finalizing for these arrangements as discussed in sections V.J.4. through V.J.6. of this final rule. Given the changes to the financial arrangement provisions discussed in V.J. will not be effective until July 1, 2017, Figure 5 is not applicable until July 1, 2017.

Figure 5: FINAL CJR FINANCIAL ARRANGEMENTS



K. Beneficiary Incentives Under the CJR Model

We proposed 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 proposed 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 proposed 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 final 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. As discussed in section V.L. of this final rule, 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 proposed 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 proposed to include these requirements in the regulations at §§ 510.515(d)(3) and 510.515(d)(4). We sought comment on our proposal. We also sought comment on the proposed

additional requirements for compliance with proposed section § 510.110 and the deletion of § 510.515(e). No comments were submitted in response to our proposed amendments to the beneficiary engagement incentives under the CJR model. Though we did not propose to change our policies regarding beneficiary engagement incentives under the CJR model commenters provided comments on beneficiary engagement incentives for the EPM, which mirrors the CJR model's policies.

We refer readers to section III.I.9 for a detailed discussion of comments and responses in regards to beneficiary engagement incentives under these models.

Final Decision: After consideration of the public comments received, we are finalizing the proposals, without modification. We are making changes related to beneficiary incentives effective July 1, 2017 in order to align the CJR model with the EPMs, avoid confusion and preserve the existing CJR regulations until these changes take effect.

L. Access to Records and Record Retention

We proposed to consolidate the requirements under CJR for access to records and record retention and apply them more broadly in the model. The approach mirrors our proposed records retention policies for the EPMs, which are discussed in detail in section III.H. of this final rule. We refer readers to that section for further discussion of our proposed policies and rationale.

We proposed to add § 510.110 to the CJR regulations, which would apply to documentation regarding beneficiary notifications, financial arrangements, and beneficiary incentives. Because we proposed to consolidate all of the existing records access and retention requirements in one place, we proposed to delete §§ 510.500(e) and § 510.515(c). We further proposed 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 proposed 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 proposed 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 final rule. Thus, we proposed 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 proposed 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 proposed 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 sought 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. The following is a

summary of the comments received and our responses.

Comment: Generally, commenters were supportive of our proposal in § 510.110 to consolidate the requirements under the CJR model for access to records and record retention and apply them more broadly in the CJR model. However one commenter stated that requiring participant hospitals, CJR collaborators, collaboration agents, downstream collaboration agents, and any other individuals or entities performing CJR activities to 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, is an excessive policy, and would burden entities and individuals involved in the CJR model. The commenter suggested that CMS reduce the 10 year record retention to 6 years, as the commenter believes that proposal is more consistent with other CMS programs. Further, one commenter recommended that CMS also request access to records on gainsharing and other savings-related payments so as to help examine the extent to which savings are equitably being shared by facilities with participating physicians and other healthcare professionals.

Response: We note that the 10-year record retention policy is the current policy of the CJR model. While we understand the commenter's concern that 10 years is excessive, we note that, once initiated, appeals and recalculation disputes can be lengthy processes and believe that maintaining this requirement as proposed would give both the participant and CMS as well as those conducting any audit, evaluation, inspection, or investigation, the resources to prepare and respond to issues that may take several years to surface. We appreciate the comment concerning CMS requesting access to records on gainsharing and other saving-related payments, and note that in these final regulations CMS may request from participant hospitals and their related CJR collaborators, collaboration agents, and downstream collaboration agents, records of the calculation, distribution, receipt, or recoupment of gainsharing payments, alignment payments, distribution payments, and downstream distribution payments.

Final Decision: After consideration of the public comments received, we are finalizing the proposal without modification. Since the changes to the financial arrangement provisions discussed in V.J. will not be effective until July 1, 2017, we are also making amendments to related sections effective July 1, 2017 to avoid confusion and preserve the existing CJR regulations until these changes take effect.

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 proposed 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 proposed to amend our regulations at § 10.620 to reflect this change.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification.

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 the CJR model 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 in performance year 2. 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 where 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 noted 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.pdf*). 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 denied, 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. As we stated in the proposed rule, we believe it was 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 in performance year 2, 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 proposed that when the hospital provides the beneficiary with the discharge notice in accordance with the requirements of § 510.405(b)(4) (which elsewhere in this final rule we are renumbering as § 510.405(b)(3), and therefore will refer to this provision by its new number throughout this section), 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, as we stated in the proposed rule, 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 proposed to require hospitals to keep a record of discharge planning notice distribution to CJR beneficiaries. We proposed to 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 proposed 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 proposed that beginning with episodes that are initiated on or after January 1, 2017, when the SNF waiver is available, if a participant hospital discharged a beneficiary without a qualifying 3-day inpatient stay to a SNF that was 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 would be financially liable for the SNF stay if no discharge planning notice was 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)(3), we proposed that the participant hospital would not be financially liable for the cost of the SNF stay and the normal Medicare FFS rules for coverage of SNF services will apply. We proposed that, in cases where the participant hospital provides a discharge planning notice in compliance with the requirements of § 510.405(b)(3) 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 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)(3), we proposed 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 proposed 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 proposed to clarify 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 sought comment on these proposals. Specifically, we sought 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 denied 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)(3). We sought 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 sought comment on any other related issues that we should consider in connection with the 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 proposed to amend our regulations at § 510.610 to reflect the change. We also proposed 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.

We received comments on similar waivers for the EPM, which we addressed in III.J of the EPM final rule. The following is a summary of the comments received on the CJR SNF 3-day waiver and our responses.

Comment: Commenters requested clarification discharge planning as it relates to application and use of the SNF 3-day waiver.

Response: CMS requires participant hospitals to provide written notice to beneficiaries informing them of potential financial liability associated with non-covered services presented as an option as part of discharge planning, as outlined at § 510.405(b)(4) of the CJR final rule, and amended in this final rule as § 510.405(b)(3). We refer readers to the CJR final rule (80 FR 73516–73521) and § 510.405(b)(3) for further discussion of this requirement.

Comment: Some commenters proposed that CMS modify the Bundled Payments for Care Initiative (BPCI) SNF 3-day waiver to more closely align with the CJR model's SNF 3-day waiver.

Response: We did not make any proposals in this rule with respect to BPCI.

Comment: Some commenters inquired about the process if a hospital wishes to utilize the SNF 3-day waiver, but the beneficiary wishes to remain in the hospital.

Response: As stated in 80 FR 73516, the CJR model does not seek to limit the beneficiary's ability to choose among Medicare providers or the range of services available. Decisions about the length of an inpatient stay are not addressed in this rule.

Final Decision: After consideration of the public comments received, we are finalizing the proposal without modification to cover services furnished under the SNF waiver in cases where the beneficiary met the criteria at § 510.205 on the date of discharge from the anchor hospitalization, based on information available as of that date. We are also finalizing the proposal to hold the participant hospital financially responsible for denied 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)(3). We are not finalizing the proposal to specify that the SNF waiver will be available for use for episodes that begin on or after January 1, 2017, as the change is no longer necessary given the effective date of this final rule. The final policies for financial liability for non-covered SNF services provided due to incorrect application of the SNF 3-day rule waiver are set forth in § 510.610.

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. We refer to the discussion following our proposals for the final criteria required for the APM to be an Advanced APM. 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 the proposed rule (81 FR 50794), we proposed 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. We refer to the discussion following our proposals for the final criteria required for the APM to be an Advanced APM. 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 the 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 sought comment on whether we should allow participant hospitals that are rural hospitals, SCHs, MDHs, or RRCs to elect a higher stop-loss limit for 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 noted 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 the 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 proposed 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 proposed 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 the 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, non-physician 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 Program 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 made proposals in subsequent 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 sought 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.

Based on the proposals for Advanced APM criteria in the Quality Payment Program proposed rule (81 FR 28161), we sought to align the design of the CJR model Advanced APM track with the proposed Advanced APM criteria and enable CMS to have the necessary information on Eligible Clinicians to make the requisite QP determinations. As detailed in the Quality Payment Program final rule with comment period, QP 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 77013). The three criteria for an Advanced APM were finalized in the Quality Payment Program final rule with comment period (81 FR 77008), and we continue to align the design of the CJR model Advanced APM track with the finalized Advanced APM criteria so that the CJR track that meets such criteria may be an Advanced APM. To be determined to be an Advanced APM, an APM must meet three Advanced APM criteria identified in § 414.1415 and discussed specifically later in this section.

First, 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 (81 FR 77406). Specifically, where the APM participants are hospitals, the APM must require each hospital to use CEHRT. As addressed in the Quality Payment Program final rule with comment period, 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 now finalized in the Quality Payment Program final rule with comment period, so that a track of the CJR model may meet the finalized criteria to be an Advanced APM, we proposed that those CJR participant hospitals who choose to participate in Track 1 of the CJR model 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. We believe that this proposal set forth in the EPM proposed rule would allow CJR participant hospitals who use and attest to use of CEHRT to be in an APM that meets the first finalized Advanced APM criterion.

Second, the APM must provide for payment to participants 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. We interpret this criterion to require the APM to incorporate quality measure results as a factor when determining payment to participants under the terms of the APM as described in the Quality Payment Program final rule with comment period (81 FR 77414). In order to align the CJR model Advanced APM track with the Quality Payment Program final rule with comment period, the quality measures on which the Advanced APM bases payment to participants 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 77418):

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 final rule with comment period, because the statute identifies outcome measures as a priority measure type and we want to encourage the use of outcome measures for quality performance assessment in APMs, we further finalized 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 77418). Therefore, according to the requirements finalized in the Quality Payment Program final rule with comment period and the quality measures adopted for the CJR model in the CJR Final Rule (80 FR 73375), the CJR model will meet the second finalized criterion of the Advanced APM criteria.

Third, the Quality Payment Program final rule with comment period requires that for an APM to meet the Advanced APM criteria, 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. For the purposes of the EPM, the generally applicable nominal amount standard for an Advanced APM in the Quality Payment Program final rule with comment period (81 FR 77425) means the total amount an APM Entity potentially owes CMS or foregoes under an APM must be at least equal to 3 percent of the expected expenditures for which an APM Entity is responsible under the APM. The generally applicable financial risk standard (81 FR 77422) means when an APM Entity's actual expenditures for which the APM Entity is responsible under the APM exceed expected expenditures during a specified QP Performance Period, the APM Entity is required to owe payment(s) to CMS. We refer to the Quality Payment Program final rule with comment period for a discussion regarding why we did not finalize the specific level of marginal risk or minimum loss rate (81 FR 77426). However, consistent with the commitments we made to adhere to the proposed marginal risk and minimum loss rate requirements in the Quality Payment Program proposed rule, we note that the financial risk in this final rule when the EPMs involve downside risk exceeds the proposed marginal risk and minimum loss rate requirements proposed for the Quality Payment Program. As discussed in section III.C. of the CJR Final Rule (80 FR 73324 through 73358), the final total initial risk of expected expenditures for EPM participants of 5 percent, except for rural hospitals, SCHs, MDHs, and RRCs subject to special protections at 3 percent, beginning in performance year 2 when downside risk first applies to all participants would meet the total potential risk element of the nominal risk amount standard for Advanced APMs finalized in the Quality Payment Program final rule with comment period (81 FR 77427) because it is greater than the value of at least 3 percent of expected expenditures. Therefore, according to the requirements finalized in the Quality Payment Program final rule with comment period and the payment methodology for CJR participant hospitals finalized in the CJR Final Rule (80 FR 73324 through 73358), all CJR participant hospitals in performance year 2 will be in an APM that meets the third finalized criterion of the Advanced APM criteria.

Finally, we finalized in the Quality Payment Program final rule with comment period (81 FR 77442) that for Advanced APMs, such as episode payment models, in which there are some Advanced APM Entities that include Eligible Clinicians on a Participation List and other Advanced APM Entities that identify Eligible Clinicians only on an Affiliated Practitioner List, we will identify Eligible Clinicians for QP determinations based on the composition of the Advanced APM Entity. In the scenario that applies to the CJR model, which includes only hospitals as Advanced APM Entities on the Participation List, for those Advanced APM Entities where there is an Affiliated Practitioner List that identifies Eligible Clinicians, that Affiliated Practitioner List will be used to identify the Eligible Clinicians for purposes of QP determinations, and those Eligible Clinicians will be assessed individually. Thus, to operationalize the CJR model as an Advanced APM, our proposal for the CJR model to identify Eligible Clinicians on a clinician financial arrangements list to construct the Affiliated Practitioner list would identify those Eligible Clinicians for purposes of QP determination, consistent with the policies finalized in the Quality Payment Program final rule with comment period.

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 proposed 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 sought comment on our proposals for CJR tracks and participant hospital requirements.

We received a number of comments on our proposals in this section that applied to both the EPMs and the CJR model, and no comments unique to the CJR model. We refer to sections III.A.2.a. and b. of this final rule for a summary of the comments and our responses.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, with modification to use the term ''specified'' for consistency with CEHRT attestation in other CMS programs, to include in § 510.120(a) the CEHRT use and attestation for CJR participant hospitals.

For performance year 2 through 5, CJR participant hospitals choose either of the following:

- CEHRT use. Participant hospitals attest in a form and manner specified 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.
- No CEHRT use. Participant hospitals do not attest in a form and manner specified 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.

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 final 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 final 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 proposed 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). The Quality Payment Program final rule with comment period (81 FR 77444) modified this process to identify eligible clinicians on the Affiliated Practitioner List for QP determinations at any one of three snapshots. The first snapshot will be on March 31 of the QP Performance Period, the second snapshot will be on June 30 of the QP Performance Period, and the third snapshot will be on August 31, which will be the last day of the QP Performance Period.

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 sought comments on the proposal for submission of this information. We noted that we were 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.

We received a number of comments on our proposals in this section that applied to both the EPMs and the CJR model and no comments unique to the CJR model. We refer to section III.A.2.c. of this final rule for a summary of the comments and our responses.

Final Decision: After consideration of the public comments received, we are finalizing the proposal in § 510.120(b), with modification to include on the clinician financial arrangements list all individuals with financial arrangements under the CJR model in 2017 through June 30, 2017 under the existing definitions and provisions of Part 510 and from July 1, 2017 and thereafter under the provisions effective July 1, 2017 as finalized in section V.J. of this final rule, and for CJR participant hospitals that meet and attest to the CEHRT use requirement to also submit on a no more than quarterly basis a clinician financial arrangements list. While we are finalizing the regulations generally as proposed, effective with the effective date of this final rule, we are delaying until July 1, 2017 the effective date of certain provisions that refer to individuals with financial arrangements for which the financial arrangements provisions take effect July 1, 2017. The implementation of the reporting requirements for the clinician financial arrangements list in two stages in 2017 will ensure that all physicians, nonphysician practitioners, and therapists with financial arrangements in association with CJR hospital participants that attest to CEHRT use can be reported on the clinician financial arrangements lists during the snapshots in 2017 for the Quality Payment Program, regardless of the

changes to the definitions and types of collaborators under the CJR model effective July 1, 2017.

Effective with the effective date of this final rule, each participant hospital that chooses CEHRT use 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 and entities for the period of the CJR performance year specified by CMS:

• CJR collaborators. For each CJR collaborator who is a physician, nonphysician practitioner, or therapist in private practice during the period of the CJR performance year specified by CMS:

++ The name, TIN, and NPI of the CJR collaborator.

++ The start date and, if applicable, end date, for the sharing arrangement between the CJR participant hospital and the CJR collaborator.

• Practice collaboration agents. For each physician, nonphysician practitioner, or therapist who is a CJR practice collaboration agent during the period of the CJR performance year specified by CMS:

++ The name and TIN of the CJR collaborator and the name, TIN, and NPI of the practice collaboration agent.

++ The start date and, if applicable, end date, for the distribution arrangement between the CJR collaborator and the practice collaboration agent.

• Attestation to no individuals. If there are no individuals that meet the requirements to be reported, 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.

Effective July 1, 2017, the provisions for practice collaboration agents on the clinician financial arrangements list will be revised to use the term collaboration agent instead, stating:

• Collaboration agents. For each physician, nonphysician practitioner, or therapist who is a collaboration agent during the period of the CJR performance year specified by CMS:

++ The name and TIN of the CJR collaborator and the name, TIN, and NPI of the collaboration agent.

++ The start date and, if applicable, end date, for the distribution arrangement between the CJR collaborator and the collaboration agent.

Effective July 1, 2017, new provisions for downstream collaboration agents on the clinician financial arrangements list will be added, stating:

• Downstream collaboration agents. For each physician, nonphysician practitioner, or therapist who is a downstream collaboration agent during the period of the CJR performance year specified by CMS—

++ The name and TIN of the CJR collaborator and the name and TIN of the collaboration agent and the name, TIN, and NPI of the downstream collaboration agent.

++ The start date and, if applicable, end date, for the downstream distribution arrangement between the collaboration agent and the downstream collaboration agent.

4. Documentation Requirements

For each participant hospital that chooses to meet and attest to CEHRT use, we proposed that the participant hospital must maintain documentation of its 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 proposed 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 sought comment on this proposal for required documentation.

Final Decision: We did not receive comments pertaining to § 510.120(c). Therefore, we are finalizing the proposal for CJR participant hospital documentation of attestation to CEHRT use and clinician financial arrangements lists submitted to CMS, with modification to implement the documentation provisions in two stages.

The following documentation requirements apply to CJR participant hospitals choosing CEHRT use. We note that while the requirement for CJR participant hospitals to maintain documentation of attestation to CEHRT use and clinician financial arrangements lists will be effective on the effective date of this final rule, the effective date of the provision for retention and the provision of access to the required documentation will delayed until July 1, 2017 to correspond to the similar delay in the effective date of § 510.110 to July 1, 2017, for reasons described elsewhere in this final rule.

• Each participant hospital that chooses CEHRT use must maintain documentation of their attestation to CEHRT use and clinician financial arrangements lists.

• The participant hospital must retain and provide access to the required documentation in accordance with § 510.110.

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.[137] 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.[138]

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.[139] 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

[137] 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.

[138] Anderson L et al. Exercise-based cardiac rehabilitation for coronary heart disease. Cochrane Database Syst Rev. 2016 Jan 5;1:CD001800.

[139] 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.

CMS.[140 141 142] Among beneficiaries 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.[143] 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 requirement for physician supervision of CR; and inadequate insurance payment.[144 145 146 147]

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.[148] 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.[149]

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.[150] ICR program sessions are limited to 72 one-hour sessions, up to 6 sessions per day, over a period of up to 18 weeks.[151] 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.[152]

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 believed that there were important advantages to proposing such an incentive in conjunction with the proposed EPMs that are also discussed in this final 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 to provide the foundation 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

[140] Suaya, J.A., Shepard, D.S., Normand, S.L., Ades, P.A., Prottas, J., Stason, W.B.. Use of cardiac rehabilitation by Medicare beneficiaries after myocardial infarction or coronary bypass surgery. Circulation. 2007;116:1653–1662.

[141] 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.

[142] Centers for Medicare and Medicaid Services (CMS). Cardiac rehabilitation programs. In: Medicare National Coverage Determinations Manual, chapter 1, part 1, section 20.10.

[143] Medicare Part A and B claims from 2013 through 12 month follow-up, Chronic Conditions Warehouse.

[144] Balady, G.J., Ades, P.A., Bittner, V.A., 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.

[145] Suaya, J.A., Shepard, D.S., Normand, S.L., Ades, P.A., Prottas, J., Stason, W.B. Use of cardiac rehabilitation by Medicare beneficiaries after myocardial infarction or coronary bypass surgery. Circulation. 2007;116:1653–1662.

[146] Wenger, N.K. Current State of Cardiac Rehabilitation. J Am Coll Cardiol 2008;51:1619–31.

[147] 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.

[148] *https://www.medicare.gov/coverage/cardiac-rehab-programs.html.*

[149] Section 1861(eee)(1) of the Act.

[150] 42 CFR 410.49(b)(1)(vii).

[151] Section 1861(eee)(1) of the Act.

[152] 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).

could make the proposed CR incentive payment more effective (if it is amplified by the broader care coordination infrastructure encouraged 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.

The following is a summary of the comments received and our responses.

Comment: Many commenters encouraged the implementation of this incentive payment model and reminded CMS that they believe timely referral of beneficiaries that have had an AMI or a CABG to CR programs promotes better adherence to CR service protocols, which will yield improved coordination, care management, and secondary risk reduction during the episode of care for the beneficiary. Other commenters stated their support for the proposed testing of an incentive payment was based on the compelling evidence in the proposed rule that the completion of a CR/ICR program can significantly reduce the risk of subsequent heart attacks and cardiac-related mortality. A commenter suggested that if these incentives for hospitals to increase the use of cardiac rehabilitation are implemented, CMS must educate physicians and other health care providers about the value of cardiac rehabilitation in improving patient outcomes, reducing hospital readmission rates, and lowering health care costs to increase referrals and ensure enrollment.

Response: We appreciate the recognition from commenters that evidence from multiple studies show that CR services improve health outcomes, but also that these services are underutilized. 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 treatment among beneficiaries that have had an AMI or a CABG, we believe that incentivizing the use of CR/ICR services is an important component of meeting this need. We continue to believe the proposed approach will permit CMS to appropriately evaluate this model and support testing the proposed hypotheses—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 and to examine each intervention's separate effects on the quality and efficiency of the care beneficiaries receive—with the strongest available evidence. We recognize that education programs about the value of CR/ICR services, including The Million Hearts national initiative to focus clinical attention on the prevention of heart attack and stroke, could complement these incentive payments.

2. General Design of the CR Incentive Payment Model

We proposed 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 EPMs, we proposed 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 final rule would be financially accountable for the AMI or CABG model episode. Thus, we expected that EPM participants would be highly engaged in care management of beneficiaries for the 90-day post-discharge duration included in the episode and could be able to capitalize on that engagement to encourage greater use of medically appropriate CR/ICR services if they were also selected for participation in the CR incentive payment model. Therefore, under the CR incentive payment model, we proposed 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 proposed to provide a CR incentive payment specifically to selected hospitals that are not AMI or CABG model participants (hereinafter FFS–CR participants). The 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 proposed 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.[153] 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 proposed 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

[153] 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.

service protocols, an expectation that is supported by data showing that patients who are referred early to CR were more likely to enroll.[154]

Historical claims data show that more than half of beneficiaries who receive one CR session go on to complete at least 25 sessions.[155] 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 proposed 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 final rule for EPM–CR participants and FFS–CR participants, respectively. Furthermore, we refer to section III.J.8. of this final rule for a discussion of the 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 final rule for discussion of the 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-covered 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 appropriate for CR incentive payments to selected AMI and 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 maximized 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 the 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 wanted to account for a range of factors and interactions that could potentially affect the outcomes we observed. 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.

The following is a summary of the comments received and our responses.

Comment: MedPAC commented that, while there are many barriers to enrollment for CR/ICR services, it is not clear which barriers create the biggest hurdles to effective care, and this lack of clarity makes the determination of the best corrective action difficult. MedPAC noted in comment that, for example, if one of the most significant barriers is low referral rates, CMS could encourage greater referral to CR/ICR by creating claims-based physician or hospital quality measures for all providers who care for beneficiaries with AMI and CABG. These measures could gauge the share of beneficiaries who receive CR/ICR services and the share who receive some minimum number of CR/ICR services. However, MedPAC also noted that tackling these barriers may require a multifaceted approach. Finally, MedPAC recommended that CMS not move forward with the proposed CR/ICR incentive payment model if CMS elects to implement the AMI and CABG EPMs, as they believe the proposed approach may be unnecessarily costly for the Medicare program, and seems overly complex.

Response: While we acknowledge that many barriers to CR/ICR services exist, multiple provider types furnish CR/ICR services, and services are provided for many indications, it would be unreasonable to test multiple proposals to address these concerns simultaneously, as such tests would make the assignment of appropriate controls difficult and assessment of impacts and outcomes from such proposals challenging to attribute to just one proposal. CMS proposed that EPM–CR participants be defined as hospitals that are AMI or CABG model participants located in the MSAs selected for the EPM–CR participation, and similarly proposed that FFS–CR participants are hospitals located in the MSAs selected for FFS–CR participation. We continue to believe the proposed approach will permit CMS to appropriately evaluate this model and support testing the proposed hypotheses—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 and to examine each intervention's separate effects on the quality and efficiency of the care beneficiaries receive—with the strongest available evidence. We proposed the CR incentive payment model to test the effects on quality of care and Medicare expenditures of providing explicit financial incentives in addition to, rather than in lieu of, current Medicare expenditures 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. We continue to expect that EPM participants would be highly engaged in care management of

[154] Grace, S.L. 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.

[155] Analysis of CR/ICR services utilization in 2013 Medicare FFS Parts A and B claims.

beneficiaries for the 90-day post-discharge duration included in the episode and could be able to capitalize on that engagement to encourage greater use of medically appropriate CR/ICR services if they were also selected for participation in the CR incentive payment model. Therefore, we are finalizing the proposal to implement the CR/ICR incentive payment model simultaneously with the EPMs, rather than test multiple incentives for the provision of CR/ICR services.

Comment: A commenter referencing the CR incentive payment model expressed concern that this voluntary program may become be required in the future and encouraged CMS to utilize this model to identify the patient population for whom this service improves outcomes.

Response: We appreciate the commenter's concern however the design of this model will not identify additional populations of beneficiaries who might show improved health outcomes beyond those undergoing AMI or CABG. Furthermore, we believe there is strong evidence already identifying those patient populations for whom CR/ICR services improve health outcomes.[156]

Comment: Several commenters stated support for the concept of cardiac rehabilitation incentive payments as proposed, whether or not these payments are tied to episode payments. A few commenters noted that CMS does not expressly define the proposed CR/ICR incentive payment model as separate and distinct from the EPMs. Given the similarities in patient populations and the proposed overlap of certain MSAs, these commenters expressed concern that there could be some confusion as to whether or not these models are in fact separate and distinct, and requested that CMS clarify in expressed terms what the case may be.

Response: In the proposed rule, we describe the proposed CR/ICR incentive payments as separate and distinct from reconciliation payments and Medicare repayments for EPM–CR participants determined under § 512.305(d). The proposed CR/ICR incentive payment under the CR/ICR incentive payment model is a more 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.

[156] Anderson, L. et al. Exercise-based cardiac rehabilitation for coronary heart disease. Cochrane Database Syst Rev. 2016 Jan 5;1:CD001800.

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 final rule. The selection process would identify the 98 EPM MSAs from the 294 MSAs eligible for selection for the AMI and CABG models under the proposed rule. We proposed 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 is discussed 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 were 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, we proposed 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 considered 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 considered 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 considered 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 proposed the selection of CR MSAs via a modified stratified random selection algorithm in which these groups serve as the selection strata. Specifically, we proposed 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 proposed to implement it in a consistent manner between the EPM–CR areas and the FFS–CR areas. As such, we proposed 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 proposed 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 section VI.C. of this final rule. We similarly proposed 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 final rule and that meet all provisions in sections III.B.2. through III.B.4. of this final 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 final 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 sought comments on our proposed approach to selecting MSAs and identifying CR participants.

The following is a summary of the comments received and our responses.

Comment: Commenters questioned the emphasis on hospitals for testing the model. These commenters noted that if this incentive program were limited to hospitals only, it would be highly unlikely to optimize physician engagement, leaving patient referral rates low. Other commenters noted that without including practice-based CR/ICR programs in the proposal, they believe the CR/ICR incentive payment model, despite its excellent intentions, would be unlikely to achieve its intended goal of driving better long-term quality cardiovascular care at lower cost. Other commenters urged CMS to expand the CR/ICR incentive payment model participants to permit physician practice-based ICR programs to be included to promote the underlying goal of increasing access to these services.

Response: While we acknowledge that many barriers to CR/ICR services exist, and multiple provider types furnish CR/ICR services, it would be unreasonable to test multiple proposals to address these concerns simultaneously, as such tests would make the assignment of appropriate controls difficult and assessment of impacts and outcomes from such proposals challenging to attribute to just one proposal. CMS proposed that EPM–CR participants be defined as hospitals that are AMI or CABG model participants located in the MSAs selected for the EPM–CR participation, and similarly proposed that FFS–CR participants are hospitals located in the MSAs selected for FFS–CR participation. We continue to believe the proposed approach will permit CMS to appropriately evaluate this model and support testing the proposed hypotheses—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 and to examine each intervention's separate effects on the quality and efficiency of the care beneficiaries receive—with the strongest available evidence. We continue to believe it is in the interest of the Medicare program and its beneficiaries for us to identify new models that maintain beneficiary choice, and disagree that the design of the CR/ICR incentive payment model will limit access to CR/ICR services for Medicare beneficiaries, as the payment model does not limit a beneficiary's ability to choose among Medicare providers and suppliers or the range of services that are available to them. Beneficiaries may continue to choose any Medicare enrolled provider or supplier, or any physician or practitioner who has opted out of Medicare, with the same costs, copayments and responsibilities as they have with other Medicare services.

We continue to 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 could be able to capitalize on that engagement to encourage greater use of medically appropriate CR/ICR services if they were also selected for participation in the CR incentive payment model. Therefore, we are finalizing the proposal to determine CR incentive payment model participants to include 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 and will compare these participants to FFS–CR participants. 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 proposed 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. 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.

Comment: Several commenters suggested that the CR incentive payment model be expanded beyond what was proposed. A commenter requested that all providers involved in any cardiac episode payment model be able to access the CR payment incentive. A commenter believed that the CR incentives should be available to all 98 cardiac EPM MSAs and thought it unfair that these would not be made universally available to all cardiac EPM participant providers. A commenter suggested that all 98 cardiac EPM–MSAs be enrolled in the CR incentive payment model as well as an additional 98 FFS–MSAs. Another commenter recommended that all cardiac EPM participant MSAs and an equal number of random eligible non-participant MSAs be enrolled in this model.

Similarly, another commenter urged that similar CR incentive payments be made available to BPCI Model 2 PGP episode initiators in order to compare and contrast physician-led cardiac episodes and hospital-led episodes.

Response: CMS is encouraged by the positive reception to the CR Incentive Payment Model and the belief that it is immediately suitable for expansion. At the same time, the incentive payments represent an additional outlay of funds beyond the current payment systems. In its role as a prudent steward of financial resources, CMS is committed to assessing the impact of this additional expenditure prior to a wider scale implementation. CMS is interested in conducting a test of the CR incentive payment model in order to assess the impact it has on both utilization and outcomes.

CMS initially considered providing access to the CR incentive to the 98 cardiac EPM MSAs only. However, after consideration, CMS decided that it was important to be able to assess the performance of EPM–CR areas relative to EPM-non CR areas, as well as the performance of EPM–CR MSAs versus FFS–CR areas and FFS–CR compared to FFS-non CR areas. The examination of all these combinations will provide insight into what factors are associated with the impacts observed.

Comment: A commenter requested additional details regarding any characteristics used in the selection of MSAs for the CR model.

Response: The characteristics for selection of the MSAs as stated in the proposed rule will include 3 dimensions of starting and completing CR services and number of CR/ICR providers and we refer the reader to section VI.C. for further details. Groupings within an MSA based on these dimensions will be created and then a stratified random selection process will be used to select participant MSAs. There will be an equal number of MSAs for eligible MSAs (EPM–CR MSAs) and those eligible but not selected for EPM (FFS–CR).

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to define CR incentive payment model participants in § 512.703, and specifically include both EPM–CR MSAs and FFS–CR MSA participants as being located in the selected MSAs meeting 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 EPM.

If a participant changes their eligibility status during the period of performance, they will become eligible for the CR incentive payment model. This may occur through concluding their participation as a BPCI initiating hospital or other means such as a new hospital being opened. The re-assessment and updating of hospital eligibility status will be performed on an ongoing periodic basis as frequently as quarterly if needed.

The selection of the CR areas will proceed as proposed with a two-step process in which 98 cardiac EPM MSAs would be chosen first and then the EPM–CR and the FFS–CR would be chosen from within CR selection groups. Seven CR selection groups were created using information about the utilization of CR in the MSA in the reference year. The groups were defined based on combinations of the following: (1) Whether there was more than one hospital provider who billed for CR services in the MSA in the reference year, (2) whether the percent of eligible Medicare FFS beneficiaries who received CR services was less than 20 percent, 20 to 30 percent or more than 30 percent, and (3) whether at least 60 percent of eligible patients who start CR services complete at least 25 sessions. The definition of seven groups used in the selection is shown in Table 52. The number of EPM–CR MSAs and the number of FFS–CR MSAs to be selected from each group is also shown in Table 52 and is proportional to the number of selected cardiac EPM MSAs in each group.

TABLE 52—CR MSA SELECTION GROUP DEFINITION AND NUMBER OF MSAS TO BE SELECTED

CR selection group No.	Number of hospitals billing for CR	Percent of eligible Medicare FFS patients starting CR	Percent of patients starting CR completing 25 sessions	Number of selection eligible MSAs	Number of cardiac EPM MSAs	Number of EPM–CR and FFS–CR MSAs to be selected from group (0.46 × # EPM)
1	1	<20%	Any	40	4	2
2	1	20% +	Any	35	16	7
3	2 +	<20%	Any	67	17	8
4	2 +	20–30%	<60%	34	13	6
5	2 +	20–30%	60% +	52	19	9
6	2 +	30% +	<60%	37	15	7
7	2 +	30% +	60% +	28	14	6
Total				293	98	45

As shown in Table 52, we are randomly selecting 2 EPM–CR and 2 FFS–CR MSAs from CR Selection Group 1 where the number two is derived by multiplying the number of cardiac EPM MSAs in the group by the selection percent and then rounding (round (4 × 0.46) = 2). The number of MSAs to be selected within the 7 CR Selection

groups are, in order, 2, 7, 8, 6, 9, 7, and 6.

We selected the participating FFS–CR and EPM–CR MSAs through random selection within groups. We selected 45 MSAs via stratified random sample from both AMI and CABG EPM participant MSAs and traditional fee for service MSAs (those not selected to participate in the AMI and CABG EPMs). EPM–CR MSAs were randomly selected from the EPM MSAs in the same selection group. Similarly, the same number of FFS–CR MSAs were randomly selected from within the MSAs in the CR selection group who were eligible for but not chosen as a cardiac EPM area.

Based on our sampling methodology, SAS for Windows Version 9.4 software was used to run a computer algorithm designed to randomly select MSAs. SAS for Windows Version 9.4 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 desired random sampling as the sample selection method. A random number seed was generated for each of the fourteen strata by using fourteen number seeds corresponding to birthdates and anniversary dates of parties present in the room. The random number seeds for stratum one through fourteen were as follows: 19851201, 20151024, 19841124, 20120827, 19590625, 19650907, 19870213, 19850714, 20090712, 20091024, 19800919, 19781023, 20120807, and 20140928. 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/.*

Table 53 shows the list of EPM–CR MSAs. Table 54 shows the list of FFS–CR MSAs.

TABLE 53—EPM–CR MSAS. CARDIAC EPM MSAS SELECTED FOR CR INCENTIVE PAYMENT MODEL

CBSA OMB No.	MSA name	CR selection group	CJR MSA
10180	Abilene, TX	7	
10780	Alexandria, LA	5	
10900	Allentown-Bethlehem-Easton, PA-NJ	5	
12220	Auburn-Opelika, AL	2	
13380	Bellingham, WA	2	
14020	Bloomington, IN	2	
14460	Boston-Cambridge-Newton, MA-NH	4	
15940	Canton-Massillon, OH	4	
15980	Cape Coral-Fort Myers, FL	3	
16700	Charleston-North Charleston, SC	5	
16860	Chattanooga, TN-GA	5	
17980	Columbus, GA-AL	1	
19100	Dallas-Fort Worth-Arlington, TX	5	
19300	Daphne-Fairhope-Foley, AL	7	
20500	Durham-Chapel Hill, NC	5	yes.
21060	Elizabethtown-Fort Knox, KY	4	
21660	Eugene, OR	6	
22520	Florence-Muscle Shoals, AL	5	
24300	Grand Junction, CO	2	
25940	Hilton Head Island-Bluffton-Beaufort, SC	7	
26580	Huntington-Ashland, WV-KY-OH	3	
26820	Idaho Falls, ID	2	
27860	Jonesboro, AR	4	
27900	Joplin, MO	4	
30620	Lima, OH	3	
30780	Little Rock-North Little Rock-Conway, AR	3	
31540	Madison, WI	6	yes.
33340	Milwaukee-Waukesha-West Allis, WI	6	yes.
33540	Missoula, MT	7	
35100	New Bern, NC	2	
35660	Niles-Benton Harbor, MI	2	
36540	Omaha-Council Bluffs, NE-IA	6	
39140	Prescott, AZ	7	
39380	Pueblo, CO	3	
39740	Reading, PA	3	yes.
40220	Roanoke, VA	5	
41100	St. George, UT	3	
41140	St. Joseph, MO-KS	7	
41420	Salem, OR	6	
44100	Springfield, IL	6	
46060	Tucson, AZ	4	
46140	Tulsa, OK	5	
46220	Tuscaloosa, AL	1	yes.
47940	Waterloo-Cedar Falls, IA	6	
48620	Wichita, KS	3	yes.

TABLE 54—FFS–CR MSAS. FFS MSAS SELECTED FOR CR INCENTIVE PAYMENT MODEL

CBSA OMB No.	MSA name	CR selection group	CJR MSA
11540	Appleton, WI	6	
12700	Barnstable Town, MA	1	
13020	Bay City, MI	2	
14010	Bloomington, IL	7	
15260	Brunswick, GA	1	
16180	Carson City, NV	2	yes.
16580	Champaign-Urbana, IL	7	
16940	Cheyenne, WY	2	
17460	Cleveland-Elyria, OH	5	
18020	Columbus, IN	2	
18580	Corpus Christi, TX	3	yes.
19340	Davenport-Moline-Rock Island, IA-IL	6	
20260	Duluth, MN-WI	6	
21780	Evansville, IN-KY	4	
22220	Fayetteville-Springdale-Rogers, AR-MO	5	
22500	Florence, SC	5	yes.
24660	Greensboro-High Point, NC	5	
25060	Gulfport-Biloxi-Pascagoula, MS	4	
25420	Harrisburg-Carlisle, PA	4	yes.
25620	Hattiesburg, MS	4	
28940	Knoxville, TN	7	
30700	Lincoln, NE	7	yes.
33740	Monroe, LA	3	yes.
34060	Morgantown, WV	3	
34620	Muncie, IN	2	
34940	Naples-Immokalee-Marco Island, FL	2	yes.
37340	Palm Bay-Melbourne-Titusville, FL	3	
37860	Pensacola-Ferry Pass-Brent, FL	3	yes.
38060	Phoenix-Mesa-Scottsdale, AZ	5	
38940	Port St. Lucie, FL	4	yes.
39460	Punta Gorda, FL	7	
40140	Riverside-San Bernardino-Ontario, CA	3	
40340	Rochester, MN	6	
40420	Rockford, IL	6	
40660	Rome, GA	5	
41180	St. Louis, MO-IL	7	yes.
41860	San Francisco-Oakland-Hayward, CA	5	yes.
42140	Santa Fe, NM	3	
42200	Santa Maria-Santa Barbara, CA	3	
42540	Scranton-Wilkes-Barre-Hazleton, PA	2	
42660	Seattle-Tacoma-Bellevue, WA	6	
42700	Sebring, FL	5	yes.
44180	Springfield, MO	6	
45780	Toledo, OH	5	yes.
47380	Waco, TX	4	

D. CR/ICR Services That Count Towards CR Incentive Payments

We proposed 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 55. 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.[157] [158]

TABLE 55—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.

[157] 42 CFR 410.49.

[158] 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.

We proposed 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 proposed 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 proposed 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 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 proposed 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 final 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 sought comments on our proposal to establish which CR/ICR services count towards CR incentive payments.

The following is a summary of the comments received and our responses.

Comment: A commenter suggested that EPM beneficiaries be offered the opportunity to participate in an independent CR program, as it has been the experience of this commenter that many patients see positive outcomes similar to those of patients who participate in more traditional CR programs. However, the commenter offering this suggestion also raised the concern that such programs may inadvertently be financially penalized because they do not follow the proposed structure of CR visits. Another commenter referenced exposure to numerous studies on and examples of integrated, remote CR programs, with reported similar efficacy, higher enrollment, and higher completion rates compared to traditional CR, and recommended CMS support these alternative models with the belief that such alternatives will foster innovation, enable cost-effective and tailored options for CR.

Response: While we appreciate all suggestions for considered improvements to the range and type of services offered, we are limited by the scope of this model to testing the provision of services that can be recognized through HCPCS coding procedures and therefore will finalize provision of incentive payments for services described by HCPCS codes for CR/ICR services in Table 55.

Comment: Commenters generally agreed with the proposed CR/ICR services that should count towards CR incentive payments. There were additional recommendations from commenters to align incentive payments with other aspects of a CR/ICR program, such as duration or frequency of sessions, while other commenters proposed alternative programs including examples such as physical and occupational therapy, pulmonary rehabilitation, home health therapy, and construction of a new program termed virtual cardiac rehabilitation to take place in the patient's home.

Response: We proposed 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 that report CR/ICR services as displayed in Table 55. These HCPCS codes have been active since prior to 2013 through the present. We note that CMS specifies the CR/ICR 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. We continue to believe that CR/ICR services are unique as an underutilized Medicare-covered 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 appropriate for CR incentive payments to selected AMI and 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. As a result, we are finalizing this proposal because we continue to believe this structured approach will contribute to our ability to test and evaluate the effects 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.

Comment: Some commenters expressed confusion regarding the process by which ICR programs are approved by CMS. Others suggested the need for clarification as to how individual sites wishing to furnish ICR services be able to participate. A commenter was concerned that EPM participant hospitals that do not have their own CR/ICR programs will not be eligible for payments under the CR Incentive Payment Model. A commenter requested that CMS clarify that all ICR programs covered under the CR incentive payment model receive approval under the NCD process, as this commenter believes the NCD process serves an important function in

ensuring that these programs meet the underlying statutory requirements.

Response: Approved ICR programs will continue to be required to meet the statutory requirements set forth in section 1861(eee)(4) of the Act. The NCD process, as authorized by section 1862(l) of the Act will continue to be used to determine whether an ICR program falls within the scope of this Part B benefit. An ICR program will continue to be evaluated in an open, transparent, and publicly engaging process. The standards for an ICR program are included in Section 410.49(c) of this subpart. CR participants without their own CR/ICR programs will receive the CR incentive payment based on the CR/ICR service utilization of beneficiaries attributed to them, regardless of the specific provider or supplier that furnished the CR/ICR services to the beneficiary during the episode or care period.

Comment: A commenter believes a significant majority of PFS claims for CR services are misleading. This commenter submitted an analysis of Medicare PFS claims for HCPCS code 93798 by specialty and identified the top five most frequently occurring specialties to be cardiology, internal medicine, family practice, cardiac electrophysiology, and emergency medicine. Based on these data, the commenter strongly questioned the appropriateness of the physician's office for the provision of CR services, and urged CMS to scrutinize PFS claims paid for delivery of CR services, as the commenter believes these claims are simple coding errors, or possible fraud/abuse. The commenter recommended that OPPS claims for CR/ICR services would be the accurate source to track for the CR incentive payment model.

Response: We thank the commenter for providing their analysis. While most CR/ICR services are billed and paid under the OPPS because they are furnished in the hospital outpatient department, CR/ICR services are also covered under Medicare when furnished in a physician's office where they are paid under the PFS.[159] PFS claims for CR/ICR services furnished in the physician's office report place of service code 11 (office). Our analysis showed that more than 95 percent of CR/ICR services for beneficiaries with AMI or CABG were billed under the OPPS. In addition, for CR/ICR services billed under the PFS, the physician's office was more frequently reported than the hospital outpatient department. In some cases, there were OPPS and PFS claims for the same beneficiary for the same day and the same CR/ICR service HCPCS code, but it was extremely rare for the PFS claim to have a place of service code for the physician's office in these cases, occurring in only 0.01 percent of AMI care periods and 0.02 percent of CABG care periods. These uncommon circumstances could either reflect incorrect billing or an actual care pattern where the same beneficiary received CR/ICR services on the same day in both the hospital outpatient department and physician's office. Nevertheless, our analysis of historical claims data showed no concerning patterns about coding errors on claims for CR/ICR services.

As discussed in the CY 2010 PFS Final Rule (74 FR 61879), we note that when a CR/ICR service is furnished in a hospital outpatient department, a physician cannot bill the Medicare contractor for CR/ICR unless the physician personally performs the CR/ICR service. To personally perform the CR/ICR service, the physician would provide direct care to a single patient for the entire session of CR/ICR that is being reported. The hospital would report the CR/ICR service and be paid the OPPS payment amount for the facility services associated with the CR/ICR services. The physician would report place of service code 19 or 22 (Off Campus-Outpatient Hospital or On Campus-Outpatient Hospital, respectively) on the PFS claim. A physician cannot bill under the PFS for CR/ICR services furnished in a hospital for which the physician furnishes only supervision or for services furnished in part by others. If the physician furnishes no direct CR/ICR services for a given session on a given day or provides direct CR/ICR services for less than the full session, then only the hospital would report the CR/ICR services and these services would be paid only under the OPPS. Thus, to be sure that we are capturing all unique sessions of CR/ICR services furnished in the hospital outpatient department or physician's office, without duplication in counting those services, we will include all CR/ICR services paid under the OPPS but only those CR/ICR services that report place of service code 11 on PFS claims in the CR/ICR services that count toward CR incentive payments.

We note that CR/ICR services will be continue to be paid by the Medicare program under the OPPS and the PFS throughout the CR incentive payment model performance years for CR beneficiaries and are subject to all applicable rules governing the submission of claims for services for payment by Medicare. We refer to sections III.J.8. and VI.F.7. of this final rule for our discussion of the waiver of the physician definition to 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/ICR services furnished to an EPM–CR or FFS–CR beneficiary during an AMI or CABG episode or AMI care period or CABG care period, respectively. We will rely upon the CR/ICR services paid by Medicare under the OPPS or to any supplier reporting place of service code 11 on the PFS claim for determining the CR/ICR services furnished to EPM–CR and FFS–CR participants. All CR/ICR services billed to Medicare must also meet the billing requirements outlined in the Medicare Claims Processing Manual.[160] CR/ICR services billed to Medicare outside the episode must continue to meet coverage requirements described in 42 CFR 410.94 and any applicable National Coverage Determinations.[161]

We will monitor throughout the CR incentive payment model the utilization of CR/ICR services, including the place of service. If this monitoring raises concerns about erroneous claims or potential fraud and abuse based on significant changes in the distribution of CR/ICR services being billed and paid for CR beneficiaries in the physician's office and the hospital outpatient department compared to historical patterns and current patterns of CR/ICR services furnished to Medicare beneficiaries not in the CR incentive payment model, we may more closely examine the claims for these services and/or refer these circumstances to Medicare contractors for further investigation.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, with modification, to establish which CR/ICR services count towards CR incentive payments in § 512.705 as CR/ICR services identified by the HCPCS codes for CR/ICR services in the CR performance year when those CR/ICR services are paid under the OPPS or to

[159] 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.

[160] Claims Processing Requirements for Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Services Furnished on or After January 1, 2010. Chapter 32, Section 140.2.2. Medicare Claims Processing Manual.

[161] Intensive Cardiac Rehabilitation (ICR) Programs. Chapter 1, Part 1, Section 20.31.1–3. Medicare National Coverage Determinations (NCD) Manual.

any supplier reporting place of service code 11 on a PFS claim. This modification to limit CR/ICR services from suppliers to those reporting place of service code 11 on the PFS claim, rather than all CR/ICR services from suppliers, ensures that we can establish a unique, unduplicated count of CR/ICR services furnished in the hospital outpatient department and in the physician's office to a CR beneficiary for purposes of the CR incentive payment to CR participants.

Table 56 displays the HCPCS codes currently used for reporting CR/ICR services and that will be used counting CR/ICR services under the CR incentive payment model.

TABLE 56—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.

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 sought to propose an incentive for CR participants that was sufficient to encourage them to increase clinically appropriate CR/ICR service referrals for beneficiaries; reduce barriers to beneficiary adherence to 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 proposed 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 proposed 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 55 and the units of service billed.

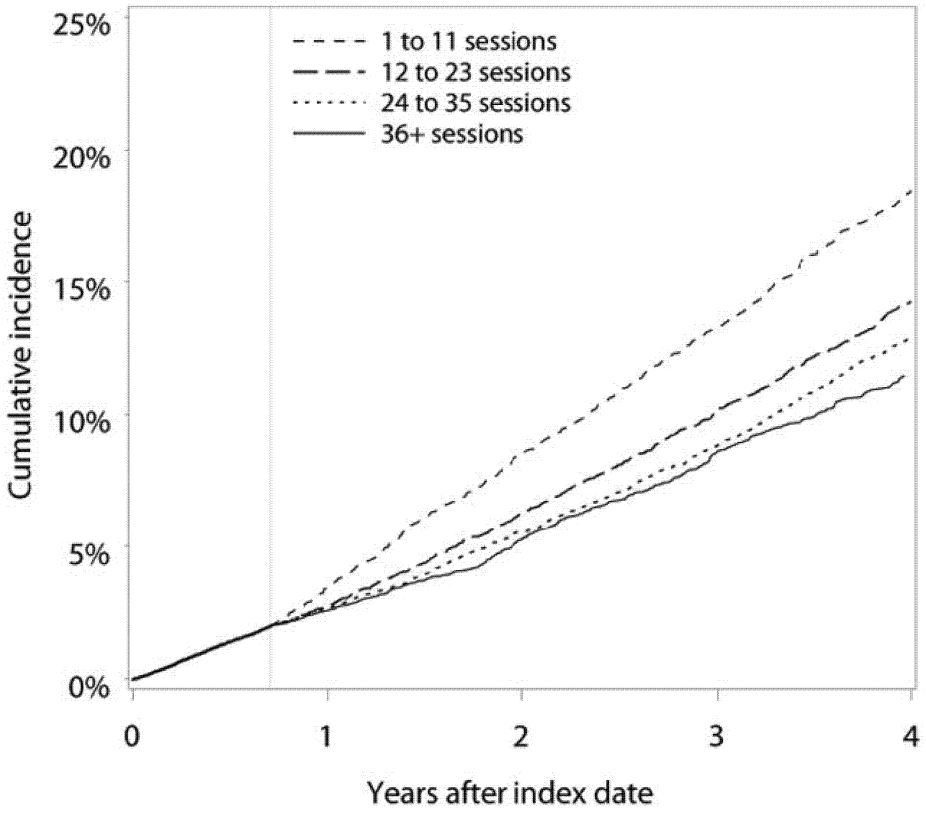
The initial level of the per-service CR incentive amount that would count toward the CR amount would be $25 per CR/ICR service for each of the first 11 CR/ICR services paid for by Medicare during an AMI or CABG model episode or AMI care period or CABG care period. We believe that $25 is an appropriate 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.[162] Figure 6 replicates Figure 2 from that study.

[162] 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.

FIGURE 6: CUMULATIVE INCIDENCE OF MORTALITY BY NUMBER OF CARDIAC REHABILITATION SESSIONS ATTENDED[163]



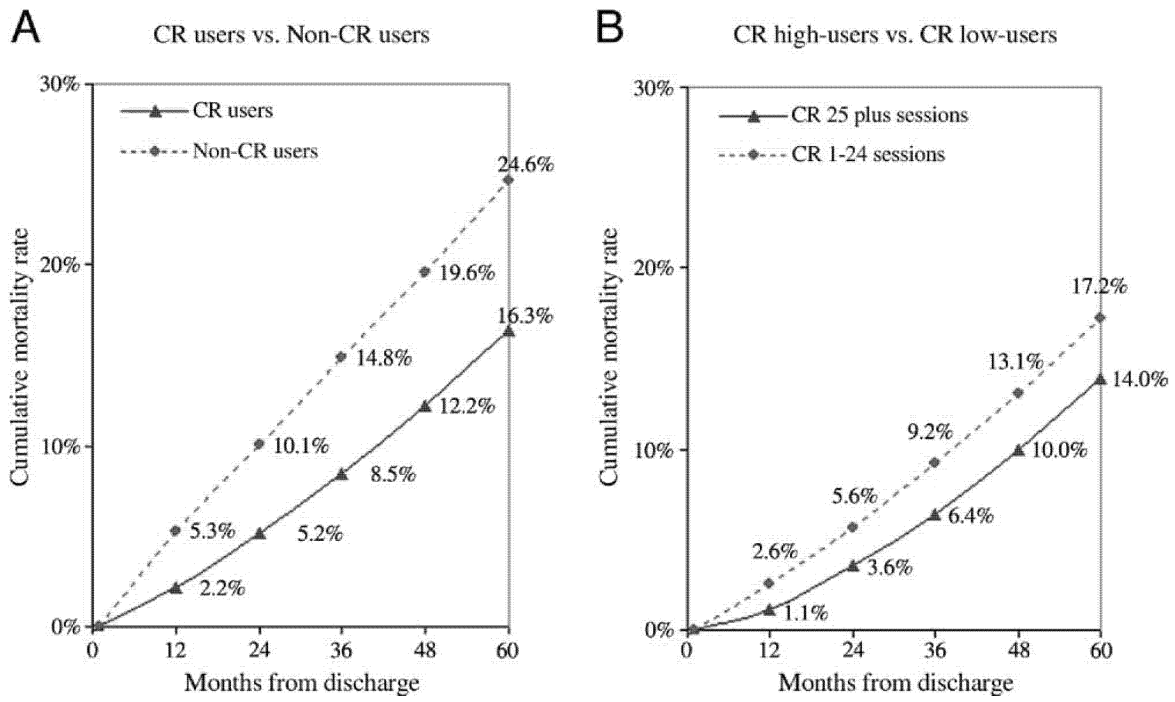
No. at risk					
Overall	30,161				
1 to 11 sessions		5937	4883	3865	2859
12 to 23 sessions		6933	5716	4427	3223
24 to 35 sessions		10,978	8955	6905	4885
36 sessions		5465	4513	3523	2481

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.[164] Figure 7 replicates Figure 1 from that study.

[163] 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.

[164] 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 7: ESTIMATES OF CUMULATIVE MORTALITY RATES FOR PROPENSITY-BASED MATCHED GROUPS OF CR USE[165]



We did 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 showed 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.[166] ICR program sessions are limited to 72 one-hour sessions, up to 6 sessions per day, over a period of up to 18 weeks.[167]

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 final rule for EPM–CR and FFS–CR participants, respectively.

Because the CR incentive payment would be made to the CR participant

[165] 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.

[166] 42 CFR 410.49(b)(1)(vii).

[167] 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 final 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. The 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 were proposed 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 EPMs 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.

The following is a summary of the comments received and our responses.

Comment: A few commenters requested CMS consider the feasibility of expanding the number of CR/ICR incentive payment model beneficiaries to include all diagnoses eligible for CR coverage through Medicare and/or enable all EPM participants which are selected for the AMI/CABG model to be eligible for participation in the CR program.

Response: While we acknowledge that CR/ICR services are provided for many indications, it would be unreasonable to test multiple proposals to address these concerns simultaneously, as such tests would make the assignment of appropriate controls difficult and assessment of impacts and outcomes from such proposals challenging to attribute to just one proposal. CMS proposed that EPM–CR participants be defined as hospitals that are AMI or CABG model participants located in the MSAs selected for the EPM–CR participation, and similarly proposed that FFS–CR participants are hospitals located in the MSAs selected for FFS–CR participation. We proposed the CR incentive payment model to test the effects on quality of care and Medicare expenditures of providing explicit financial incentives in addition to, rather than in lieu of, current Medicare expenditures 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. We continue to 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 could be able to capitalize on that engagement to encourage greater use of medically appropriate CR/ICR services if they were also selected for participation in the CR incentive payment model.

Comment: Commenters offered a variety of perspectives on the duration of the period of time for which the CR/ICR incentive payment would be made. A commenter suggested that the incentives as stated should be sufficient to encourage the timely enrollment of patients in to CR but noted that the 90-day period will likely not be sufficient to maximize their full effect on improving adherence if they are only in effect for 90 days after index event. A few commenters further encouraged CMS to consider the option of having the incentives maintained beyond the 90-day period. In contrast, one commenter noted that the timing of the payments as proposed may serve as an incentive to enroll patients as soon as possible and make program adjustments to allow for more active participation during the 90-day time period. Therefore, the commenter reasoned, it would be incumbent on the CR/ICR programs to implement strategies that would result in immediate referral to get patients enrolled within seven days of hospital discharge and remove barriers to more active participation to fully complete the 36 sessions during the 90-day period. A few other commenters expressed uncertainty around the structure of the CR incentive payment and requested that CMS confirm that CR/ICR incentive payments will persist for EPM beneficiaries after their 90-day EPM episode ends, citing their experiences of a lag in time before which a referral for CR/ICR services is made and their experience with the period of time over which a CR/ICR course of treatment takes place. Similarly, several commenters requested that CMS confirm that CR/ICR incentive payments will be made in addition to, rather than in lieu of, the underlying Medicare FFS payments to providers for CR/ICR services.

Response: While we acknowledge that CR/ICR services often continue beyond the 90- day post-discharge duration we proposed for the CR incentive payment model, it would be unreasonable to test multiple proposals to address these concerns simultaneously, as such tests would make the assignment of appropriate controls difficult and assessment of impacts and outcomes from such proposals challenging to attribute to just one proposal. We proposed the CR incentive payment model to test the effects on quality of care and Medicare expenditures of providing explicit financial incentives in addition to, rather than in lieu of, current Medicare expenditures 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. We continue to 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 could be able to capitalize on that engagement to encourage greater use of medically appropriate CR/ICR services if they were also selected for participation in the CR incentive payment model. Therefore, we are not extending incentive payments at this time as we believe the proposal to provide a CR incentive payment specifically to EPM–CR participants is

reasonable when it aligns with the AMI or CABG episode of care because these participants are already engaged in managing the AMI or CABG model beneficiary's overall care for a period of time following hospital discharge and will compare these participants to FFS–CR participants.

Comment: Commenters raised concern that the proposed timing of the CR incentive payment model did not align with the panoply of patient experiences. A commenter stated that not all patients need the full complement of CR/ICR sessions, and another stated that not all cardiac patients are candidates for cardiac rehabilitation services. To this end, commenters submitted alternative proposals, including combining payments for CR/ICR services into the bundled payment for AMI and CABG.

Response: While we agree that improved outcomes have been demonstrated in patients who participate in as little as one CR session per week over 36 weeks (74 FR 61875), the proposed general design of the CR incentive payment model is consistent with the belief 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.[168] We believe this model may yield improved coordination, care management, and secondary risk reduction during the episode of care after AMI or CABG for the beneficiary. Additionally, CMS 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, and believe that extending CR/ICR incentive payments beyond the 90-day episode is not aligned with the proposed rationale. We remind all commenters that section 410.49(f) includes coverage for a maximum of two 1-hour CR 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.

Comment: Many commenters expressed support for the CR/ICR incentive payments as proposed, and encouraged implementation, as they believe the result will show support of its broader use. A commenter noted that the incentive payments are in the right amounts and appropriately tiered for the initial demonstration program. Several commenters expressed opposing viewpoints as to the sufficiency of the CR/ICR incentive payment, and MedPAC questioned whether such a large amount would be necessary to induce changes in provider behavior. A commenter noted that it does not have the expertise to determine whether the proposed monetary payment is sufficient to achieve the stated goal, and encouraged CMS to seriously consider comments from hospitals and the community of cardiology professionals to ensure the sufficiency of the incentive payment. Another commenter encouraged CMS to revisit the amount of the incentive payments after 6 months to observe the effects of the model policies on service utilization, long-term outcomes, and Medicare expenditures to assess if they are sufficiently high to encourage plan participants to identify and remove beneficiary barriers to provision of CR/ICR services. A commenter noted that despite the CR/ICR incentive payment, even participant hospitals that share CMS' goal of increasing clinically appropriate services may be unlikely to be able to devote staff and financial resources to encourage beneficiary participation in programs such as CR/ICR whose benefits, while important, primarily affect the cost of services needed by beneficiaries long after the AMI or CABG episode ends. Many commenters questioned the extent to which CMS provided sufficient evidence supporting the sufficiency of the CR incentive payment amount.

Several other commenters submitted both general and specific concerns with the proposed CR/ICR incentive payment amount. MedPAC commented that the proposed incentive payment of $175 per CR/ICR service once a beneficiary exceeds 11 CR/ICR services considerably exceeds the amount Medicare pays for each service itself, could add up to a substantial amount per beneficiary, and expressed uncertainty as to how CMS determined the level of the proposed payment incentive amount. Several commenters proposed alternative amounts for CR/ICR incentive payments, including (1) bundled payment for all CR/ICR services, which could be divided into the following four categories: 5 or less sessions, $500 allowed; 6–12 sessions, $1000; 13–24 sessions, $2000; 25–36 sessions, $3000; (2) offer of a higher level of per-service CR/ICR incentive amount or adding a tier for increasing the number of enrollees from an underserved group; (3) make interim incentive payments during the year; and (4) increase in payment for the initial session of CR/ICR services provided to the patient from $25 to $175 as this first session is fundamental to enrolling the patient, beginning the rehabilitation process, and reflecting the intense resources necessary in the initial evaluation, enrollment, and education of the patient.

Response: We understand the commenters' concerns and appreciate alternative proposals that are in the spirit of testing the outcomes of the proposed model. 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 [169] [170] and evidence that beneficiaries who completed 25 or more CR sessions had lower mortality compared to beneficiaries who completed 1–24 CR sessions.[171] [172] Furthermore, we did not propose to set a cap on the number of CR/ICR services that would count toward the CR payment amount during an AMI or CABG model episode or AMI care period or CABG care period. We believe the proposed approach, rather than the alternative recommendations of the commenters, 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

[168] 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.

[169] Intensive Cardiac Rehabilitation (ICR) Programs. Chapter 1, Part 1, Section 20.31.1–3. Medicare National Coverage Determinations (NCD) Manual.

[170] 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.

[171] 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.

[172] 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.

utilization of services that has been shown to result in improved outcomes.

Since such incentive payments specific to the provision of CR/ICR services have not previously been tested in this way, we will test to determine whether there are sufficient payment amounts applicable and available to increase utilization of CR/ICR services. We do know that an important design element of any incentive payment model is the threshold or benchmark [173] used to determine which CR participants will receive incentive payments. For this design element, we believe we have presented strong evidence in support of proposed benchmarks that are clear, transparent, and for which CR participants can attain meaningful improvements. Therefore, the proposed incentive payment amount 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.

We may 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 EPMs and Medicare FFS program payment methodologies for overall care.

Comment: A minority of commenters stated confusion as to the extent to which CR incentive payments would be made in addition to or in lieu of payments to providers for CR/ICR services.

Response: We reiterate that under the CR incentive payment model, a CR incentive payment to EPM–CR and FFS–CR participants would be made under the model. Regular Medicare program payments would continue to be made to providers and suppliers that furnish and bill for CR/ICR services to beneficiaries in AMI or CABG episodes or AMI care periods or CABG care periods.

Comment: A few commenters raised concern as to the means to implement a value-based incentive design for a CR/ICR model, as these commenters believe the proposed CR/ICR incentive payment model to be a utilization-based model. Such alternative proposals included a general focus on outcomes associated with use of CR/ICR services and a specific focus on outcome metrics (for example, 30-day mortality, re-hospitalization rates) as well as process metrics (referral to CR, statin use) for those processes that are well established and evidence-based. To this end, a few commenters requested that CMS work with the healthcare community to determine appropriate patient-reported outcomes measures for CR/ICR services prior to finalizing the proposed EPMs. Without specific outcome measures attributed to this model, commenters suggested that some policy makers might incorrectly conclude that CR/ICR services are not important. Furthermore, commenters stated that these quality measures would permit alignment with tracks for Advanced APMs and MIPS APMs. Several commenters suggested inclusion of patient-reported outcome (PRO) metrics, and requested that CMS work with the healthcare community to determine appropriate PRO metric(s). It was suggested by these commenters that such outcomes may identify appropriate length of rehabilitation. Additionally, MedPAC recommended creating claims-based physician or hospital measures for all providers who care for beneficiaries with AMI and CABG, and then such measures could gauge the share of beneficiaries who receive CR/ICR services.

Response: 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, the rationale for utilization of such services is built on a strong evidence base of improved health outcomes for beneficiaries who have had an AMI or a CABG. Therefore, this model is designed to reward increased EPM–CR participant referral of AMI and CABG model beneficiaries to CR/ICR programs. Additionally, we remind all commenters that historical claims data show that more than half of beneficiaries who receive one CR session go on to complete at least 25 sessions.[174] Furthermore, we note that an outcomes assessment is part of the CR benefit established by Congress in section 144(a) of the MIPPA, which is designed to ensure CR programs enhance the patient's clinical outcomes. Section 410.49 of this subpart further describes the assessment of outcomes. While we appreciate the remark that quality measures are required for an APM to qualify as an Advanced APM under the QPP final rule, we remind all commenters that an APM must also require participants to bear financial risk (or be a Medical Home Model expanded under section 1115A(c) of the Act) and utilize CEHRT, which CMS did not propose for the CR/ICR incentive payment model. Thus, we are finalizing our CR incentive payment model without including separate and distinct quality measures.

Comment: MedPAC commented that the same outcomes could be accomplished by simply carving out payment for CR/ICR services from the EPM bundled payment and continuing to pay for these services separately, without incentive payments for EPM participants.

Response: CMS 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. Therefore, we disagree that the same test could be accomplished by simply carving out CR/ICR services from a bundled payment for a broadly defined cardiac episode-of-care. The CR incentive payment is not a payment for the CR/ICR services themselves. Rather, it is for the CR participant work to coordinate and increase the utilization of the beneficiary's participation in CR/ICR services following hospital discharge. A carve-out of the payments for CR/ICR services from the EPM episode would also not allow us to examine the effects of a CR incentive payment in the context of an underlying episode or FFS payment methodology for overall care. We will continue to monitor the effects of this model on EPM–CR and FFS–CR participants.

Comment: Most commenters agreed that the primary goal of an incentive payment model should be to recruit the vast majority of prospective patients into cardiac rehabilitation, with much less emphasis on how many sessions they attend. A commenter shared their experience that for patients who have been diligent in performing an exercise program prior to cardiac event and/or performing a home exercise program since cardiac event, only one or several sessions may be all that is necessary to insure that these patients will obtain the documented benefits of regular exercise. Another commenter shared their experience, particularly in the past 5–10 years, that most cardiac rehabilitation participants, particularly those who have not been very active pre- and post-cardiac event, can achieve reasonable improvements in exercise skills and

[173] Damberg CL, et al. (2014) Measuring Success in Health Care Value-Based Purchasing Programs. Retrieved October 31, 2016, from the RAND Corporation Web site: *http://www.rand.org/pubs/research_reports/RR306.html.*

[174] Analysis of CR/ICR services utilization in 2013 Medicare FFS Parts A and B claims.

confidence with just 6 to 24 sessions of cardiac rehabilitation exercise. To this end, many commenters expressed concern that they believe there is a lack of standardization around CR programs, and it may be unclear which number of sessions be tied to CR/ICR incentive payments. A commenter encouraged CMS to study the appropriate length of these programs.

Response: We disagree, and refer the commenters to research demonstrating that beneficiaries who completed more CR sessions had lower mortality compared to beneficiaries that completed fewer sessions.[175] [176] We believe that the CR incentive payment model has an evidence-based focus on payment of the CR incentive payment based on the number of sessions beneficiaries attend. The proposed model is also focused in scope so as to best understand the effects on quality of care and Medicare expenditures for providing explicit financial incentives to CR participants to increase CR/ICR utilization for beneficiaries following hospitalization for treatment of AMI or CABG. Therefore, we believe that such research and development of a standardized CR program is outside the scope of the proposed rule.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, with modification as discussed in the previous section, for determining the amount of the CR incentive payments in § 512.710(a) based on CR/ICR services paid by Medicare to any provider or any supplier reporting place of service code 11 on the claim for CR beneficiaries. We are finalizing the proposal, without modification, in § 512.710(b) for determination of the CR incentive payment. However, we are revising our proposed definitions of the terms CR amount and CR service count used in § 512.710(b) to incorporate the same limitation to include only those CR/ICR services on supplier claims that report place of service code 11 as previously discussed. Therefore, CR amount means the dollar amount determined by the number of CR/ICR services paid by Medicare to any provider or to any supplier reporting place of service code 11 on the claim for a beneficiary in an AMI or CABG model episode or AMI care period or CABG care period. Similarly, CR service count means the number of CR/ICR services paid by Medicare to any provider or to any supplier reporting place of service code 11 on the claim for a beneficiary in an AMI or CABG model episode or AMI care period or CABG care period.

As we proposed, we will determine 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. We will determine 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. Finally, we will sum the CR amounts determined previously 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. The determination of the CR incentive payment occurs at the same time that CMS carries out the reconciliation process for an EPM performance year.

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 proposed 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, we would also note that we proposed 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 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 proposed 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 final 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 did 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 did not propose that CR incentive payments 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 final rule for further discussion of considerations regarding financial arrangements under the CR incentive payment model.

Likewise, we proposed to exclude CR incentive payments when updating

[175] 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.

[176] 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.

quality-adjusted target prices for EPM-CR participants for performance years 3–5 of the EPMs 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 sought comments on our proposals to keep CR incentive payments separate and exclusive.

The following is a summary of the comments received and our responses. We refer to section VI.G of this final rule for a summary of the comments and our response on our discussion in the proposed rule of financial arrangements under the CR incentive payment model.

Comment: A commenter raised concern that while CMS proposed to exclude CR incentive payments from the calculation of episode spending and quality-adjusted target prices for AMI and CABG episodes, the actual FFS payments to providers of CR/ICR services will be included in both calculations. To this end, another commenter suggested that if efforts to increase CR utilization are successful, many EPM participants will not be eligible for reconciliation payments; in addition, this commenter believes that EPM participant hospitals that do not have their own CR/ICR programs will not be eligible for CR incentive payments under the CR incentive payment model.

Response: We acknowledge that FFS payments for CR/ICR services will be included in the calculation of AMI and CABG actual episode spending because these services are related and included in AMI and CABG episodes. We proposed that the CR incentive payment itself be separate and excluded from AMI and CABG episodes because this incentive payment 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. However, we also believe that there is potential for CR/ICR services to improve the quality of care and reduce spending during the AMI and CABG episodes themselves. For example, CR/ICR services for which a CR incentive payment may ultimately be made under the CR incentive payment model may provide additional transferable benefits on cost and quality to beneficiaries during EPM episodes, including the potential benefit experienced by beneficiaries simply by virtue of their participation in CR/ICR programs, increased interaction with the health care delivery system, and frequent follow-up. Furthermore, EPM–CR participants may see benefit from the patient's own behavior change as a result of being under supervision, as such interactions through CR/ICR services could impact, for example, adherence to medication therapies after discharge, and/or seeking of follow-up care from a primary care physician or appropriate specialist. Therefore, any increased spending for CR/ICR services for beneficiaries in AMI and CABG episodes attributable to EPM–CR participants may be offset by reductions in spending for other episode services, such as readmissions or emergency care. We disagree with the assumption that EPM–CR participants cannot achieve savings in the EPMs that result in reconciliation payments due to reduced spending on other episode service after referring EPM beneficiaries for an increased number of CR/ICR services over historical CR/ICR utilization. We also reiterate that EPM–CR participants that do not have their own CR/ICR programs will be eligible for CR incentive payments under the CR incentive payment model based on the CR/ICR utilization of AMI and CABG model beneficiaries attributed to them, regardless of where those beneficiaries receive CR/ICR services. Finally, as we stated previously, the design of the CR incentive payment model will 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 CR incentive payment and the underlying EPM and FFS payment methodologies.

Comment: A commenter recommended that the cardiac rehabilitation payment should be included in the bundled payment for AMI and CABG.

Response: We assume that this comment refers to the CR incentive payment, and we disagree with such a recommendation as this model proposed a 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. FFS payments for CR/ICR services themselves are included in EPM episode spending. Thus, we proposed and are finalizing that the CR incentive payment be separate for EPM–CR participants.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, to keep 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 in § 512.710(c) through (e).

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 proposed 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 final rule, we did not include such additional information in the CR incentive payment report.

For EPM–CR participants, we proposed to issue this annual report at the same time we issue the reconciliation report specified in § 512.305(f). For FFS–CR participants, we proposed 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 sought 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.

We received no comments specific to our proposals for the CR incentive payment report.

Final Decision: We are finalizing our proposal, without modification, in § 512.710(f) to issue a CR incentive payment report for each CR performance year to EPM–CR and FFS–CR participants to include 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.

4. Timing for Making CR Incentive Payments

We proposed 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 final rule and the appeals process for EPM participants described in section III.D.8. of this final rule. In the case of a FFS–CR participant, these payments would occur at the same time as was proposed for EPM–CR participants, subject to the appeals process described in section VI.F.2. of this final rule.

The proposed timing for making CR incentive payments is included in § 512.710(g). We sought comments on our proposed timing for making CR incentive payments.

The following is a summary of the comments received and our responses.

Comment: A commenter stated support for the proposal to establish an incentive payment that would be paid retrospectively, as this commenter believes that cardiac rehabilitation is very important in improving patient health outcomes and reducing hospital readmissions. In contrast, another commenter offered an alternative proposal for the timing of CR incentive payments, and recommended CMS make interim incentive payments during the year so as to monitor take-up rates to see if the incentive level needs to be adjusted.

Response: We appreciate the comments on the proposed timing for making CR incentive payments. However, we will not make interim CR incentive payments through the performance year based on claims for CR/ICR services furnished to CR beneficiaries that reflect less than a full model performance year. Given the lag in claims submission and payment in the Medicare FFS program for Part B services, we are not confident that we could gather sufficient reliable information in a period of less than a year that would cause us to reconsider the CR incentive payment methodology, including the amount, based on accurate observations of complete CR/ICR service utilization for model beneficiaries. In addition, changing the CR incentive payment methodology, including the amount, would require rulemaking, for which we would need sufficient information on true utilization changes and evaluation findings to propose a revised methodology.

Therefore, we believe that the proposed retrospective methodology that provides the CR incentive payment once per year to each CR participant after the end of the CR performance year is administratively straightforward for CMS and CR participants and will allow us to provide accurate CR incentive payments based on the CR/ICR utilization for CR beneficiaries. It will be possible with this payment methodology to monitor utilization of CR/ICR services for beneficiaries attributable to EPM–CR and FFS–CR participants, and we will continue to consider whether future proposals to change the CR incentive payment methodology are warranted based on our monitoring and early model implementation experience. Thus we are finalizing our proposed timing for the CR incentive payment.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, for the timing of making CR incentive payments in § 512.710(g). CMS makes CR incentive payments on a retrospective basis subject to the appeals process for EPM participants in § 512.310 and makes the CR incentive payments, if any, at the same time as for EPM–CR participants, subject to the provisions in § 512.720.

F. Provisions for FFS–CR Participants

1. Access to Records and Retention for FFS–CR participants

In section III.H. of this final 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 proposed 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 proposed 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 sought 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 sought 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.

The following is a summary of the comments received and our responses.

Comment: A commenter requested that CMS lower the duration of record retention requirement for the CR incentive payment model from ten years, as this commenter believes ten years is an excessive amount of time for participating hospitals, collaborators, collaboration agents, and downstream collaboration agents to maintain documentation on this model.

Response: While we appreciate the commenter's concern that ten years may seem excessive, we note that, once initiated, appeals and recalculation disputes can be lengthy processes and believe that maintaining this requirement as proposed would give both the participant and CMS, as well as those completing any audit, evaluation, inspection, or investigation, the resources to prepare and respond to issues that may take several years to surface. We continue to believe that these record retention requirements can be applied to categories of information that are broader than those solely related to financial arrangements, and therefore will consider requesting access to records that will assist in evaluating and measuring the CR incentive payment model goals.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification, for access to records and record retention for FFS–CR participants and other individuals and entities providing items and services to FFS–CR beneficiaries in § 512.715.

2. Appeals Process for FFS–CR Participants

a. Overview

In section III.D.8. (81 FR 50877 through 50880) of the 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 proposed to establish CR incentive payment model appeals process for FFS–CR participants that have the same requirements as we proposed 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.

Final Decision: CMS did not receive any comments on this section. Therefore, we are finalizing the proposal without modification.

b. Notice of Calculation Error (First Level Appeal)

We proposed 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 proposed 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 proposed 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 calculation 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 sought comment on the proposed notice of calculation error requirements.

Final Decision: We did not receive any comments on this section. Therefore, we are finalizing the proposal without modification.

c. Dispute Resolution Process (Second Level of Appeal)

We proposed the following dispute resolution process. First, we proposed 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 proposed 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 proposed 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 proposed it would first need to submit a calculation error form. Where the FFS–CR participant does not timely submit a calculation error form, we proposed 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' 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 proposed 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 proposed CMS would process the request as discussed later in this section.

We proposed that the reconsideration review would be an on-the-record review (a review of briefs and evidence only). The CMS reconsideration official would make reasonable efforts to notify the 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 final 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 proposed the following requirements in § 512.720 (b) for the reconsideration process:

- If the FFS–CR participant is dissatisfied with CMS' 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' response to the FFS–CR participant's notice of calculation error, then CMS' 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 sought comment on the proposed reconsideration process for the CR incentive payment model.

Final Decision: We did not receive any comments on this section. Therefore, we are finalizing the proposal without modification.

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 proposed 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 proposed 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 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. This does not apply to the limitations on review in sub-paragraph (e).

In summary, we proposed 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 sought comment on the proposed exception to the process and notice of termination.

Final Decision: CMS did not receive any comments on this section. Therefore, we are finalizing the proposal without modification.

e. Limitations on Review

In summary, we proposed 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 sought comment on the proposed limitations on review.

The proposals for the appeals process for FFS–CR participants are included in § 512.720. We sought 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 sought comment on whether we should develop an alternative appeal process. In addition, we sought 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.

Final Decision: CMS did not receive any comments on this section. Therefore, we are finalizing the proposal without modification.

3. Data Sharing for FFS–CR Participants

a. Overview

Section III.K. of the proposed rule (81 FR 50945 through 50948) discussed our proposed policies for the types and formats of financial data that we would make available to EPM participants, the frequency with which we would make these data available, and the authority for making these data available to EPM participants. Specifically, in section III.K.2. of the proposed rule (81 FR 50946), we proposed to provide certain financial data in two formats. First, we proposed 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 proposed 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 proposed to 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 the proposed rule (81 FR 50945 through 50947), we also noted our view that making this information available to EPM participants would provide the participants with 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 proposed in section III.K.3. of the proposed rule (81 FR 50945) to provide comparable aggregate regional data to EPM participants. Our proposal to make these regional data available was based on our proposal to use regional pricing data to determine benchmark and quality-adjusted target prices for EPM participants, and these aggregate regional data would assist participants in better understanding the basis of these prices. In section III.K.4. of the proposed rule (81 FR 50946), we proposed to make 3 years of baseline data available to EPM participants prior to the models' start date, which we believe would help the participants assess their practice patterns, identify cost drivers, and ultimately redesign their care practices to improve efficiency and quality. In section III.K.5. of the proposed rule (81 FR 50946), we proposed 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 we stated in section III.K.6 of the proposed rule (81 FR 50946 through 50947), 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 the proposed rule (81 FR 50944 through 50945), 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 final 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 health care outcomes and reduced health care 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 proposed 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 also note that we did 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 proposed to make these data available in either summary or claims-level format, depending on the FFS–CR participant's request. Also, we proposed to make these data available consistent with the same schedule we proposed 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 proposed 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 sought comments on our data sharing proposals.

The following is a summary of the comments received and our responses.

Comment: Commenters were supportive of CMS' efforts to provide beneficiary-level and summary claims data available to selected FFS hospitals selected for the CR incentive payment model upon request. Commenters also were supportive of our proposal to make this data available as frequently as monthly, and encouraged us to follow a monthly data release schedule for FFS–CR participants as soon as the EPMs are implemented, instead of sending the FFS–CR data quarterly since more frequent data updates would be useful in managing care under EPMs.

Response: We appreciate these comments and realize that more frequent data releases will assist many hospitals that are selected for the CR incentive payment model in understanding care patterns and identifying opportunities for improved efficiencies in care delivery. Accordingly, we are modifying our proposal to make these data available on a quarterly basis to make these data available ''no less frequently'' than on a quarterly basis with the goal of making these data available on a monthly basis as soon as we have the operational capabilities needed for monthly distribution.

Final Decision: After consideration of the public comments we received, we are modifying our proposal at § 512.725(b)(2) to no longer limit the availability of updated CR data to a frequency ''as frequently as on a quarterly basis throughout the FFS–CR participant's participation'' to instead ''no less frequently than on a quarterly basis throughout the FFS–CR participant's participation'' with the goal of making these data available as frequently as on a monthly basis if practicable.

4. Compliance Enforcement for FFS–CR Participants and Termination of the CR Incentive Payment Model

In section III.F. (81 FR 50911 through 50914) of the 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 EPMs 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

proposed to establish compliance enforcement for the CR incentive payment model for FFS–CR participants that is substantively similar to the requirements as we proposed 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 EPMs, 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 EPMs 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 EPMs 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 proposed 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' 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 proposed 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 proposed 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 of this chapter;
- 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 proposed 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 sought comment on our proposals for compliance enforcement as it is related to FFS–CR participants. In addition, we sought 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 proposed 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.

Final Decision: We did not receive any comments on this section. Therefore, we are finalizing the proposal without modification.

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 were included in proposed § 512.735. We sought 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.

We received no comments on the proposals for enforcement authority for FFS–CR participants in the CR incentive payment model.

Final Decision: We are finalizing the proposals in § 512.735 for the enforcement authority for FFS–CR participants, without modification. In the final provisions:

- 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.
- 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.

6. Beneficiary Engagement Incentives for FFS–CR Participants

We proposed to allow EPM participants to provide beneficiary engagement incentives under certain conditions as discussed in section III.I.9. of the proposed rule (81 FR 50929 through 50931) 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 would 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. In the proposed rule, we discussed our belief that one mechanism that may be useful to CR participants in achieving this goal would be 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 did not believe there were 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 believed 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 could 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 met the potential need for transportation to CR/ICR services for AMI and CABG model beneficiaries under an EPM–CR participant.

We proposed 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 proposed 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 were—

- 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 EPMs, we proposed 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 were included in proposed § 512.740. We sought comment on our proposed provisions for beneficiary engagement incentives for FFS–CR participants and welcomed comment on additional or alternative program integrity safeguards. We also sought 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.

The following is a summary of the comments received and our responses.

Comment: Multiple commenters claimed that a significant barrier to CR/ICR program participation is beneficiary cost-sharing due to the high cumulative costs associated with completion of multi-session CR/ICR treatment, although the evidence is largely anecdotal. A commenter referenced a recent study that found that in a multiracial population, low socioeconomic status, lack of insurance and copayment were independent risk factors of poor adherence to CR after adjusting for race. They stated that additional research in this area would be helpful in addressing cost as a barrier to participation in CR/ICR services. The commenters urged CMS to lower or eliminate beneficiary copayments under the CR incentive payment model. A commenter suggested that a tiered-copayment structure could be applied that would provide successive reductions in copayments the longer the beneficiary remains in the program. In this example, the first six sessions would be a full copayment, followed by a percentage reduction for the next six and an additional percentage reduction for the remaining sessions. Another commenter requested that CMS allow CR incentive payment model participants to use the CR incentive payment to decrease the cumulative copayment for CR services and claims that this would assist in increasing the utilization of CR/ICR services.

Response: We appreciate the interest of the commenters in additional strategies that could assist in beneficiary adherence to the recommended CR/ICR treatment plan for those who are included in the CR/ICR incentive payment model. We note that most beneficiaries in traditional Medicare have supplemental coverage, specifically employer-sponsored, Medicaid, and Medigap in descending order of prevalence.[177] In 2011, only 19 percent of beneficiaries in traditional Medicare did not have supplemental coverage. Thus, while we recognize that without supplemental coverage the cumulative copayments associated with multiple sessions of CR/ICR services could be significant and discourage beneficiary participation, most of the beneficiaries in the CR/ICR incentive payment model would not experience significant out-of-pocket costs for the services themselves because their supplemental coverage would help to cover those costs. Thus, we do not believe it is necessary to lower or eliminate beneficiary copayments in order to test the CR incentive payment model under Medicare FFS, and we have concerns that such provisions could result in program integrity issues such as patient steering toward a particular provider.

Comment: A number of commenters expressed support for CMS' proposal to allow transportation to be provided as a beneficiary engagement incentive under the CR incentive payment model by FFS–CR participants. The commenters agreed that transportation is a fundamental beneficiary engagement incentive that will increase access to CR/ICR services by removing barriers to enrollment and attendance. Several commenters requested clarification about whether specific types of support would qualify as transportation under the proposed beneficiary engagement incentives policy, including parking fees, rebates, or waivers; taxi services; gasoline for mileage traveled to CR/ICR services; a gas card; and public transportation card. With regard to the specific types of potential transportation support listed, a commenter urged CMS to clarify that FFS–CR participants have flexibility in how they offer the benefit. Another commenter recommended that CMS allow a higher amount of transportation incentives for beneficiaries residing in rural MSAs for whom accessibility of the CR/ICR program is a greater challenge. A commenter who favored allowing FFS–CR participants greater flexibility beyond transportation to provide beneficiary engagement incentives nevertheless requested that should CMS not create parity in the beneficiary engagement incentives that can be offered by EPM–CR and FFS–CR participants, CMS should revise the proposal to clarify that transportation both to and from CR/ICR services would be permitted. Finally, the same commenter requested that CMS clarify the requirement that transportation must not be tied to the receipt of items or services from a particular provider or supplier other than the FFS–CR participant. As proposed, the commenter believes a FFS–CR participant would be prohibited from furnishing transportation to its site in order for a Medicare beneficiary to receive CR or ICR services from that FFS–CR participant.

While many commenters expressed appreciation for CMS' proposal to allow FFS–CR participants to offer transportation as a beneficiary engagement incentive, the commenters urged CMS to broaden the types of beneficiary engagement incentives that can be provided by FFS–CR participants to model beneficiaries beyond transportation. A commenter pointed out that the proposal would allow EPM–CR participants to provide the broader set of beneficiary engagement incentives available under the EPM to EPM–CR beneficiaries, allowing EPM–CR participants the flexibility to choose the most appropriate incentives, as long as the requirements for providing them under the EPM are met. The commenter reiterated CMS' stated intent in the proposed rule to create parity between EPM–CR and FFS–CR participants regarding the available regulatory flexibilities directly relevant to advancing the CR incentive payment model goals and disagreed that CMS' proposal for beneficiary engagement incentives that could be offered by FFS–CR participants would meet that objective. The commenter urged CMS to apply the EPM beneficiary engagement incentive provisions to both EPM–CR and FFS–CR participants. The commenter reasoned that doing so would enable all CR participants to develop innovative methods of increasing beneficiary utilization of CR/ICR programs and improving beneficiary adherence to CR/ICR program regimens. The commenter further acknowledged that even if in practice the vast majority of CR/ICR programs ultimately relied exclusively on providing transportation as a beneficiary engagement incentive, CMS would nevertheless have created the opportunity for both EPM–CR and FFS–CR participants to explore alternatives.

Other commenters provided specific examples of items and services that could be provided as beneficiary engagement incentives that would assist in increasing CR/ICR program enrollment and adherence to the CR/ICR

[177] The Henry J. Kaiser Family Foundation. An Overview of Medicare. April 1, 2016. *http://kff.org/medicare/issue-brief/an-overview-of-medicare.*

treatment plan, including mobile applications for phones to text health messages between sessions; activity devices to track calories and steps; and evidence-based support/counseling weight management services or programs. A commenter asserted that these items and services would be allowed as beneficiary engagement incentives in the EPM and have been shown to improve adherence and foster self-management behaviors in the CR setting. Several commenters recommended that CR participants be able to offer financial incentives to model beneficiaries, such as a per session payment of $10 to $20 if the beneficiary completes the treatment program; payment by the CR participant to rebate part of the beneficiary's copayment to reward adherence; or a financial incentive that offers assistance to accommodate work or child/elder care obligations while the beneficiary attends CR/ICR sessions. Other commenters suggested that beneficiary engagement incentives could include vouchers for continued enrollment in exercise programs; gym memberships; diet and nutrition services and tobacco cessation services; and a preventive cardiology visit for review and reassessment of patient-centric goals. Another commenter requested clarification about regarding beneficiary engagement incentives can be used to assist with incorporating technology platforms needed to operate home-based cardiac rehabilitation.

Response: We appreciate the support of the commenters for our proposal to allow FFS–CR participants to provide transportation as a beneficiary engagement incentive to FFS–CR beneficiaries and the robust information provided by the commenters about other beneficiary engagement incentives that could help FFS–CR participants to advance the goals of the CR incentive payment model of increasing CR/ICR service care coordination and the medically necessary utilization of CR/ICR services for beneficiaries following hospitalization for AMI or CABG. As we stated in the proposed rule (81 FR 50897), 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. While undoubtedly transportation has the potential to be an important beneficiary engagement incentive for FFS–CR beneficiaries to enhance their adherence to the CR/ICR treatment plan, we believe that our proposal for FFS–CR beneficiary engagement incentives was too narrow and would not have allowed FFS–CR participants sufficient flexibility to provide other beneficiary engagement incentives to help advance the goals of the model, while EPM–CR participants may be able to provide those incentives based on their participation in the EPM, as discussed in section III.I.9. of this final rule. Therefore, we will adopt beneficiary engagement incentive requirements for FFS–CR participants that are modeled closely after those we are finalizing for the EPMs to address the interests of the commenters in providing a broader array of beneficiary incentives under the CR incentive payment model and aligning the requirements for EPM–CR and FFS–CR participants who want to furnish beneficiary incentives to EPM–CR and FFS–CR beneficiaries. We sought comment on the proposal for beneficiary engagement incentives in the EPMs and respond to those comments in section III.I.9. of this final rule.

We note that under the EPMs, the item or service provided as a beneficiary engagement incentive must be a preventive care item or service or an item or service that advances a clinical goal for a beneficiary in an EPM episode, where the goals are—

- Beneficiary adherence to drug regimens;
- Beneficiary adherence to care plan;
- Reduction of readmissions and complications resulting from treatment for the EPM clinical condition; and
- Management of chronic disease and conditions that may be affected by treatment for the EPM clinical condition.

FFS–CR participants are responsible for increasing CR/ICR service care coordination and the medically necessary utilization of CR/ICR services for beneficiaries following hospitalization for AMI or CABG. The AMI and CABG models both focus on beneficiaries with the same clinical conditions as the CR incentive payment model. The CR incentive payment model's ultimate goal is improving beneficiary health and reducing the cost of health care. Increased utilization of CR/ICR services for beneficiaries following AMI and CABG is known to contribute to that ultimate goal based on the components of the CR/ICR program, and the utilization of CR/ICR services for which the model will make a CR incentive payment is only an interim process measure that has an association with the longer-term outcomes we are seeking to achieve.

Section 410.49(b)(2) defines the components of a cardiac rehabilitation and an intensive cardiac rehabilitation program as:

- Physician-prescribed exercise each day cardiac rehabilitation items and services are furnished;
- Cardiac risk factor modification, including education, counseling, and behavioral intervention, tailored to the patients' individual needs;
- Psychosocial assessment;
- Outcomes assessment; and
- An individualized treatment plan detailing how components are utilized for each patient.

Therefore, we believe that the clinical goals of the CR model for the purpose of FFS–CR participants providing beneficiary engagement incentives can be appropriately identified as the same as those of the EPMs, related to improving beneficiary adherence to recommended treatments and improving beneficiary health. We will identify the same clinical goals for beneficiary engagement incentives that may be provided by FFS–CR participants as for the EPMs, noting that some contribute to the immediate CR incentive payment model objective of increasing CR/ICR service utilization (for example, beneficiary adherence to a care plan) and others to the longer-term improvement of beneficiary health that is expected to result from increased utilization of CR/ICR services (for example, management of chronic disease and conditions that may be affected by treatment for AMI or CABG).

The final regulations for the beneficiary engagement incentive payments that may be provided by FFS–CR participants are parallel to the final regulations for beneficiary engagement incentives under the EPMs, with the exception of the conforming changes that are necessary due to FFS–CR participant participation in the CR incentive payment model, rather than an EPM; the specific clinical conditions of AMI and CABG that are included in the CR incentive payment model; and use of the terms AMI care period and CABG care period rather than EPM episode to define the duration of time during which the beneficiary engagement incentive can be provided by the FFS–CR participant.

We note that, like the EPMs, the FFS–CR participant beneficiary engagement incentive requirements allow the provision of items and services as in-kind patient engagement incentives but do not allow FFS–CR participants to pay

money to FFS–CR participants for any purpose, including completion of the treatment program or as a rebate of CR copayments. While we can understand the potential benefit of such payments in engaging FFS–CR beneficiaries to advance the goals of the CR incentive payment model by financially rewarding their participation in CR/ICR services, we do not believe that we could include provide sufficient safeguards against patient steering if we were to permit such payments as beneficiary engagement incentives.

With regard to the commenters requesting specific clarification about transportation incentives, the final beneficiary engagement incentives requirement for FFS–CR participant use no longer are specific to transportation. Therefore, we encourage those commenters to review the final requirements and ensure that all beneficiary engagement incentives, including transportation, provided by FFS–CR participants to FFS–CR beneficiaries meet the requirements. We note that the final requirements include that the item or service must not be tied to the receipt of items or services from a particular provider or supplier so that a FFS–CR participant who offers transportation as a beneficiary engagement incentive to CR/ICR services furnished by the FFS–CR participant would need to make comparable transportation support available for CR/ICR services furnished by another provider so that the availability of transportation would not be used to steer the beneficiary to a particular CR/ICR service provider.

Regarding the request by a commenter for clarification about whether beneficiary engagement incentives can be used to assist with incorporating technology platforms needed to operate home-based cardiac rehabilitation, we note that Medicare does not cover home-based CR. Any home-based CR activities could not be billed to Medicare and would not contribute to the FFS–CR participant's CR incentive payment.[178] In addition, technology platforms provided as a beneficiary engagement incentive by a FFS–CR participant would need to meet all the requirements specified in this final rule for beneficiary engagement incentives for FFS–CR participant use.

We are finalizing in the proposals in § 512.740 beneficiary engagement incentives to be provided by FFS–CR participants, with modification to our proposals for comparability to EPM beneficiary engagement incentives. 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 CR incentive payment model in FFS–CR participants. Such waivers would be promulgated separately from this final 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. Any fraud and abuse waivers issued in connection with the FFS–CR beneficiary engagement incentives model will be available at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html* and on OIG's Web site. No waivers of any fraud and abuse authorities are being issued in this final rule.

Comment: A commenter requested clarification about what considerations could be given for beneficiary adherence to a CR/ICR treatment plan when the most convenient CR program is a rural CAH and the CR participant's location where their CR program resides is beyond a reasonable distance from the beneficiary's home. The commenter recommended that CR participants be permitted to extend transportation beneficiary engagement incentives to model beneficiaries who are receiving CR from rural non-CR participants due to a distance barrier in order for transportation cost barriers to CR service adherence to be reduced for rural beneficiaries as it is for beneficiaries receiving CR at the CR participant. Other commenters who requested that CMS broaden the beneficiary engagement incentives permitted for FFS–CR participants requested clarification about whether these incentives could still be provided if a FFS–CR beneficiary was referred to a CR program at a location other than at the FFS–CR participant.

Response: We appreciate the opportunity to clarify the beneficiary engagement incentive policies for CR participants whose model beneficiaries obtain CR/ICR services at different locations. Under our policies that apply to CR participants, beneficiary engagement incentives must be provided directly by the EPM–CR or FFS–CR participant or by an agent of the EPM–CR or FFS–CR participant under the EPM or FFS–CR participant's direction and control to the EPM–CR or FFS–CR beneficiary during an AMI episode or AMI care period, respectively, or during a CABG episode or CABG care period. Therefore, while we limit who may provide the beneficiary engagement incentives to a model beneficiary to safeguard against patient steering to any particular provider, transportation to CR/ICR services or other items and services provided as in-kind patient engagement incentive may be provided by the FFS–CR participant to the model beneficiary, regardless of where the beneficiary receives CR/ICR services. Therefore, in the example raised by the commenter, the CR participant where the beneficiary was hospitalized for AMI or CABG that initiated the AMI episode or AMI care period would be permitted to provide transportation to CR services at the CAH near the beneficiary's home as an in-kind patient engagement incentive, subject to all the other requirements for beneficiary engagement incentives for EPM or FFS–CR participants, as applicable to the specific CR participant, being met. In this scenario, we note that the CR incentive payment for CR/ICR services utilized by the beneficiary would be made to the CR participant, not the CAH, although the CAH would be paid for all CR services furnished to the beneficiary under the applicable Medicare FFS payment system.

Final Decision: After consideration of the public comments received, we are finalizing the proposals in § 512.740 for beneficiary engagement incentives provided by FFS–CR participants, with modification to allow beneficiary engagement incentives that are subject to the same overall requirements as the EPM but as applicable to AMI care periods and CABG care periods under the CR incentive payment model. Beneficiary engagement incentives provided by FFS–CR participants must meet the following requirements:

FFS–CR participants may choose to provide in-kind patient engagement incentives to beneficiaries in an AMI care period or CABG care period under the CR incentive payment model, subject to the following conditions:

- 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.
- The item or service provided must be reasonably connected to medical care provided to an FFS–CR beneficiary during an AMI care period or CABG care period.
- The item or service must be a preventive care item or service or an item or service that advances a clinical goal, as listed later in this section, for a beneficiary during an AMI care period or CABG care by engaging the

[178] Medicare Claims Processing Manual. Chapter 32—Billing Requirements for Special Services. Section 140.2—Cardiac Rehabilitation Program Services Furnished On or After January 1, 2010.

beneficiary in better managing his or her own health.

• The item or service must not be tied to the receipt of items or services outside the AMI care periods or CABG care periods.

• The item or service must not be tied to the receipt of items or services from a particular provider or supplier.

• The availability of items or services must not be advertised or promoted except that a beneficiary may be made aware of the availability of items or services at the time the beneficiary could reasonably benefit from them.

• The cost of the item or service must not be shifted to another federal health care program, as defined at section 1128B(f) of the Act.

Beneficiary engagement incentives involving technology are subject to the following additional conditions:

• Items or services involving technology provided to a beneficiary may not exceed $1,000 in retail value for any one beneficiary in any one AMI care period or CABG care period.

• 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 AMI care period or CABG care period.

• Items of technology exceeding $100 in retail value must—

++ Remain the property of the FFS–CR participant; and

++ Be retrieved from the beneficiary at the end of the AMI care period or CABG care period. The FFS–CR 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.

The following are the clinical goals of the CR incentive payment model, 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 AMI or CABG.

• Management of chronic diseases and conditions that may be affected by treatment for AMI or CABG.

Documentation of beneficiary engagement incentives:

• FFS–CR participants must maintain documentation of items and services furnished as a beneficiary engagement incentive that exceeds $25 in retail value.

• 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.

• 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 AMI care period or CABG care period as described previously in this section.

• The FFS–CR participant must retain and provide access to the required documentation in accordance with § 512.715.

7. Waiver of Physician Definition for FFS–CR Participants Furnishing CR and ICR Services

a. Overview of Program Rule Waivers Under an EPM

In section III.J. of this final rule, we finalized the 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. The purpose of such flexibilities is to increase EPM 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 are 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. We have used this authority to implement similar program rule waivers in other models, such as the CJR model, as discussed in section III.J. of this final rule.

b. General Physician Requirements for Furnishing CR and ICR Services

A cardiac rehabilitation (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 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). 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

• Establish, review, and sign an individualized treatment plan every 30 days, as described at § 410.49(b)(2)(v).

c. Waiver of Physician Definition for EPM–CR Participants Furnishing CR and ICR Services

In section III.J.8. of this final rule, for cardiac rehabilitation and intensive cardiac rehabilitation services provided in an EPM–CR participant under the proposed AMI and CABG models, we are waiving 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 the EPM–CR 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 are implementing the EPM–CR waiver to provide greater program flexibility that might increase the availability of CR and ICR services to AMI and CABG model beneficiaries. This waiver is codified at § 512.630 in this final rule.

d. Waiver of Physician Definition for FFS–CR Participants Furnishing CR and ICR Services

Services provided under CR and ICR programs may be furnished to those beneficiaries in a FFS–CR participant hospital eligible to receive a CR incentive payment. To provide greater

program flexibility that might increase the availability of CR and ICR services to beneficiaries in a FFS–CR participant hospital, we proposed 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 for FFS–CR participants 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 in furnishing CR and ICR services under § 410.49. This proposed waiver for FFS–CR participants is similar to the physician definition waiver for EPM–CR participants discussed in section III.J.8. of this final rule. All other definitions and requirements related to a physician or supervising physician under § 410.49 continue to apply. This proposed waiver of the physician definition would be terminated if the FFS–CR participant is terminated or is not in compliance with the CR incentive payment requirements.

This proposed waiver for FFS–CR participants was codified at proposed § 512.745. We sought comments on this proposed CR/ICR waiver to allow nonphysician practitioners to perform the specified physician functions for the provision of CR/ICR services in a FFS–CR participant.

We received a number of comments on our proposals to provide a CR/ICR waiver to the physician definition that applied to both the EPM–CR participants and FFS–CR participants, and no comments were unique to the FFS–CR participants. We refer to section III.J.8. of this final rule for a summary of the comments and our responses.

Final Decision: After consideration of the public comments received, we are finalizing the proposal, without modification to 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 in furnishing CR and ICR services under § 410.49. This waiver for FFS–CR participants is similar to the physician definition waiver for EPM–CR participants discussed in section III.J.8. of this final rule. All other definitions and requirements related to a physician or supervising physician under § 410.49 continue to apply. This waiver of the physician definition would be terminated if the FFS–CR participant is terminated or is not in compliance with the CR incentive payment model. This waiver for FFS–CR participants is codified at § 512.745 in this final rule.

G. Considerations Regarding Financial Arrangements Under the CR Incentive Payment Model

As discussed in section VI.E.2. of the proposed rule (81 FR 50981), we proposed to not permit the inclusion of CR incentive payments in sharing arrangements for EPM participants specified in proposed § 512.500. Similarly, we did 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, in the proposed rule we described our expectation that in many cases the CR participant that would be 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.[179] 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 might 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 expected 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 expected 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 might 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 expected 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 recognized in the proposed rule, 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 sought 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 requested 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 sought 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

[179] 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.

incentive payment model, we noted that we may make specific proposals around CR incentive payment model financial arrangements in future rulemaking.

The following is a summary of the comments received and our responses.

Comment: Several commenters urged CMS to allow CR participants to share CR incentive payments with other providers under the CR incentive payment model to assist CR participants in meeting the model goals of increasing CR/ICR service care coordination and the medically necessary utilization of CR/ICR services for beneficiaries following hospitalization for AMI or CABG. Without sharing arrangements that are not permissible under existing fraud and abuse laws, the commenters believe the model goals may be challenging to achieve while retaining beneficiary freedom of choice of CR/ICR service provider, especially in some geographic areas of the country. In one example provided by a commenter, a tertiary referral center could receive patients for CABG or treatment of AMI from distant hospitals with more limited cardiac capacity. While the tertiary referral center would be the EPM–CR or FFS–CR participant in the CR incentive payment model, the beneficiary would commonly return home to their community for CR/ICR services. The commenter claimed that the opportunity for the tertiary referral center to share some of the CR incentive payment with the referring community hospital to augment the available resources of the local CR/ICR program to facilitate service availability and beneficiary adherence to the CR/ICR treatment plan would be valuable. Some commenters expressed concern that without permitting sharing arrangements of the CR incentive payment between the CR participant and other providers of CR/ICR services, the CR incentive payment model would not incentivize adherence to CR/ICR programs at rural hospitals, CAHs, and any other CR program that is not a CR participant. The commenters believe that beneficiaries should have the choice to select where they receive CR/ICR services, and encouraged CMS to design the model such that it supports and incentivizes this choice. In general, a number of commenters urged CMS to adopt flexibility in the financial arrangements permitted under the CR incentive payment model, which they believe would lead to broader utilization of CR/ICR services.

Response: We appreciate the information provided by the commenters about the potential benefits of certain financial arrangements under the CR incentive payment model. In response to the commenters who expressed concerns about beneficiary freedom of choice of CR/ICR provider under the CR incentive payment model, we do not agree that the absence of specific financial arrangements being permitted under the model is a risk to beneficiary freedom of choice or results in the model not incentivizing CR/ICR treatment plan adherence at any CR provider that is not a CR participant. The CR participant will receive a CR incentive payment based on the totality of CR/ICR services furnished to beneficiaries in AMI and CABG episodes or AMI care periods and CABG care periods, regardless of where the beneficiary receives CR/ICR services. Therefore, the model provides a financial incentive to CR participants to coordinate CR/ICR services with any CR/ICR program selected by the beneficiary, although as we noted in the proposed rule (81 FR 50989), historically that CR program has been most commonly that of the discharging hospital who would be the CR participant. We also expect that CR participants will support the beneficiary's choice of CR/ICR provider that is most likely to result in greater beneficiary adherence to the CR/ICR treatment plan, and that the choice of a local CR/ICR provider would often be of mutual benefit to the beneficiary and CR participant by increasing the likelihood that the beneficiary will receive more CR/ICR services than at a remote CR program. While we appreciate the interest of some commenters in sharing the CR incentive payment with other providers, our model design generally relies on the CR participant who is accountable under the CR incentive payment model itself carrying out the model implementation activities, including coordination of CR/ICR services to CR beneficiaries. To the extent CR participants may wish to engage other individuals and entities to advance the CR incentive payment model goals of increased CR/ICR service care coordination and the medically necessary utilization of CR/ICR services, we expect that financial relationships with these individuals and entities will be narrowly focused on certain activities related to the CR participant's specific plan to advance the goals of the model. We also expect that all of these relationships will solely be based on the level of engagement of the individual's or entity's resource to directly support the CR participant's CR incentive payment model implementation.

We made no proposals for financial arrangements under the CR incentive payment model. As we stated in the proposed rule (81 FR 50989), based on the comments on this rulemaking 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. We especially need to consider the safeguards that would be needed for such financial arrangements to ensure program integrity, protect against abuse, and ensure that the goals of the CR incentive payment model would be met, because we do not have precedent with other CMS models and programs that have a similar design to the CR incentive payment model. Thus, we expect that all relationships established between CR participants and other individuals and entities for purposes of the CR incentive payment model will only be those permitted under existing law and regulation.

Final Decision: We made no specific proposals for financial arrangements under the CR incentive payment model that would allow CR participants to enter into financial arrangements with other individuals and entities to share CR incentive payments, beyond relationships permitted under existing law and regulation. We will consider the information provided by the commenters and our early experience with implementation of the model and we make proposals about 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. However, we have summarized the anticipated information collection requirements in the Regulatory Impact Analysis.

VIII. Regulatory Impact Analysis

We have examined the impact of this rule as required by Executive Order 12866 and other laws and Executive Orders requiring economic analysis of the effects of final rules.

A. Statement of Need

1. Need for EPM Final Rule

This final 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 or 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 EPMs we are finalizing in this rule 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 EPMs we are finalizing in this rule, 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 EPM 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 efficient service delivery, and incentivizing higher-value care across the inpatient and post-acute care spectrum. The goal for the EPMs we are finalizing in this rule is to improve the quality of care provided to beneficiaries in an applicable episode while reducing episode spending.

The AMI, CABG, and SHFFT models require the participation of hospitals in multiple geographic areas that might not otherwise participate in testing episode payment for the EPM 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 the new EPMs requires 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 will test and evaluate the impact of episode payment for three EPMs (AMI, CABG, and SHFFT models) in a variety of circumstances, including those hospitals that may not otherwise participate in such a test.

2. Need for CJR Modifications

This final rule also includes 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 finalized in this rule clarify and update provisions of the CJR model and create alignment between CJR and the AMI, CABG, and SHFFT models. The primary impact of these changes are: (1) Incorporation of BPCI and CJR 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 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 57, we estimate a total aggregate impact of $159 million in net Medicare savings over the duration of the AMI, CABG, and SHFFT models, July 2017 through December 2021. As detailed in Table 59, we estimate the changes in the CJR model finalized in this final rule, along with the revised assumption about the percentage of participating hospitals that will report voluntary quality data during the performance years, will lower the net Medicare savings by $26 million over the duration of the CJR model (April 2016 through 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 AMI, CABG, and SHFFT 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 participants may respond to the model test 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 the Medicare program to the participating hospital. As long as reductions in Medicare FFS spending for participating hospitals are equally offset through greater reconciliation payments from the Medicare program to those participating hospitals, the financial impact to the Medicare program should not be significantly different from our estimate.

As detailed in Table 60, we estimate a total aggregate impact between $29 million in net Medicare costs and $32 million in net Medicare savings from July 2017 through 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.

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 final rule triggers these criteria.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed rule and subsequent final rule that imposes substantial direct requirement costs on state and local governments, pre-empts state law, or otherwise has federalism implications. We do not believe that there is anything in this final rule that either explicitly or implicitly pre-empts any state law, and furthermore we do not believe that this final rule will have a substantial direct effect on state or local governments, preempt states law, or otherwise have a federalism implication.

C. Anticipated Effects

1. Overall Magnitude of the Model and Its Effects on the Market

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 final 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 final 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 final 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 finalized our proposal to test the AMI and CABG models in 98 MSAs out of 293 MSAs (we proposed to use 294 MSAs, however, due to the Vermont All Payer model being exempted from the final EPMs as discussed in section III.B.2 of this final rule, the number of eligible MSAs dropped to 293) eligible for selection, as described in section III.B.5. of this final rule; we finalized our proposal to test the SHFFT model in 67 MSAs in which CJR is currently operating as discussed in section III.B.4. of this final rule. In the 2014 calendar year there were 136,000 episodes for AMI, and 42,000 for CABG in the 294 MSAs proposed as 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 finalized 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 we finalized relate to the calculation of quality-adjusted target prices, which will now incorporate reconciliation payments and Medicare repayments in years 3 through 5 of the model and include modifications to the calculation of composite quality scores. For the CJR final rule we assumed that hospitals would not report voluntary THA/TKA patient-reported outcome-based data to CMS. Given our experience with performance year 1 of CJR, we revised our assumption for this analysis to assume that 27 percent of participants in performance years 1 and 2, 63 percent of participants in performance year 3, and 99 percent of participants in performance years 4 and 5 will report this quality data. These modifications along with the revised assumptions regarding quality reporting raise the costs estimated to the Medicare program by $26 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 finalized our proposal 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 final rule. As discussed subsequently in this analysis and displayed in Table 60, this is likely to result in an impact between $29 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 the EPM and CR 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 the EPM and CR models or may utilize results from CMS evaluations of these models.

Because it is unclear whether and how spillover effects may apply 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.

2. Effects on the Medicare Program

a. EPMs

Under this final rule, we 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 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 will test and evaluate 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 these episodes 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.[180]

We believe that by requiring participation by a large number of hospitals with diverse characteristics, the EPMs will result in a robust data set for evaluating this payment approach, and will stimulate the rapid development of new evidence-based knowledge. Testing the EPMs in this manner will 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 EPMs, as described further in section III.B.2. of this final 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 will end 90 days after the date of discharge from the anchor hospitalization. The EPM episodes will 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 designated EPM participant hospitals to be the episode initiators and to be financially responsible for episode cost under the proposed EPMs. We 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. Participating geographic areas, based on MSAs, were selected through a random sampling methodology. We believe the 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.3. of this final rule, we will 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, will be combined to calculate an actual EPM episode payment. The actual EPM episode payment will then be reconciled against an established EPM quality-adjusted target price. The amount of this calculation, if positive, will be paid to the participant in a reconciliation payment. If negative, we will require repayment from the participant beginning in performance year 2 of the EPMs for participants who elect early downside risk and performance year 3 for participants who do not elect early downside risk. EPM participants' quality performance also will 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 will be eligible for a reconciliation payment.

We will phase in the requirement that participants whose actual EPM episode payments exceed the quality-adjusted target price pay the difference back to Medicare during performance years 2, 3 and 4 for participants who elect early downside risk and during performance years 3 and 4 for those who do not elect

[180] 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.

early downside risk. Under this final rule, Medicare will 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, 3 and 4 for participants who elect early downside risk beginning January 1, 2018 and for performance years 3 and 4 for participants who do not elect early downside risk.

Due to the clinical characteristics and common patterns of care in AMI model episodes, we will perform 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. of this final rule. We also will limit how much a participant can gain or lose based on its actual EPM episode payments relative to quality-adjusted target prices; we are finalizing 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 final rule.

Based on the mix of financial and quality incentives, the 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 January 2013 through March 2016 to simulate the impact that the EPMs would have on Medicare spending for AMI, CABG, and SHFFT model episodes. Specifically, we applied the methodology provided in this final 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 which have historical data for SHFFT procedures. For the AMI and CABG models, we applied this methodology to the hospitals in the 98 MSAs selected for participation in the cardiac EPMs. Quality-adjusted target prices were calculated based on hospital performance from 90-day episodes starting between January 2013 and December 2015. Specifically, all IPPS hospitals in the selected MSAs were included in this analysis after applying the model-specific hospital exclusions based on participation in BPCI Models 2 or 4 for the AMI, PCI, CABG, or SHFFT models, as appropriate, as established in this final rule. Individual episodes were removed if they initiated a BPCI episode that had precedence over the EPM.

We identified the anchor hospitalization based on episode definition criteria in section III.C. of this final 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 final rule. Payments during the 90-day episodes were calculated using standardized Medicare payment amounts.

We trended utilization and prices in the prior years to match national performance for episodes starting from January 2015 through December 2015. BPCI reconciliation payments were then credited to BPCI episodes during this time frame. We then incorporated the final outlier policy to cap spending for high cost outlier episodes such that payments were capped at the price MS–DRG anchor value that is 2 standard deviations above the regional mean as described in section III.D. of this final 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.D.7.c. of this final 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.D. of this final rule. The computed hospital-specific weight, the hospital's wage index, and a discount specific to the hospital's quality category based on historical quality performance for EPM participants was then applied back to the price.

After calculating quality-adjusted target prices for applicable MS–DRGs for each hospital for performance years 1 and 2, we compared these quality-adjusted target prices against actual performance between January 2015 and December 2015. We capped actual spending for individual episodes based on the methodology in this final rule for high cost outlier spending episodes. After incorporating the 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 summed 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) and aggregated the difference for all episodes for a participant within the performance year, creating the NPRA. Any positive NPRA amount greater than the stop-gain limit was capped at the stop-gain limit of 5 percent in performance years 1, 2, and 3, 10 percent in performance year 4, and 20 percent in performance year 5. In addition, any negative NPRA amount exceeding the stop-loss limit was capped at the stop-loss limit as described in section III.D. of this final rule, with a 5 percent repayment limit in performance year 2 (for participants who elect early downside risk), 5 percent repayment limit in performance year 3, 10 percent repayment limit in performance year 4, and 20 percent repayment limit in performance year 5. For rural hospitals, MDHS, SCHs and RRCs, the repayment limit was capped at the stop-loss limit as described in section III.A.2.a. of this final rule, with a 3 percent repayment limit in performance year 2 (for participants who elect early downside risk), 3 percent repayment limit in performance year 3, and 5 percent repayment limit in performance years 4 and 5. As described in section III.D.7.e. of this final 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 must repay Medicare for the difference. Assuming no change in hospital behavior, very few hospitals are expected to have average post-episode spending exceeding 3 standard deviations from their regional mean. Based on an analysis of 30-day

post episode spending for EPMs starting in the 2015 calendar year, very few hospitals in the MSAs selected for the EPM had average post-episode spending exceeding 3 standard deviations. The estimates in the impact analysis are rounded to the nearest million, and the estimated post-episode reconciliation payments to be made from hospitals to the Medicare program are minimal and estimated to round down to 0 million.

As described in section III.E. of this final rule, we are finalizing the use of a composite quality score for each EPM, where the composite quality score reflects a combination of outcome and patient experience measures, and, as described later in this section, we have incorporated this approach in our estimate of impacts. Under the EPMs, 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 all EPMs, 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' will not be eligible for a reconciliation payment and will be subject to a 3 percent discount. Hospitals assigned as 'acceptable' will be eligible for a reconciliation payment and will be subject to a 3 percent discount. Hospitals assigned as 'good' will be eligible for a reconciliation payment and will be subject to a 2 percent discount. Lastly, hospitals assigned as 'excellent' will be eligible for a reconciliation payment and will be subject to a 1.5 percent discount. We note that for participants who elect early downside risk, in performance years 2, 3 and 4, the applicable discount for repayment would be 1 percentage point less than the effective discount applied for a reconciliation payment while for hospitals who do not elect early downside risk the applicable discount for repayment in years 3 and 4 will be 1 percentage point less than the effective 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. As discussed in section III.E. of this final rule, we calculated 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.

Early experience in CJR shows that 27 percent of hospitals submitted voluntary quality data in performance year 1. In addition, prior experience in the Medicare program indicates that when payment is tied to voluntary reporting of quality measures most hospitals report such measures. For this analysis, we assume that hospitals will report voluntary measure increasingly throughout the performance years and that most hospitals in the EPMs will submit voluntary measures to qualify for the reduced discount by the fourth and fifth performance year. Therefore, for this analysis we assume in performance year 1 and 2 that 27 percent of hospitals will submit voluntary quality data. We anticipate that 27 percent will submit quality data in performance year 2, and assume 63 percent submission of quality data in performance year 3, and 99 percent in performance years 4 and 5 for the EPM and CJR models. For the AMI and CABG models, we developed composite quality scores for all eligible hospitals among the 98 selected MSAs. Hospitals in these MSAs were assigned to a performance percentile and assigned the corresponding quality performance score points listed in Tables 24 and 28 of this final rule, based on their performance in the historical performance data described earlier. Hospitals that did not have a reported measure result were assigned to the 50th performance percentile. Hospitals assigned a quality measure performance percentile for the most recent year that 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 the participating MSAs were assigned to a performance percentile and assigned the corresponding quality performance score points listed in Table 30 of this final rule, based on their performance in the historical performance data described earlier. Hospitals that did not have a reported measure result were assigned to the 50th performance percentile. Hospitals assigned a quality measure performance percentile for the most recent year that improved by at least 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.E. of this final 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 (July 1, 2017 through December 31, 2017), we calculated the NPRA using a blended quality-adjusted target price calculated for performance year 1, that is two-thirds hospital experience and one-third region experience, and applied no downside risk to participants as described in section III.D. of this final rule. 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 applied the 5 percent stop-gain limit on the estimated reconciliation payments made to participants with 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 a blended 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 for 1 percent of the hospitals to model an estimated rate of participants who will elect voluntary downside risk, a 5 percent stop-gain limit was applied to reconciliation payments for the remaining 99 percent of participants to model those who will not elect voluntary downside risk. Finally, a 3 percent stop-loss and stop-gain limit was applied for rural hospitals, sole community hospitals, Medicare dependent hospitals, rural referral centers and low-volume participants as defined in section III.D.2.c. of this final rule.

For the simulation in performance year 3, we rebased episode prices to incorporate the reconciliation payments (as described in section III.D. of this final rule) simulated from the first performance year. To simulate reconciliation for performance 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 5 percent stop-loss and stop-gain limit on reconciliation payments and repayments for participants with the exception of a 3 percent stop-loss and stop-gain limit on reconciliation payments and repayments from rural hospitals, sole community hospitals, Medicare dependent hospitals, rural referral centers, and certain low-volume hospitals as defined in section III.D.2.c.of this final rule. 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 10 percent for all participants, with the exception of a 5 percent stop-loss and stop-gain limit for rural hospitals, sole community hospitals, Medicare dependent hospitals, rural referral centers, and low-volume hospitals as defined in section III.D.2.c of this final rule.

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 for all participants, with the exception of a 5 percent stop-loss and stop-gain limit for rural hospitals, sole community hospitals, Medicare dependent hospitals, rural referral centers, and certain low-volume hospitals as defined in section III.D.2.c of this final rule.

The final results were then adjusted under the assumption that the percentage of EPM episodes excluded due to enrollment in Next Generation ACOs, Shared Savings Program ACOs in Track 3, and End Stage Renal Disease (ESRD) Seamless Care Organizations for performance years 1 through 5 would match the percentage of the FFS population prospectively assigned to these models for 2017. It was also assumed that 99 percent of EPM revenue would come from hospitals that choose not to elect downside risk in year 2.

(2) Analyses

TABLE 57—ESTIMATES OF IMPACT ON THE MEDICARE PROGRAM BY THE FINAL EPM *

	Year(s)					Across all 5 years of proposed models
	2017	2018	2019	2020	2021	
AMI net financial impact	3	9	(8)	(10)	(27)	(34)
CABG net financial impact	3	6	(5)	(6)	(14)	(16)
SHFFT net financial impact	5	11	(21)	(32)	(71)	(109)
Total: Net financial impact of all EPM proposals	10	25	(34)	(49)	(112)	(159)

* **Note:** In millions. Totals do not necessarily equal the sums of rounded components.

Table 57 summarizes the estimated impact for the AMI, CABG, and SHFFT models. Our model estimates that the Medicare program will save $159 million over the 5 performance years (2017 through 2021).

The first performance year of the EPMs is expected to cost the Medicare program $10 million in reconciliation payments made to participants. Participants that receive reconciliation payments must earn a quality rating of ''Acceptable'' or better and are the participants that provide lower cost care relative to quality adjusted target prices, which reflect both hospital and regional historical spending.

In the second performance year of the EPMs, the Medicare program on net is expected to pay $25 million to participants. This includes $26 million in reconciliation payments made by the Medicare program to participants, and $1 million in payments made to the Medicare program from participants that elect downside risk in year 2. Participants may elect early downside risk beginning January 1, 2018 as discussed in section III.D.2.c. of this final rule. For participants who do not elect early downside risk, downside risk will not be applied for the entirety of the second performance year. For participants who elect early downside risk in performance year 2, a 5 percent stop-loss and stop-gain limit will apply, subject to a 3 percent stop-loss and stop-gain limit for rural hospitals, sole community hospitals, Medicare dependent hospitals, rural referral center hospitals and certain low-volume hospitals. These limits would cap the total amount of repayments paid by participants to the Medicare program. For this analysis, we assumed 10 percent of participants will elect early downside risk.

In the third performance year of the models, net reconciliation payments are expected to be $34 million in savings to the Medicare program. This includes $33 million in payments from the Medicare program to participants, and $67 million in payments from participants 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 is expected to create greater variation between the quality-adjusted target price and participants' own experience. The stop-gain and stop-loss limits of 20 percent for performance year 5 apply, with a stop-gain and stop-loss limit of 5 percent for rural hospitals, sole community hospitals, Medicare dependent hospitals, rural referral centers hospitals, and certain low-volume hospitals. As a result, net payments are expected to be $49 million from participants to the Medicare program in the fourth year and $112 million in the fifth year. In performance year 4 this includes $59 million in payments from the Medicare program to participants, and $108 million in payments from participants to the Medicare program. In performance year 5 this includes $59 million in payments from the Medicare program to participants, and $171 million in payments from participants to the Medicare program. These estimated savings in years 4 and 5 represent an average of 2.1 percent of total episode spending in those years. The total savings to the Medicare program after the 5 performance years is expected to be $159 million out of $15.0 billion or 1.0 percent of total episode spending.

Table 58 summarizes the estimated reconciliation payments for the AMI, CABG, and SHFFT models over the 5 performance years (2017 through 2021) for the selected MSAs.

TABLE 58—ESTIMATES OF RECONCILIATION PAYMENTS

Numbers in millions	Performance Period					
	July 2017–December 2017	2018	2019	2020	2021	Over 5 years
All EPM episodes						
Total dollars included in NRPA calculation	$743	$3,259	$3,440	$3,670	$3,912	$15,023
Net reconciliation and repayment dollars	10	25	−34	−49	−112	−159
Payments from CMS to hospitals	10	26	33	59	59	187
Repayments from hospitals to CMS	0	−1	−67	−108	−171	−346
Financial impact as a percentage of dollars included in model	1.4%	0.8%	−1.0%	−1.3%	−2.9%	−1.1%
Acute Myocardial Infarction episodes						
Total dollars included in NRPA calculation	235	1,026	1,079	1,151	1,227	4,718
Net reconciliation and repayment dollars	3	9	−8	−10	−27	−34
Payments from CMS to hospitals	3	9	13	22	22	68
Repayments from hospitals to CMS	0	0	−21	−32	−49	−102
Financial impact as a percentage of dollars included in model	1.3%	0.9%	−0.7%	−0.9%	−2.2%	−0.7%
Coronary Artery Bypass Grafting episodes						
Total dollars included in NRPA calculation	146	669	704	751	800	3,070
Net reconciliation and repayment dollars	3	6	−5	−6	−14	−16
Payments from CMS to hospitals	3	6	6	12	12	38
Repayments from hospitals to CMS	0	0	−11	−18	−26	−55
Financial impact as a percentage of dollars included in model	1.8%	0.9%	−0.7%	−0.8%	−1.7%	−0.5%
Hip and Femur Procedures Except Major Joint episodes						
Total dollars included in NRPA calculation	362	1,564	1,657	1,768	1,884	7,235
Net reconciliation and repayment dollars	5	11	−21	−32	−71	−109
Payments from CMS to hospitals	5	11	14	26	26	81
Repayments from hospitals to CMS	0	0	−35	−58	−97	−190

TABLE 58—ESTIMATES OF RECONCILIATION PAYMENTS—Continued

Numbers in millions	Performance Period					
	July 2017–December 2017	2018	2019	2020	2021	Over 5 years
Financial impact as a percentage of dollars included in model	1.2%	0.7%	−1.3%	−1.8%	−3.8%	−1.5%

(3) Uncertainties

These estimates are somewhat uncertain. As a result, the EPMs could produce more Medicare savings or could result in additional costs to the Medicare program. This analysis assumes that the incentives under the models drive no change in utilization of services within the episode, as this would not materially affect the estimated financial impacts to the Medicare program. The prospective prices for the episodes incorporate price updates from the FFS payment systems, but no change in utilization for the performance years is assumed. If there is a national increase in utilization within each episode that is not driven by the incentives under the models, 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 incentives under the models, then costs to the Medicare program may increase due to greater reconciliation payments paid by Medicare to participants.

We also assume that 27 percent of hospitals will submit voluntary measures in performance years 1 and 2, consistent with current experience in performance year 1 for CJR. We assume the percentage of hospitals that submit quality data will increase in 63 percent in performance year 3, and 99 percent in performance years 4 and 5 to qualify for the reduced discount. As a sensitivity test, if no hospitals report the voluntary measures for any of the three EPMs, the models together are estimated to save the Medicare program an additional $27 million over the 5 performance years.

Additionally, we were unable to fully estimate the impact of the proposal in section III.D. of this final rule 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 will 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. of this final rule, beginning in July 2017 we will exclude from AMI, CABG, and SHFFT episodes beneficiaries aligned to ACOs in the Next Generation ACO model, Shared Savings Program Track 3, and ESRD ESCOs in the Comprehensive ESRD Care Initiative in tracks with downside risk for financial losses. Excluding these beneficiaries from the EPMs will have the effect of reducing the number of eligible episodes and therefore the expected savings generated by implementation of the EPMs. To model the impact of these exclusions, we assume that the percentage of the FFS population aligned to the Next Generation ACO model, Shared Savings Program Track 3, and ESRD ESCOs in the Comprehensive ESRD Care initiative remains constant over the 5 performance years of the EPM model, and is similar to the distribution of beneficiaries aligned to these models for the 2017 calendar year.

Due to the uncertainty of estimating the impacts of the EPMs, actual results could be higher or lower than these estimates. 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. Our analysis presents the cost and transfer payment effects of this final rule to the best of our ability. We solicited comments on the assumptions and analysis presented.

The following is a summary of the comments received and our responses.

Comment: A commenter noted that the impacts in the proposed rule did not present costs and savings attributable to the cardiac rehabilitation incentive payment model separate from the AMI, CABG and SHFFT EPM costs and savings and requested that we provide this information.

Response: We appreciate the interest of the commenter to obtain a breakdown of costs and savings attributable to the cardiac rehabilitation incentive payment model. We have presented disaggregated cardiac rehabilitation incentive payment model costs and savings in this final rule.

Comment: One commenter expressed concern for the potential economic impact that the EPMs may have on beneficiaries' families and family caregivers such as increased home health care needs. The commenter stated that they believe there is a great deal of economic impact on families due to missed work or other out of pocket costs which might increase due to shortened stays at inpatient or rehabilitation facilities resulting from the EPMs. The commenter requested that CMS provide detailed modeling of the economic impacts on family caregivers, including direct out of pocket costs and missed work associated with caring for family members who are beneficiaries in an EPM.

Response: We appreciate the commenter's concern for the potential economic impact on in-home family care providers. However, we do not believe that this is something that can be accurately modeled given the high amount of uncertainty regarding the volume of additional in-home family-provided care that might potentially be spurred by the EPMs.

Comment: A commenter requested that we provide greater detail with regard to the modeling methods utilized in our estimates. The commenter requested that we further explain the implication on physician practice under the model.

Response: Our estimates of the impacts of the EPMs do not include assumptions about behavioral change on the part of providers and suppliers or other entities other than participating hospitals as a result of the EPMs. The EPMs could enable participants to consider the most appropriate strategies for care redesign with collaborating entities including physicians, such as—(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.

In addition, as discussed in section I.B.5. of this final rule, the EPMs create an opportunity for physicians to collaborate in order to participate in Track 1 of the EPMs to be eligible for qualification for Advanced APM. For purposes of modeling impacts, we have assumed that only 1 percent of participants will elect to take on downside risk in performance year 2 to qualify as an Advanced APM. Participation in the Advanced APMs may result in net profits or losses for collaborating physicians. For more information on Advanced APMs, please see the MIPS and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models final rule with comment period (81 FR 77008 through 77831). We refer readers to Table 57, where we provide the estimated impact associated with the implementation of the EPMs.

b. CJR

We are finalizing our proposal 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 are also finalizing our proposal 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 finalized in this final rule 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 for performance years 3–5. We also updated our prior assumption regarding CJR participation with voluntary reporting of quality data to be more consistent with prior experience. The estimates assume that 27 percent of CJR participants will submit quality data in performance years 1 and 2, consistent with preliminary results regarding quality reporting in performance year 1. The model then assumes that more hospitals will submit quality data over time to qualify for a lower discount, with 63 percent reporting quality data in performance year 3, and 99 percent in performance years 4 and 5.

To simulate changes in the calculation of the CJR composite scores, we used quality data as publicly reported on Hospital Compare in 2015 and 2016 to estimate 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 calculated 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 99 percent of hospitals participating in the CJR model will voluntarily submit patient-reported outcome measures to qualify for the lower discount by performance year 4.

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, consistent with the methodology finalized in section III.E., 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 finalized 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. The number of hospitals estimated to be affected by the post-episode spending calculation is anticipated to be small, and the estimated post-episode reconciliation amount is estimated to round down to 0 million.

(2) Analyses

TABLE 59—ESTIMATES OF IMPACT ON THE MEDICARE PROGRAM BY THE 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	1	2	10	11	2	26

* In millions. Totals do not necessarily equal the sums of rounded components.

Modifications to the CJR model as established in this final 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 CJR model modifications in this final 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 $4 million in spending. The total estimated net financial impact to the Medicare program from both the modifications in the final rule and revised assumptions are $26 million in Medicare spending. Due to the uncertainty of estimating the impacts of this model, actual results could be higher or lower than this estimate. 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 final 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. The CR incentive payment model will 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 will 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 will also 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 CR incentive payment and the underlying EPM and FFS payment methodologies. We will 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 beneficiaries that received cardiac rehabilitation services within 90 days of discharge, to beneficiaries that did not receive cardiac rehabilitation services within 90 days of discharge. We found that among beneficiaries 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 beneficiaries 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. However, adjusting for age, sex and case-mix may not fully account for other characteristics in the cardiac rehabilitation population compared to patients who did not receive such services that may account for the difference in Medicare spending.

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 beneficiaries receiving cardiac rehabilitation services, as well as any reduction in Medicare spending due to more beneficiaries receiving cardiac rehabilitation services. For the 90 MSAs selected for the cardiac rehabilitation incentive payment model, we used final action Medicare claims data for the 2015 calendar year to calculate what the cardiac rehabilitation incentive payments would be for all beneficiaries receiving cardiac rehabilitation services within 90 days of an AMI and CABG hospitalization. For a given increase in the proportion of beneficiaries observed in the 2015 calendar year that received cardiac rehabilitation services (see table 60), we calculated both the cost of the cardiac rehabilitation incentive payments for these additional beneficiaries, as well as the estimated reduction in Medicare spending over a 3-year period due to these additional beneficiaries receiving cardiac rehabilitation services. We estimated spending based on the pricing structure described in section VI.E. of this final rule. For a given rate of beneficiaries receiving cardiac rehabilitation services, we summed the costs of CR incentive payments. We then subtracted the estimated reduction in Medicare spending due to the increase in the rate of beneficiaries receiving cardiac rehabilitation services relative to the rate receiving such services in the 2015 calendar year to arrive at the net financial impact. This analysis considers the impact of increased utilization on transfer payments from Medicare to providers, as well as beneficiary copays and coinsurance.

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 60—RANGE OF POTENTIAL LONG-TERM IMPACT OF CARDIAC REHABILITATION INCENTIVE PAYMENT MODEL *

Year	Increase in cardiac rehabilitation utilization		
	No increase	2 percentage points	4 percentage points
2017	2	2	2
2018	6	6	6
2019	7	4	1
2020	7	2	(3)
2021	8	1	(7)
2022	.....	(8)	(16)
2023	.....	(5)	(10)
2024	.....	(3)	(5)
Total: 2017–2024	29	(1)	(32)

* In millions of dollars. Totals do not necessarily equal the sums of rounded components.

Table 60 summarizes the estimated impact for the CR incentive payment model. Our model estimates that the impact on Medicare spending may range from up to $29 million of spending to $32 million of savings between 2017 and 2024, depending on the change in utilization of CR/ICR services under the model. The estimate only considers the financial effects of additional beneficiaries receiving CR/ICR services, and does not take into account potential changes in the volume of CR/ICR services that beneficiaries 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 the impacts of this model, actual results could be higher or lower than this estimate. Our analysis presents the cost and transfer payment effects of this final rule to the best of our ability. We solicited comments on our assumptions and analysis presented in the proposed rule (81 FR 50989 through 51002). However, we did not receive comments on this topic.

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, the Medicare program funded a 3-year demonstration, the ACE Demonstration. The demonstration used a prospective global payment for a single episode-of-care as an alternative approach to payment for service delivery under traditional Medicare FFS. The episode-of-care was defined as a combination of Parts A and B services furnished to Medicare FFS beneficiaries during an inpatient hospital stay for any one of a specified set of cardiac and orthopedic MS–DRGs. The 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 this 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 and we are finalizing refinements to the CJR in this final rule to support successful implementation. The design of the EPMs finalized in this rule incorporates early learnings from the CJR model.

Finally, although we project savings to Medicare under the EPMs and updated 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 EPMs do not affect beneficiary cost sharing for services or premiums paid by beneficiaries. If there is a shift in services utilized within each episode, then beneficiary cost sharing could be higher or lower than would otherwise be experienced.

We finalized the use of several patient outcomes and patient experience measures to tie payment to quality performance with the intent that this approach encourages 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 episodes provides participants with new incentives to improve the health and well-being of the Medicare beneficiaries they treat.

Additionally, the 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 EPMs and CJR allow participants to enter into risk-sharing arrangements with certain other providers, and participants may recommend 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 final rule, given that participants would receive a reconciliation payment when they are able to reduce average spending per episode 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 cases 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 are finalizing that as part of the payment definition (see section III.D. of this final rule) that participants would be financially responsible for certain outlier post-episode payments occurring in the 30-day window subsequent to the end of the 90-day episode.

Lastly, we note that Medicare payments for services will continue to be made for each Medicare FFS payment system under the CJR model and the EPMs. Because we are finalizing our proposal 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. In our analysis of impacts, we assume that beneficiary payments will not be affected, as only the participant will be subject to the reconciliation process. If participants are successful in improving quality or care while reducing costs, beneficiaries may benefit through reduced out-of-pocket expenditures across the episode. Alternatively, if participants respond to the incentives under the models by shifting medical care outside of the 90-day bundle, than this may negatively impact the quality of care that beneficiaries receive.

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 604 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. The models finalized in this rule do not require participation of hospitals located outside of MSAs. We have included a more protective stop-loss policy for certain IPPS hospitals that are 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 reclassified to rural in accordance with § 412.103. The models finalized in this rule 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 finalized additional financial protections for rural hospitals (in addition to other protections under the EPMs for Medicare Dependent Hospitals, Rural Referral Centers, Sole Community and certain low-volume participants). In performance year 2, a rural hospital which qualifies for reduced stop-loss and stop-gain limits and elects downside risk 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 year 3, a rural hospital could owe Medicare no more than 3 percent of quality-adjusted target prices for the hospital's episodes in an EPM. In performance years 4 and 5, a rural hospital could owe Medicare no more than 5 percent of the sum of quality-adjusted target prices for the hospital's episode in an EPM. Although we are finalizing these additional protections, we believe that few rural hospitals will be included in the models, and therefore that few will need these 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 final rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

We solicited public comments on our estimates and analysis of the impact of our proposals on small rural hospitals.

The following is a summary of the comments received and our responses.

Comment: Some commenters were concerned that this rule may have a negative impact or create unnecessary burden on small rural hospitals. One commenter reported concern that the EPMs could have a negative financial impact on small rural hospitals. Another commenter stated that the EPMs may reduce access for rehabilitation services in rural areas. This commenter stated that they are concerned non-rural EPM participant hospitals may encourage beneficiaries to receive care at providers affiliated with or within close proximity to the non-rural EPM participant hospital, which could negatively impact volume of services provided by rural hospitals. The commenter also stated that beneficiaries living in rural settings might therefore be forced to choose between relocating to less rural areas to receive appropriate care or to simply not receive appropriate post-acute care and follow-up.

Response: We understand the commenters' concern that the EPMs may have negative financial implications on rural hospitals. To limit the impact on rural hospitals, we have largely excluded them from the MSAs

eligible for EPM. As discussed in section III.D.7.c.(1) of this final rule, we provide additional protections for rural hospitals in the EPMs. We have also established, in § 512.450, that participants may not limit beneficiary choice to any list of providers or suppliers in any manner other than that permitted under applicable statutes and regulations including small rural hospitals.

We recognize that rural IPPS hospitals, SCHs, MDH and RRCs often serve as the only sites of care for beneficiaries living in rural areas, and these providers may have limited resources to contain costs under the EPMs. Additionally, they may have a limited number of providers and suppliers with which to coordinate care, such as CAHs that are reimbursed at a higher cost-based rate. As a result, we have provided for more protective stop-loss limits for these groups of IPPS hospitals in order to include them in the models while alleviating some financial risk. We believe that these models will not have a significant impact on the operations of a substantial number of small rural hospitals. The discussion of separate financial loss limits for certain hospitals that may be less equipped to tolerate risk is included in § 512.305(c)(2)(iii)(C).

We appreciate the comment regarding the potential impact of this model on rural providers, particularly small rural hospitals. As we note in section III.D.7.c.(1) of this final rule, we are providing additional protections for rural IPPS hospitals, SCHs, MDHs, RRCs and certain low-volume hospitals located in the MSAs selected for participation in the models. As discussed in section III.D.7.c.(1), we note that these categories of hospitals often have special payment protections or additional payment benefits under the Medicare program because we recognize the importance of preserving Medicare beneficiaries' access to care from these 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 final 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 final 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 beneficiaries, and receive payments in accordance with Medicare FFS payment methodologies.

Accordingly, we have determined that this final rule will not have a significant impact on a substantial number of small entities.

6. Effects on Collection of Information

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, CABG and SHFFT models), described in more detail in section III.E. of this final 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, for EPM participants there will be no required information collection activities for 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 need to submit the five key clinical data elements for at least 90 percent of eligible AMI discharges to receive credit for successful submission and two additional points toward the participant's AMI model composite quality score.

We are unable to provide a direct cost estimate for hospitals at this time, but 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 CABG model, the voluntary quality measure is successful submission of data to the Society of Thoracic Surgeons Adult Cardiac Surgery Database (STS measure). We anticipate that for the majority of CABG model participants, there will be no additional burden of reporting as the STS measure as most CABG participants are already submitting data for this measure.

We do not anticipate significant operational difficulties as we plan to work collaboratively with the STS Registry to receive the data files following each data collection period as prescribed by the STS Registry. EPM participants who are not members of the STS Proprietary Registry, but are a HQR participating facility would have access to SFT. Data files can be securely sent via SFT in a transitional submission format available to systems using a spreadsheet-based approach.

We are unable to provide a direct cost estimate for hospitals at this time, but expect to learn more as part of the CABG model testing.

For the SHFFT model, the voluntary quality measure is based on THA/TKA patient-reported outcome-based measure data submission, 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 patient-reported outcome-based data 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 is 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. For these participants, the burden of developing data collection systems will be minimal.

Participating hospitals must meet the following information submission requirements for each performance year in order to fulfill the successful THA/TKA patient-reported outcome-based data collection criterion. In performance year 1, participants must submit pre-operative data for at least 60 percent of eligible procedures or at least 75 cases performed between September 1, 2016 and June 30, 2017. In performance year 2, participants must submit post-operative data for at least 60 percent of eligible procedures or at least 75 cases performed between September 1, 2016 and June 30, 2017 and also must submit pre-operative data for at least 70 percent of eligible procedures or at least 100 cases. In performance year 3, participants must submit post-operative data for at least 70 percent of eligible procedures or at least 100 cases performed between July 1, 2017 and June 30, 2018 and also must submit pre-operative data for at least 80 percent of eligible procedures or at least 200 cases performed between July 1, 2018 and June 30, 2019. In performance year 4, participants must submit post-operative data for at least 80 percent of eligible procedures or at least 200 cases performed between July 1, 2018 and June 30, 2019 and also must submit pre-operative data for at least 80 percent of eligible procedures or at least 200 cases performed between July 1, 2019 and June 30, 2020. In performance year 5, participants must submit post-operative data for at least 80 percent of eligible procedures or at least 200 cases performed between July 1, 2019 and June 30, 2020 and also must submit pre-operative data for at least 80 percent of eligible procedures or at least 200 cases performed between July 1, 2020 and June 30, 2021.

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.

Overall, we anticipate the net burden of voluntary data submissions in the AMI, CABG 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. The submission of clinician financial arrangements lists (no more frequently than quarterly) for Track 1 EPMs and the Track 1 CJR model may create some additional administrative requirements for certain EPM and CJR participants.

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 sought comment on any burden derived from this requirement. In total, we anticipate marginal additional reporting burden resulting from this final rule.

The following is a summary of the comments received and our responses.

Comment: A commenter expressed concern over increased quality data reporting in the EPMs and the CJR model. The commenter stated that, to date, they have utilized extensive resources to maintain compliance with CJR quality reporting requirements and are concerned about further quality reporting requirements for the EPMs. The commenter requested that CMS delay quality reporting requirements due to the resource investment necessary to comply with EPM quality reporting requirements.

Response: We appreciate the commenter's concern over potential burden associated with quality data reporting in the EPMs. As discussed in section III.E.3. of this final rule, EPM participants are not required to report quality data for reconciliation payment eligibility. While EPM participants may choose to increase their financial opportunity under the model by successfully submitting data for future measure development, as discussed in sections III.E.3.d. of this final rule, reporting data for future measure development is not required for reconciliation payment eligibility.

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 final rule does not include any mandate that would result in spending by state, local or tribal governments, in the aggregate, or by the private sector in the amount of $146 million in any 1 year.

D. Alternatives Considered

Throughout this final rule, we have identified the policies and alternatives that we have considered, and provided information as to the possible effects of these alternatives and the rationale for each of the policies we have finalized. We solicited and welcomed comments on our proposals, on the alternatives we identified, and on other alternatives that we should consider, as well as on the costs, benefits, or other effects of these.

We note that our estimates are limited to hospitals in the CJR model, hospitals that will be included in the SHFFT model, hospitals selected to participate in the AMI and CABG models, and the FFS–CR participants. This final 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 welcomed 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. of this final rule, we will 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 have defined beneficiary inclusion based only on the principal diagnosis code which would have reduced the number of episodes included in the EPMs.

As discussed in section III.E. of this final rule, we allow participants to qualify for a higher composite quality score in the AMI, CABG and SHFFT models based on submission of voluntary measures or data. 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, CABG and SHFFT models are estimated to result in an additional $27 million savings over the 5 performance years.

As discussed in section VI of this final rule, we have finalized our proposal for 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. In the proposed rule, we 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 61, we have prepared an accounting statement showing the classification of transfers, benefits, and costs associated with the provisions in this final rule. The accounting statement is based on estimates provided in this regulatory impact analysis. As described in Table 57, we estimate this final EPM model will result in savings to the federal government of $159 million over the 5 performance years of the model from 2017 to 2021. Table 58 shows the annualized change in net federal monetary transfers, and potential reconciliation payments to participants net of repayments from participants that are associated with the EPM provisions of this final rule as compared to baseline. As described in Table 59, we estimate the modifications to the CJR model finalized in this final rule will result in a reduced savings to the federal government of $26 million over the 5 performance years of the model from 2016 to 2020. As described in Table 60, we estimate the range of impact for this final CR model to be between a cost of $29 to a savings of $32 million over 2017 to 2024. In Table 61, the overall annualized change in payments (for all provisions finalized in this final rule) based on a 7 percent and 3 percent discount rate, results in net federal monetary transfer from the participant

IPPS hospitals to the federal government of $13 million and $16 million respectively over the period of 2016 to 2024. For purposes of the accounting statement, we assumed no change in the rate of beneficiaries receiving cardiac rehabilitation services.

This final rule does not result in any significant additional administrative burden on participants.

TABLE 61—ACCOUNTING STATEMENT (2016–2024), ESTIMATED IMPACTS FOR EPISODE PAYMENT MODELS (2017–2021), CHANGES TO COMPREHENSIVE CARE FOR JOINT REPLACEMENT (2016–2020), AND CARDIAC REHABILITATION INCENTIVE PAYMENT MODEL (2017–2024) ASSUMING NO CHANGE IN THE RATE OF PATIENTS RECEIVING CARDIAC REHABILITATION SERVICES

Category	Primary estimate (millions)	Source citation (RIA, preamble, etc.)
Transfers	.....	
Annualized monetized transfers: Discount rate 7%	$13	Change from baseline to final changes (Tables 57, 59, and 60).
Annualized monetized transfers: Discount rate 3%	16	
From whom to whom?	From Participant IPPS Hospitals to Federal Government.	

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 final rule, we estimate that the financial impact of the AMI, CABG, and SHFFT EPM models proposed here would be net federal savings of $159 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 decrease in savings of $26 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 $29 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 amends 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. Adding in alphabetical order definitions for ''Applicable discount factor'', ''Area'', ''CEHRT'', ''CJR beneficiary,'' and ''Episode benchmark price'';

■ b. Removing the definition of ''Episode target price'';

■ c. Revising the definitions of ''HCPCS'', ''HHA'', and ''Historical episode payment'';

■ d. Adding in alphabetical order a definition for ''Hospital'';

■ e. Removing the definition of ''IPPS hospital (or hospital)'';

■ f. Adding in alphabetical order a definition for ''Quality-adjusted target price'';

■ g. Revising the definition of ''Quality improvement points''; and

■ h. Adding in alphabetical order a definition of ''Therapist in private practice''.

The additions and revisions read as follows:

§ 510.2 Definitions.

* * * * *

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.

Area means, as defined in § 400.200 of this chapter, the geographical area within the boundaries of a State, or a State or other jurisdiction, designated as constituting an area with respect to which a Professional Standards Review Organization or a Utilization and Quality Control Peer Review Organization has been or may be designated.

* * * * *

CEHRT means certified electronic health record technology that meets the requirements of 45 CFR 170.102. .

CJR beneficiary means a beneficiary who meets the beneficiary inclusion criteria in § 510.205 and who is in a CJR episode.

* * * * *

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).

* * * * *

HCPCS stands for Healthcare Common Procedure Coding System.

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 adds 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).

* * * * *

Therapist in private practice means a therapist that—

(1) Complies with the special provisions for physical therapists in private practice in § 410.60(c) of this chapter;

(2) Complies with the special provisions for occupational therapists in private practice in § 410.59(c) of this chapter; or

(3) Complies with the special provisions for speech-language pathologists in private practice in § 410.62(c) of this chapter.

* * * * *

■ 3. Section 510.2 is further amended, effective July 1, 2017, 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. Revising the definition of ''CJR collaborator'';

■ e. Adding in alphabetical order a definition for ''Collaboration agent'';

■ f. Removing the definition of ''Collaborator agreement'';

■ g. Adding in alphabetical order a definition for ''CORF'';

■ 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'',

■ j. Adding in alphabetical order definitions for ''Member of the NPPGP or NPPGP member'', ''Member of the TGP or TGP member'', and ''NPPGP'';

■ k. Removing the definition of ''Practice collaboration agent'';

■ l. Revising the definition of ''Provider of outpatient therapy services'';

■ m. Adding in alphabetical order definitions of ''TGP''; and

■ n. In the definition of ''Therapist'' by removing the phrase ''the following as defined at § 484.4:'' and adding in its place the phrase ''the following individuals as defined at § 484.4 of this chapter:''.

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 Shared Savings Program and is not in Track 3.

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.

* * * * *

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) Therapist in private practice.

(8) CORF.

(9) Provider of outpatient therapy services.

(10) Physician Group Practice (PGP).

(11) Hospital.

(12) CAH.

(13) Non-Physician Provider Group Practice (NPPGP).

(14) Therapy Group Practice (TGP).

* * * * *

Collaboration agent means an individual or entity that is not a CJR collaborator and that is either of the following:

(1) A member of a PGP, NPPGP, or TGP that has entered into a distribution arrangement with the same PGP, NPPGP, or TGP in which he or she is an owner or employee, and where the PGP, NPPGP, or TGP is a CJR collaborator.

(2) An ACO participant or ACO provider/supplier that has entered into a distribution arrangement with the same ACO in which it is participating, and where the ACO is a CJR collaborator.

* * * * *

CORF stands for comprehensive outpatient rehabilitation facility.

* * * * *

Distribution arrangement means a financial arrangement between a CJR collaborator that is an ACO, PGP, NPPGP, or TGP and a collaboration agent for the sole purpose of distributing some or all of a gainsharing payment received by the ACO, PGP, NPPGP, or TGP.

Distribution payment means a payment from a CJR collaborator that is an ACO, PGP, NPPGP, or TGP 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, an NPPGP member, or a TGP member that has entered into a downstream distribution arrangement with the same PGP, NPPGP, or TGP in which he or she is an owner or employee, and where the PGP, NPPGP, or TGP is a collaboration agent.

Downstream distribution arrangement means a financial arrangement between a collaboration agent that is both a PGP, NPPGP, or TGP 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, NPPGP, or TGP.

Downstream distribution payment means a payment from a collaboration agent that is both a PGP, NPPGP, or TGP and an ACO participant to a downstream collaboration agent, under a downstream distribution arrangement,

composed only of distribution payments.

* * * * *

Member of the NPPGP or *NPPGP member* means a nonphysician practitioner or therapist who is an owner or employee of an NPPGP and who has reassigned to the NPPGP his or her right to receive Medicare payment.

Member of the TGP or *TGP member* means a therapist who is an owner or employee of a TGP and who has reassigned to the TGP his or her right to receive Medicare payment.

* * * * *

NPPGP means an entity that is enrolled in Medicare as a group practice, includes at least one owner or employee who is a nonphysician practitioner, does not include a physician owner or employee, and has a valid and active TIN.

* * * * *

Provider of outpatient therapy services means an entity that is enrolled in Medicare as a provider of therapy services and furnishes 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.

* * * * *

TGP means an entity that is enrolled in Medicare as a therapy group in private practice, includes at least one owner or employee who is a therapist in private practice, does not include an owner or employee who is a physician or nonphysician practitioner, and has a valid and active TIN.

* * * * *

■ 4. Section 510.110 is added to subpart B, effective July 1, 2017, 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.

■ 5. 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 specified 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 specified 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.

(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 and entities for the period of the CJR performance year specified by CMS:

(1) *CJR collaborators.* For each physician, nonphysician practitioner, or therapist in private practice who is a CJR collaborator 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) *Practice collaboration agents.* For each physician, nonphysician practitioner, or therapist who is a practice collaboration agent during the period of the CJR performance year specified by CMS:

(i) The name and TIN of the CJR collaborator and the name, TIN, and NPI of the practice collaboration agent.

(ii) The start date and, if applicable, end date, for the distribution arrangement between the CJR collaborator and the practice collaboration agent.

(3) [Reserved.]

(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 CJR 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 CJR 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) [Reserved.]

■ 6. Section 510.120 is amended, effective July 1, 2017, by revising paragraph (b)(2) and by adding paragraphs (b)(3) and (c)(2) to read as follows:

§ 510.120 CJR participant hospital CEHRT track requirements.

* * * * *

(b) * * *

(2) *Collaboration agents.* For each physician, nonphysician practitioner, or

therapist who is a collaboration agent during the period of the CJR performance year specified by CMS:

(i) The name and TIN of the CJR collaborator and the name, TIN, and NPI of the collaboration agent.

(ii) The start date and, if applicable, end date, for the distribution arrangement between the CJR collaborator and the collaboration agent.

(3) *Downstream collaboration agents.* For each physician, nonphysician practitioner, or therapist who is a downstream collaboration agent during the period of the CJR performance year specified by CMS—

(i) The name and TIN of the CJR collaborator and the name and TIN of the collaboration agent and the name, TIN, and NPI of the downstream collaboration agent.

(ii) The start date and, if applicable, end date, for the downstream distribution arrangement between the collaboration agent and the downstream collaboration agent.

* * * * *

(c) * * *

(2) The CJR participant hospital must retain and provide access to the required documentation in accordance with § 510.110.

■ 7. Section 510.205 is amended by adding paragraph (a)(6) to read as follows:

§ 510.205 Beneficiary inclusion criteria.

(a) * * *

(6) For episodes beginning on or after July 1, 2017, are not prospectively assigned to—

(i) An ACO in the Next Generation ACO model;

(ii) An ACO in a track of the Comprehensive ESRD Care Model incorporating downside risk for financial losses; or

(iii) A Shared Savings Program ACO in Track 3.

* * * * *

■ 8. Section 510.300 is amended by—

■ a. Revising the section heading;

■ b. Revising paragraphs (a) introductory text and (a)(1) through (3);

■ c. Redesignating paragraph (a)(5) as paragraph (a)(6);

■ d. Adding a new paragraph (a)(5);

■ e. Revising the paragraph (b) subject heading and revising paragraphs (b)(1) introductory text and (b)(3), (5), and (7);

■ f. Adding paragraph (b)(8); and

■ g. 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 (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.

* * * * *

■ 9. Section 510.305 is amended by—

■ a. Revising paragraphs (e) introductory text, (e)(1)(ii) and (v), (f)(1)(i) and (ii), (f)(2), (g)(2), and (h)(6);

■ b. Adding paragraph (h)(7);

■ c. Revising paragraph (i); and

■ d. Adding paragraph (j).

The revisions and additions 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 (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 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.

* * * * *

(2) Reconciliation payment. If the amount described in paragraph (f)(1) of this section is positive and the composite quality score described in § 510.315 is acceptable (defined as greater than or equal to 5.00 and less than 6.9), good (defined as greater than or equal to 6.9 and less than or equal to 15.0), or excellent (defined as greater than 15.0), Medicare pays the participant hospital a reconciliation payment in an amount equal to the amount described in paragraph (f)(1) of this section.

* * * * *

(g) * * *

(2) If the hospital's composite quality score described in § 510.315 is acceptable (defined as greater than or equal to 5.00 and less than 6.9), good (defined as greater than or equal to 6.9 and less than or equal to 15.0), or excellent (defined as greater than 15.0), and the hospital is determined to have a positive NPRA under § 510.305(e)), the hospital is eligible for a reconciliation payment.

* * * * *

(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 (excluding Track 3 for CJR episodes that initiate on or after July 1, 2017).

(iii) The Comprehensive ESRD Care Initiative (excluding a track with downside risk for CJR episodes that initiate after July 1, 2017).

(iv) The Next Generation ACO model (excluding CJR episodes that initiate on or after 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 3 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.

■ 10. Section 510.310 is amended by—

■ a. Revising paragraphs (a) introductory text and (a)(1) and (2);

■ b. Removing paragraph (a)(3);

■ c. Redesignating 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); and

■ h. Revising newly designated paragraph (e)(6).

The revisions and additions read as follows:

§ 510.310 Appeals process.

(a) *Notice of calculation error (first level of appeal).* Subject to the limitations on review in subpart D of this part, if a participant hospital wishes to dispute calculations involving a matter related to payment, reconciliation amounts, repayment amounts, the use of quality measure results in determining the composite quality score, or the application of the composite quality score during reconciliation, the participant hospital is required to provide written notice of the calculation error, in a form and manner specified by CMS.

(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. This does not apply to the limitations on review in paragraph (e) of this section.

(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.

■ 11. 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); and

■ d. Revising paragraphs (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 6.9 and less than or equal to 15.0.

(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 15.0.

■ 12. 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).

■ 13. Section 510.405 is amended by revising paragraph (a)(1) and (b) to read as follows:

§ 510.405 Beneficiary choice and beneficiary notification.

(a) * * *

(1) As part of discharge planning and referral, participant hospitals must provide a complete list of HHAs, SNFs, IRFs, or LTCHs that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, IRF, or LTCH, in the geographic area requested by the patient.

(i) This list must be presented to CJR beneficiaries for whom home health care, SNF, IRF, or LTCH services are medically necessary.

(ii) Participant hospitals must specify on the list those post-acute care providers on the list with whom they have a sharing arrangement.

(iii) Participant hospitals may recommend preferred providers and suppliers, consistent with applicable statutes and regulations.

(iv) 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.

(v) Participant hospitals must take into account patient and family preferences when they are expressed.

* * * * *

(b) *Required beneficiary notification*—(1) *Participant hospital detailed notification.* Each participant hospital must provide written notification to any Medicare beneficiary that meets the criteria in § 510.205 of his or her inclusion in the CJR model. The notification must be provided upon admission to the participant hospital if the admission that initiates the CJR episode is not scheduled with the participant hospital in advance. If the admission is scheduled in advance, then the participant hospital must provide notice as soon as the admission is scheduled. In circumstances where, due to the patient's condition, it is not 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 CJR 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 or the 1–800–MEDICARE helpline.

(v) A list of the providers, suppliers, and ACOs with whom the CJR participant hospital has a sharing arrangement. This requirement may be fulfilled by the participant hospital including in the detailed notification a Web address where beneficiaries may access the list.

(2) *CJR collaborator notice.* A participant hospital must require every CJR collaborator to provide written notice to applicable CJR beneficiaries of the structure of the CJR model and the existence of its sharing arrangement with the participant hospital.

(i) A CJR participant hospital must require every CJR collaborator (other than PGPs) that furnishes an item or service to a CJR beneficiary during a CJR episode to provide written notice to the beneficiary of the structure of the model and the existence of the individual's or entity's sharing arrangement. The notice must be provided no later than the time at which the beneficiary first receives an item or service from the CJR collaborator during a CJR episode. In circumstances where, due to the patient's condition, it is not feasible to provide notification at such time, the notification must be provided to the beneficiary or his or her representative as soon as is reasonably practicable.

(ii) A participant hospital must require every PGP that is a CJR collaborator where a member of the PGP furnishes an item or service to a CJR beneficiary during a CJR episode to provide written notice to the beneficiary of the structure of the model and the existence of the entity's sharing arrangement under the model. The notice must be provided no later than the time at which the beneficiary first receives an item or service from any member of the PGP, and the required PGP notice may be provided by that member. In circumstances where, due to the patient's condition, it is not feasible to provide notice at such times, the notice must be provided to the beneficiary or his or her representative as soon as is reasonably practicable.

(3) *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 post-acute care 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 care 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 transferred 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)(3)(i) of this section that the beneficiary will be responsible for payment for the services furnished by the SNF during that stay, except those services that would be covered by Medicare Part B during a non-covered inpatient SNF stay.

■ 14. Section 510.405 is further amended, effective July 1, 2017, by revising paragraphs (b)(1) and (2) and adding paragraph (b)(4) to read as follows:

§ 510.405 Beneficiary choice and beneficiary notification.

* * * * *

(b) * * *

(1) *Participant hospital detailed notification.* Each participant hospital must provide written notification to any Medicare beneficiary that meets the criteria in § 510.205 of his or her inclusion in the CJR model. The notification must be provided upon admission to the participant hospital if the admission that initiates the CJR episode is not scheduled with the participant hospital in advance. If the admission is scheduled in advance, then the participant hospital must provide notice as soon as the admission is scheduled. In circumstances where, due to the patient's condition, it is not 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 CJR episode. The participant 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. 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 or the 1–800–MEDICARE helpline.

(v) A list of the providers, suppliers, and ACOs with whom the CJR participant hospital has a sharing arrangement. This requirement may be fulfilled by the participant hospital including in the detailed notification a Web address where beneficiaries may access the list.

(2) *CJR collaborator notice.* A participant hospital must require every CJR collaborator to provide written notice to applicable CJR beneficiaries of the structure of the CJR model and the existence of its sharing arrangement with the participant hospital.

(i) With the exception of ACOs, PGPs, NPPGPs, and TGPs, a CJR participant hospital must require every CJR collaborator that furnishes an item or service to a CJR beneficiary during a CJR episode to provide written notice to the beneficiary of the structure of the model and the existence of the individual's or entity's sharing arrangement. The notice must be provided no later than the time at which the beneficiary first receives an item or service from the CJR collaborator during a CJR episode. In circumstances where, due to the patient's condition, it is not feasible to provide notification at such time, the notification must be provided to the beneficiary or his or her representative as soon as is reasonably practicable. The CJR collaborator must be able to generate a list of all beneficiaries who received such a notice, including the date on which the notice was provided to the beneficiary, to CMS upon request.

(ii) A participant hospital must require every PGP, NPPGP, or TGP that is a CJR collaborator where a member of the PGP, member of the NPPGP, or member of the TGP furnishes an item or service to a CJR beneficiary during a CJR episode to provide written notice to the beneficiary of the structure of the model and the existence of the entity's sharing arrangement. The notice must be provided no later than the time at which the beneficiary first receives an item or service from any member of the PGP, member of the NPPGP, or member of the TGP, and the required PGP, NPPGP, or TGP notice may be provided by that member respectively. In circumstances where, due to the patient's condition, it is not feasible to provide notice at such times, the notice must be provided to the beneficiary or his or her representative as soon as is reasonably practicable. The PGP, NPPGP, or TGP must be able to generate a list of all beneficiaries who received such a notice, including the date on which the notice was provided to the beneficiary, to CMS upon request.

(iii) A participant hospital must require every ACO that is a CJR collaborator where an ACO participant or ACO provider/supplier furnishes an item or service to a CJR beneficiary during a CJR episode to provide written notice to the beneficiary of the structure of the model and the existence of the entity's sharing arrangement. The notice must be provided no later than the time at which the beneficiary first receives an item or service from any ACO participant or ACO provider/supplier and the required ACO notice may be provided by that ACO participant or ACO provider/supplier respectively. In circumstances where, due to the patient's condition, it is not feasible to provide notice at such times, the notice must be provided to the beneficiary or his or her representative as soon as is reasonably practicable. The ACO must be able to generate a list of all beneficiaries who received such a notice, including the date on which the notice was provided to the beneficiary, to CMS upon request.

* * * * *

(4) *Access to records and retention.* Lists of beneficiaries that receive notifications or notices must be retained, and access provided to CMS, or its designees, in accordance with § 510.110.

■ 15. Section 510.410 is amended, effective July 1, 2017, by revising paragraphs (b)(1) introductory text, (b)(1)(i) introductory text, (b)(1)(i)(F), (b)(1)(ii), (b)(2)(i) through (v), and (b)(3) to read as follows:

§ 510.410 Compliance enforcement.

* * * * *

(b) * * *

(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.

* * * * *

(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) 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 ended prior to termination.

(3) CMS may add a 25 percent penalty to a repayment amount on the participant hospital's reconciliation report if all of the following conditions are met:

(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.

■ 16. Section 510.500 is revised, effective July 1, 2017, 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. A selection criterion that considers whether a potential CJR collaborator has performed a reasonable minimum number of services that would qualify as CJR activities will be deemed not to violate the volume or value standard if the purpose of the criterion is to ensure the quality of care furnished to CJR beneficiaries.

(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 all of 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.

(iii) All other applicable laws and regulations.

(4) The sharing arrangement must require the CJR collaborator to have or be covered by a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the CJR model that apply to its role as a CJR collaborator, including any distribution arrangements.

(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) 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 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 ACO, PGP, NPPGP, or TGP 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, NPPGP, or TGP must meet the following criteria:

(A) The PGP, NPPGP, or TGP must have billed for an item or service that was rendered by one or more PGP member, NPPGP member, or TGP member respectively 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.

(B) The PGP, NPPGP, or TGP 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, NPPGP, or TGP 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 PGP members, NPPGP members, or TGP members; 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 or NPPGP, 50 percent of the Medicare-approved amounts under the PFS for items and services billed by that PGP or NPPGP and furnished to the participant hospital's CJR beneficiaries by the PGP members or NPPGP members respectively 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 the CJR participant hospital receives from CMS must not exceed the amount of that reconciliation payment.

(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 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.

(8) A participant hospital must not make a gainsharing payment to a CJR collaborator if CMS has notified the participant hospital that such collaborator is subject to any action for noncompliance with this part or the fraud and abuse laws, or for the provision of substandard care to CJR beneficiaries 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 amount of any alignment payments must be determined in accordance with a methodology that does 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) Publicly post (and update on at least a quarterly basis) on a Web page on the CJR participant hospital's Web site—

(A) Accurate current and historical lists of all CJR collaborators, including CJR collaborator names and addresses.

(B) Written policies for selecting individuals and entities to be CJR collaborators required by § 510.500(a)(3).

(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:

(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 a CJR collaborator's gainsharing payment.

(F) Explanation for each recoupment, such as whether the CJR 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 participant hospital must keep records of all of the following:

(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.

(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.

■ 17. Section 510.505 is revised, effective July 1, 2017, to read as follows:

§ 510.505 Distribution arrangements.

(a) *General.* (1) An ACO, PGP, NPPGP, or TGP 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 CJR 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, from an NPPGP to an NPPGP member, or from a TGP to a TGP member 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 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) of this chapter, 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) of this chapter, 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 a 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 or NPPGP, 50 percent of the total Medicare-approved amounts under the PFS for items and services billed by that PGP or NPPGP for items and services furnished by PGP members or NPPGP member respectively 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.

(9) With respect to the distribution of any gainsharing payment received by an ACO, PGP, NPPGP, or TGP, 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; and

(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.

■ 18. Section 510.506 is added, effective July 1, 2017, to read as follows:

§ 510.506 Downstream distribution arrangements.

(a) *General.* (1) An ACO participant that is a PGP, NPPGP, or TGP 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 payments from an NPPGP to an NPPGP member or from a TGP to a TGP member must be determined in accordance with a methodology that is substantially based on quality of care and the provision 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) The amount of any downstream distribution payments from a PGP 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 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.

(7) Except for a downstream distribution payment from a PGP to a PGP member that complies with § 411.352(g) of this chapter, a downstream collaboration agent is eligible to receive a downstream distribution payment only if the downstream collaboration agent furnished an item or service 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 comprises the gainsharing payment from which the ACO made the distribution payment to the PGP, NPPGP, or TGP that is an ACO participant.

(8) Except for a downstream distribution payment from a PGP to a PGP member that complies with § 411.352(g) of this chapter, the total amount of downstream distribution payments for a performance year paid to a downstream collaboration agent who is a physician or nonphysician practitioner and is either a member of a PGP or a member of an NPPGP must not exceed 50 percent of the total Medicare-approved amounts under the PFS for items and services furnished by the downstream collaboration agent 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 distribution payment being distributed.

(9) 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, NPPGP, or TGP from the ACO.

(10) All downstream distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(11) 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.

(12) 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.

(13) The PGP, NPPGP, or TGP 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.

(14) The PGP, NPPGP, or TGP may not enter into a downstream distribution arrangement with any PGP member, NPPGP member, or TGP member who has—

(i) A sharing arrangement with a participant hospital.

(ii) A distribution arrangement with the ACO that the PGP, NPPGP, or TGP is a participant in.

(15) The PGP, NPPGP, or TGP 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.

■ 19. Section 510.515 is amended, effective July 1, 2017, by revising paragraphs (a)(2) and (3), (b), (c) and (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.

■ 20. 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 performance years 2 through 5 of the CJR model, CMS waives the SNF 3-day rule for coverage of a SNF stay for a beneficiary who is a CJR beneficiary 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.

(1) CMS determines the qualified SNFs for each calendar quarter based on a review of the most recent rolling 12 months of overall star ratings on the Five-Star Quality Rating System for SNFs on the Nursing Home Compare Web site. Qualified SNFs are rated an overall of 3 stars or better for at least 7 of the 12 months.

(2) CMS posts to the CMS Web site the list of qualified SNFs in advance of the calendar quarter and the waiver only applies for a beneficiary who has been discharged from an anchor hospitalization if the SNF is included on the applicable calendar quarter list for the date of the beneficiary's admission to the SNF.

(b) *Financial liability for non-covered SNF services.* 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 § 510.405(b)(3).

(3) If the participant hospital does not provide the beneficiary with a discharge planning notice in accordance with § 510.405(b)(3)—

(i) The SNF must not charge the beneficiary for the expenses incurred for such services;

(ii) The SNF must return to the beneficiary any monies collected for such services; and

(iii) 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)(3), then normal SNF coverage requirements apply and the beneficiary may be financially liable for non-covered 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.

■ 21. 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.

* * * * *

■ 22. 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 and is not in Track 3.

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 and certain non-claims-based 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 of this part 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.

Anchor hospitalization portion means the part of an EPM episode that occurs during the anchor hospitalization.

Anchor MS–DRG means the MS–DRG assigned to the 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 year 2 for EPM participants who elect early downside risk and performance years 3 and 4 for all EPM participants.

Area means, as defined in § 400.200 of this chapter, the geographical area within the boundaries of a State, or a State or other jurisdiction, designated as constituting an area with respect to which a Professional Standards Review Organization or a Utilization and Quality Control Peer Review Organization has been or may be designated.

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 of this part 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 Model.

CEHRT means certified electronic health record technology that meet the requirements of 45 CFR 170.102.

Collaboration agent means an individual or entity that is not an EPM collaborator and that is either of the following:

(1) A PGP member, an NPPGP member, or a TGP member that has entered into a distribution arrangement with the same PGP, NPPGP, or TGP in which he or she is an owner or employee, and where the PGP, NPPGP, or TGP is an EPM collaborator.

(2) An ACO participant or ACO provider/supplier that has entered into a distribution arrangement with the same ACO in which it is participating, and where the ACO is an EPM collaborator.

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.

CORF stands for comprehensive outpatient rehabilitation facility.

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 under the OPPS or to any supplier reporting place of service code 11 on the PFS claim 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 of this part.

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 under the OPPS or to any supplier reporting place of service code 11 on the PFS claim 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, PGP, NPPGP, or TGP and a collaboration agent for the sole purpose of distributing some or all of a gainsharing payment received by the ACO, PGP, NPPGP, or TGP.

Distribution payment means a payment from an EPM collaborator that is an ACO, PGP, NPPGP, or TGP 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, an NPPGP member, or a TGP member that has entered into a downstream distribution arrangement with the same PGP, NPPGP, or TGP in which he or she is an owner or employee, and where the PGP, NPPGP, or TGP is a collaboration agent.

Downstream distribution arrangement means a financial arrangement between a collaboration agent that is both a PGP, NPPGP, or TGP 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, NPPGP, or TGP.

Downstream distribution payment means a payment from a collaboration agent that is both a PGP, NPPGP, or TGP 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. Each section of the regulations applies in its entirety to each model.

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) Therapist in private practice.
(8) CORF.
(9) Provider of outpatient therapy services.
(10) PGP.
(11) Hospital.
(12) CAH.
(13) NPPGP.
(14) TGP.

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 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.

EPM volume protection hospital means an EPM participant that meets the requirements under § 512.305(c)(2)(iii)(D).

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.

Member of the NPPGP or *NPPGP member* means a nonphysician practitioner or therapist who is an owner or employee of an NPPGP and who has reassigned to the NPPGP his or her right to receive Medicare payment.

Member of the TGP or *TGP member* means a therapist who is an owner or employee of a TGP and who has reassigned to the TGP 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.

NPPGP means an entity that is enrolled in Medicare as a group practice, includes at least one owner or employee who is a nonphysician practitioner, does not include a physician owner or employee, and has a valid and active TIN.

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.

OPPS stands for the Medicare Outpatient Prospective Payment System.

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.

PFS means the Medicare Physician Fee Schedule authorized under section 1848 of the 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 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.

Provider of outpatient therapy services means an entity that is enrolled in Medicare as a provider of therapy services and furnishes 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.

TGP means an entity that is enrolled in Medicare as a therapy group in private practice, includes at least one owner or employee who is a therapist in private practice, does not include an owner or employee who is a physician or nonphysician practitioner, and has a valid and active TIN.

THA/TKA stands for total hip arthroplasty/total knee arthroplasty.

Therapist means one of the following individuals as defined at § 484.4 of this chapter:

(1) Physical therapist.

(2) Occupational therapist.

(3) Speech-language pathologist.

Therapist in private practice means a therapist that either—

(1) Complies with the special provisions for services furnished by physical therapists in private practice in § 410.60(c) of this chapter;

(2) Complies with the special provisions for services furnished by occupational therapists in private practice in § 410.59(c) of this chapter; or

(3) Complies with the special provisions for services furnished by speech-language pathologists in private practice in § 410.62(c) of this chapter.

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–DRGs 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' 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 must be implemented in the same geographic areas as the CJR model as described under § 510.105 of the chapter.

(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;

(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; or

(4) Are in Maryland, Vermont, or another state where CMS is implementing a state-wide all-payer model. In such situations all MSAs in the state may be excluded even if hospitals are otherwise being paid in accordance with the IPPS and would otherwise qualify as an eligible EPM participant.

(c) In all geographic areas where the AMI, CABG, or SHFFT models are being implemented, the accountable financial entity must 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 if the EPM participant elects downside risk and for performance years 3 through 5, EPM participants choose either of the following:

(1) *CEHRT use.* EPM participants attest in a form and manner specified 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.* EPM participants do not attest in a form and manner specified 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.

(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 and entities for the period of the EPM performance year specified by CMS:

(1) *EPM collaborators.* For each physician, nonphysician practitioner, or therapist in private practice who is an EPM collaborator 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 physician, nonphysician practitioner, or therapist who is a collaboration agent during the period of the EPM performance year specified by CMS:

(i) The name and TIN of the EPM collaborator and the name, TIN, and NPI of the collaboration agent.

(ii) The start date and, if applicable, end date, for the distribution arrangement between the EPM collaborator and the collaboration agent.

(3) *Downstream collaboration agents.* For each physician, nonphysician practitioner, or therapist who is a downstream collaboration agent during the period of the EPM performance year specified by CMS:

(i) The name and TIN of the EPM collaborator, the name and TIN of the collaboration agent and the name, TIN, and NPI of the downstream collaboration agent.

(ii) The start date and, if applicable, end date, for the downstream distribution arrangement between the collaboration agent and the downstream collaboration agent.

(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, 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 during the 90-day post-discharge period and additionally DME during the anchor hospitalization, 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 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 paragraphs (b)(4)(i) and (ii) of this section.

(iv) All PBPM model payments funded from the Innovation Center appropriation.

(c) *Updating the exclusion lists for EPMs.* (1) The EPM exclusion list that applies to each anchor MS–DRG for an EPM episode and that displays excluded MS–DRGs, ICD–9–CM and ICD–10–CM diagnosis codes, and CMS model PBPM payments is posted on the CMS Web site.

(2) On an annual basis, or more frequently as needed, CMS updates the EPM exclusion lists to reflect annual coding changes or other issues brought to CMS' attention.

(3) CMS applies the following standards when revising the EPM exclusion lists 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 are included in the EPM episode.

(ii) Items or services for chronic conditions that may be affected by the EPM episode care are related and included in the EPM episode.

(iii) Items and services for chronic conditions that are generally not affected by the EPM episode care are 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 are 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 excluded categories of diagnoses for an EPM, as described in paragraph (b)(4)(iii) of this section, are 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 § 411.20 of this chapter.

(f) Not prospectively assigned to one of the following:—

(1) An ACO in the Next Generation ACO model;

(2) An ACO in a track of the Comprehensive ESRD Care Model incorporating downside risk for financial losses; or

(3) A Shared Savings Program ACO in Track 3.

(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 episode begins with the admission of a Medicare beneficiary as described in § 512.230 to an AMI 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 an AMI model episode.* The AMI 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.

(iii) Is transferred during the anchor hospitalization for inpatient hospitalization at another hospital.

(iv) Initiates any BPCI model episode.

(b) *CABG Model*—(1) *General.* The CABG 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 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.

(iii) Initiates any BPCI model episode.

(c) *SHFFT Model*—(1) *General.* The SHFFT 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 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.

(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 anchor MS–DRGs 280–282 for participants with fewer than 75 AMI model episodes with anchor 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 anchor MS–DRGs 246–251 for participants with fewer than 125 AMI model episodes with anchor 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 CABG model episodes with anchor MS–DRGs 231–236.* The episode benchmark price for an episode with CABG anchor 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 anchor 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 anchor 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 anchor 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 anchor 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 anchor MS–DRG without major complication or comorbidity (232, 234, or 236).

(ii) *Adjustments for Certain AMI Model Episodes with CABG Readmissions.* The episode benchmark price for an AMI model episode with AMI anchor MS–DRG 280–282 or PCI anchor MS–DRG 246–251 with a readmission to any of CABG anchor 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 anchor 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 through 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 (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 3 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. A trend factor is calculated for each of the first 2 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 anchor MS–DRGs 480 through 482.

(ii) Separately for each AMI anchor MS–DRGs 280 through 282 and PCI anchor MS–DRGs 246 through 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 anchor MS–DRGs 231 through 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 anchor 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 anchor 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 anchor 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 anchor 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 anchor MS–DRGs 480 through 482.

(B) For AMI model episodes with AMI anchor MS–DRGs in 280 through 282 or PCI anchor MS–DRGs 246 through 251 and without readmissions for CABG MS–DRGs, episodes with AMI anchor MS–DRGs 280 through 282 are grouped separately from episodes with PCI anchor MS–DRGs 246 through 251.

(C) For CABG model episodes with CABG anchor MS–DRGs in 231 through 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 anchor 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 anchor MS–DRG with major complication or comorbidity (231, 233, or 235).

(ii) With AMI ICD–CM diagnosis code on the anchor inpatient claim and anchor MS–DRG without major complication or comorbidity (232, 234, or 236).

(iii) Without AMI ICD–CM diagnosis code on the anchor inpatient claim and anchor MS–DRG with major complication or comorbidity (231, 233, or 235).

(iv) Without AMI ICD–CM diagnosis code on the anchor inpatient claim and anchor 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 anchor 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, as the requirement for EPM participant repayment is waived.

(ii) Not applicable in performance year 2 as the requirement for EPM participant repayment is waived except for an EPM participant that has elected downside risk for that performance year.

(iii) In performance year 2 for an EPM participant that has elected downside risk and performance years 3 and 4 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).

(iv) Not applicable in performance year 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 EPM, as well as for calculating actual episode payments under the EPM during a performance year, subject to the exceptions noted in paragraphs (e)(1)(i) through (iii) of this section.

(i) For AMI model episodes with anchor MS–DRGs 280–282 or PCI anchor MS–DRGs 246 through 251 without readmission for CABG MS–DRGs 231 through 236, payments are capped separately based on the anchor MS–DRG.

(ii) For CABG model episodes with CABG MS–DRGs 231 through 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 anchor MS–DRGs 231 through 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 anchor 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 anchor 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 anchor 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 anchor MS–DRG without major complication or comorbidity (232, 234, or 236).

(iii) For AMI episodes with either AMI anchor MS–DRGs 280 through 282 or PCI anchor MS–DRGs 246 through 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 anchor MS–DRGs 280 through 282 or PCI anchor MS–DRGs 246 through 251 and without readmission for CABG MS–DRGs corresponding to the AMI anchor 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)(2), (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 and non-claims-based payment 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 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 paragraphs (c)(2)(iii)(C) and (D) 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—

(*i*) Five percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section for the performance year if the EPM participant elected downside risk for that year.

(*ii*) Zero percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section for the performance year for all other EPM participants.

(*2*) For performance year 3, 5 percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section for the performance year.

(3) For performance year 4, 10 percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section for the performance year.

(4) For performance year 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, 2, and 3, 5 percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section for the performance year.

(2) For performance year 4, 10 percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section for the performance year.

(3) For performance year 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.* The total amount of the NPRA and subsequent reconciliation calculation for a performance year cannot exceed the following:

(*1*) For performance year 2—

(*i*) Three percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section for the performance year if the EPM participant elected downside risk for that year.

(*ii*) Zero percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section for the performance year for all other EPM participants.

(*2*) For performance year 3, 3 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, 5 percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section for the performance year.

(D) *Financial loss limits for EPM volume protection hospitals.* EPM participants may be determined to be an EPM volume protection hospital under an EPM.

(*1*) An EPM participant is determined to be an EPM volume protection hospital under a model if their total volume of EPM historical episodes is at or below the 10th percentile of hospital-specific historical EPM episodes for hospitals with one or more episodes located in the MSAs eligible for selection into that specific EPM.

(*2*) CMS establishes thresholds as specified in paragraph (c)(2)(iii)(D)(*1*) of this section based on episodes beginning in the time period specified in § 512.300(c)(1)(i).

(*3*) For an EPM participant determined to have a low volume of episodes within a model as specified in paragraph (c)(2)(iii)(D)(*1*) but not paragraph (c)(2)(iii)(C) of this section, then the financial loss limits specified under paragraph (c)(2)(iii)(C) of this section are applied.

(iv) CMS posts to the CMS Web site the threshold established in this section and a list of CCNs of EPM participants that are classified as EPM volume protection hospitals.

(v) CMS communicates to each EPM participant whether it is classified as an EPM volume protection hospital at the same time that CMS communicates quality-adjusted target prices as described in § 512.300(c)(9).

(E) *Application of limitations on losses and gains.* CMS establishes limits on losses and gains specifically with respect to and separately for each EPM.

(d) *Determination of reconciliation or repayment amount*—(1) *General.* (i) Subject to paragraphs (c)(2)(iii)(B) and (d)(1)(iii) 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 (D) and (d)(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 § 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.

(iii) The reconciliation or repayment amount may be adjusted as described in § 512.460(b).

(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 and non-claims-based payment data available at that time, to account for final claims run-out, final changes in non-claims-based payment data, and any additional episode cancellations due to overlap or other reasons as specified in § 512.240(a)(2), (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) 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 (D) to the calculations in aggregate for that performance year (the initial reconciliation from § 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 § 512.305(c)(2)(iii)(A) through (D) to determine the subsequent calculation amount.

(ii) 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.

(iii) Because EPM participants that elected downside risk in performance year 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 zero.

(iv) Because EPM participants that have not elected downside risk in performance year 2 do not have financial repayment responsibility for performance years 1 or 2, for the performance year 2 and performance year 3 reconciliation reports only, the subsequent calculation amount (for performance year 1 or performance year 2) is applied to the performance year 1 NPRA or performance year 2 NPRA to ensure that the combined amount is not less than zero.

(b) *Additional calculations to determine the reconciliation payment or repayment amount.* CMS reduces 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 not prospectively assigned to one of the following:

(1) An ACO in the Next Generation ACO model.

(2) An ACO in Track 3 of the Medicare Shared Savings Program.

(3) An ACO in the Comprehensive ESRD Care Model that includes 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 3 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, the use of quality measure results in determining the composite quality score, or the application of the composite quality score during reconciliation, the EPM participant is required to provide written notice of the calculation 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' 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' response to the EPM participant's notice of calculation error, then CMS' 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. This does not apply to the limitations on review in paragraph (e) of this section.

(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 the 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 2 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 year 5, as well as the applicable discount factor for repayment amounts in performance year 2 for AMI model participants who elect early downside risk, and performance years 3 and 4 for all 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 3.8.

(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 6.3.

(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 6.3 and less than or equal to 15.0.

(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 15.0.

(iii) Applicable discount factor for repayment amount in performance year 2 for AMI model participants who elect

early downside risk, and years 3 and 4 for all AMI model participants.

(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 6.3.

(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 6.3 and less than or equal to 15.0.

(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 15.0.

(iv) Effective discount factor for repayment amount in performance year 5 for all AMI model participants.

(A) A 3.0 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 6.3.

(B) A 2.0 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 6.3 and less than or equal to 15.0.

(C) A 1.5 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 15.0.

(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 70 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 20 percent of the CABG model composite quality score.

(iii) If applicable, 2 additional points for successful submission of the STS CABG data that supports the following 7 measures:

(A) NQF #0134—CABG: Use of Internal Mammary Artery in Patients with Isolated CABG Surgery.

(B) NQF #0236—CABG: Preoperative Beta Blocker in Patients with Isolated CABG Surgery.

(C) NQF #0129—CABG: Prolonged Intubation (defined as >24hrs post surgery).

(D) NQF #0130—CABG: Deep Sternal Wound Infection Rate.

(E) NQF #0131—CABG: Stroke.

(F) NQF #0114—CABG: Postoperative Renal Failure.

(G) NQF #0115—CABG: Surgical Re-Exploration. The submission of this measure data is weighted at 10 percent of the CABG model composite quality score.

(iv) 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) 14.00 points for ≥ 90th.

(B) 12.95 points for ≥ 80th and < 90th.

(C) 11.90 points for ≥ 70th and < 80th.

(D) 10.85 points for ≥ 60th and < 70th.

(E) 9.80 points for ≥ 50th and < 60th.

(F) 8.75 points for ≥ 40th and < 50th.

(G) 7.70 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) 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) *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 2 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 year 5, as well as applicable discount factor for repayment amounts in performance years 2 for CABG model participants who elect early downside risk, and for performance years 3 and 4 for all 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 2.2.

(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 or equal to 3.4.

(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 3.4 and less than or equal to 16.2.

(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 16.2.

(iii) Applicable discount factor for repayment amount in performance year 2 for CABG model participants who elect early downside risk, and years 3 and 4 for all EPM participants.

(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 or equal to 3.4.

(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 3.4 and less than or equal to 16.2.

(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 16.2.

(iv) Effective discount factor for repayment amount in performance year 5 for all CABG model participants.

(A) A 3.0 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 or equal to 3.4.

(B) A 2.0 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 3.4 and less than or or equal to 16.2.

(C) A 1.5 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 16.2.

(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 year 5, as well as applicable discount factor for repayment amounts in performance year 2 for SHFFT model participants who elect early downside risk and for performance years 3 and 4 for all 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 year 2 for SHFFT model participants who elect early downside risk, and years 3 and 4 for all EPM participants.

(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.

(iv) Effective discount factor for repayment amount in performance year 5 for all SHFFT model participants.

(A) A 3.0 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 2.0 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 1.5 percentage point applicable discount factor for SHFFT model participants in the excellent quality category, defined as a SHFFT model composite quality score 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 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 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 no less frequently than 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 percent of eligible AMI anchor hospitalizations between July 1, 2017 and August 31, 2017.

(B) *Year 2.* Submit electronic health record data on over 90 percent of eligible AMI anchor hospitalizations between September 1, 2017 and June 30, 2018.

(C) *Year 3.* Submit electronic health record data on over 90 percent of eligible AMI anchor hospitalizations between July 1, 2018 and June 30, 2019.

(D) *Year 4.* Submit electronic health record data on over 90 percent of eligible AMI anchor hospitalizations between July 1, 2019 and June 30, 2020.

(E) *Year 5.* Submit electronic health record data on over 90 percent 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 percent 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 percent 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 percent 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 percent 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 percent 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 percent 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 percent 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 percent 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, EPM participants must provide a complete list of HHAs, SNFs, IRFs, or LTCHs that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, IRF, or LTCH, in the geographic area requested by the patient.

(i) This list must be presented to EPM beneficiaries for whom home health care, SNF, IRF, or LTCH services are medically necessary.

(ii) EPM participants must specify on the list those post-acute care providers on the list with whom they have a sharing arrangement.

(iii) EPM participants may recommend preferred providers and suppliers, consistent with applicable statutes and regulations.

(iv) EPM participants may not limit beneficiary choice to any list of providers or suppliers in any manner other than that permitted under applicable statutes and regulations.

(v) EPM participants must take into account patient and family preferences when they are expressed.

(2) EPM participants may not charge any EPM collaborator a fee to be included on any list of preferred providers or suppliers, nor may the EPM participant accept such payments.

(b) *Required beneficiary notification*—(1) *EPM participant detailed notification.* Each EPM participant must provide written notification to any Medicare beneficiary that meets the criteria in § 512.240 of his or her inclusion in the EPM. The notification must be provided upon admission to the EPM participant if the admission that initiates the EPM episode is not scheduled with the EPM participant in advance. If the admission is scheduled in advance, then the EPM participant must provide notice as soon as the admission is scheduled. In circumstances where, due to the patient's condition, it is not 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 EPM participant accountable for the EPM episode. The EPM participant 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. The beneficiary notification must contain all of the following:

(i) A detailed explanation of the EPM 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 or the 1–800–MEDICARE helpline.

(v) A list of the providers, suppliers, and ACOs with whom the EPM participant has a sharing arrangement. This requirement may be fulfilled by the EPM participant including in the detailed notification a web address where beneficiaries may access the list.

(2) *EPM collaborator notice.* An EPM participant must require every EPM collaborator to provide written notice to applicable EPM beneficiaries of the structure of the EPM and the existence of its sharing arrangement with the EPM participant.

(i) An EPM participant must require every EPM collaborator that furnishes an item or service to an EPM beneficiary during an EPM episode to provide written notice to the beneficiary of the structure of the EPM and the existence of the individual's or entity's sharing arrangement. The notice must be provided no later than the time at which the beneficiary first receives an item or service from the EPM collaborator during an EPM episode. In circumstances where, due to the patient's condition, it is not feasible to provide notice at such times, the notice must be provided to the beneficiary or his or her representative as soon as is reasonably practicable. The EPM collaborator must be able to generate a list of all beneficiaries who received such a notice, including the date on which the notice was provided to the beneficiary, to CMS upon request.

(ii) An EPM participant must require every EPM collaborator that is a PGP, NPPGP, or TGP where a member of the PGP, member of the NPPGP, or member of the TGP furnishes an item or service to an EPM beneficiary during an EPM episode to provide written notice to the beneficiary of the structure of the EPM and the existence of the entity's sharing arrangement. The notice must be provided no later than the time at which the beneficiary first receives an item or service from any member of the PGP, member of the NPPGP, or member of the TGP, and the required notice may be provided by that member. In circumstances where, due to the patient's condition, it is not feasible to provide notice at such times, the notice must be provided to the beneficiary or his or her representative as soon as is reasonably practicable. The PGP, NPPGP, or TGP must be able to generate a list of all beneficiaries who received such a notice, including the date on which the notice was provided to the beneficiary, to CMS upon request.

(iii) An EPM participant must require every EPM collaborator that is an ACO where an ACO participant bills for or ACO provider/supplier furnishes an item or service to an EPM beneficiary during an EPM episode to provide written notice to the beneficiary of the structure of the EPM and the existence of the entity's sharing arrangement. The notice must be provided no later than the time at which the beneficiary first receives an item or service from any ACO participant or ACO provider/supplier and the required notice may be provided by that ACO participant or ACO provider/supplier. In circumstances where, due to the patient's condition, it is not feasible to provide notice at such times, the notice must be provided to the beneficiary or his or her representative as soon as is reasonably practicable. The ACO must be able to generate a list of all beneficiaries who received such a notice, including the date on which the notice was provided to the beneficiary, to CMS or its designee upon request.

(3) *Discharge planning notice.* An EPM participant 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 at the time that the beneficiary discusses a particular post-acute care option or at the time the beneficiary is discharged, whichever occurs earlier.

(i) If the EPM participant knows or should have known that the beneficiary is considering or has decided to receive a non-covered post-acute care service or other non-covered associated service or supply, the EPM participant must notify the beneficiary that the service would not be covered by Medicare.

(ii) If the EPM participant 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 EPM

participant must notify the beneficiary in accordance with paragraph (b)(3)(i) of this section that the beneficiary will be responsible for payment for the services furnished by the SNF during that stay, except those services that would be covered by Medicare Part B during a non-covered inpatient SNF stay.

(4) *Access to records and retention.* Lists of beneficiaries that receive notifications or notices must be retained and access provided 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 collaborator, collaboration agent, or downstream collaboration agent 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 EPM, 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 of this chapter.

(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 EPM, or fails to take any action that CMS determines for program integrity reasons should have been taken to further the best interests of the 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 the 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 EPM episodes that ended prior to termination.

(3) CMS may add a 25-percent penalty to a repayment amount on the EPM participant's reconciliation report if all of the following conditions are met:

(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. A selection criterion that considers whether a potential EPM collaborator has performed a reasonable minimum number of services that would qualify as EPM activities will be deemed not to violate the volume or value standard if the purpose of the criterion is to ensure the quality of care furnished to EPM beneficiaries.

(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 all of 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.

(iii) All other applicable laws and regulations.

(4) The sharing arrangement must require the EPM collaborator to have or be covered by a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the EPM that apply to its role as an EPM collaborator, including any distribution arrangements.

(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) 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 an ACO, PGP, NPPGP, or TGP 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, NPPGP, or TGP must meet the following criteria:

(A) The PGP, NPPGP, or TGP must have billed for an item or service that was rendered by one or more PGP member, NPPGP member, or TGP member respectively 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.

(B) The PGP, NPPGP, or TGP 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, NPPGP, or TGP 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 PGP members, NPPGP members, or TGP members; 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 or NPPGP, 50 percent of the Medicare-approved amounts under the PFS for items and services billed by that PGP or NPPGP and furnished to the EPM participant's EPM beneficiaries by the PGP members or NPPGP members respectively 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 the EPM participant receives from CMS must not exceed the amount of that reconciliation payment.

(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 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.

(8) An EPM participant must not make a gainsharing payment to an EPM collaborator if CMS has notified the EPM participant that such collaborator is subject to any action for noncompliance with this part or the fraud and abuse laws, or for the provision of substandard care to EPM beneficiaries 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 amount of any alignment payments must be determined in accordance with a methodology that does 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) Publicly post (and update on at least a quarterly basis) on a Web page on the EPM participant's Web site:

(A) Accurate current and historical lists of all EPM collaborators, including EPM collaborator names and addresses.

(B) Written policies for selecting individuals and entities to be EPM collaborators required by § 512.500(a)(3).

(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) An ACO, PGP, NPPGP, or TGP 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, from an NPPGP to an NPPGP member, or from a TGP to a TGP member 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 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) of this chapter, 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) of this chapter, 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 a 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 or NPPGP, 50 percent of the total Medicare-approved amounts under the PFS for items and services billed by that PGP or NPPGP for items and services furnished by PGP members or NPPGP members respectively 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 an ACO, PGP, NPPGP, or TGP, 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.

(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, NPPGP, or TGP 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 payments from an NPPGP to an NPPGP member or from a TGP to a TGP member 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 downstream collaboration agent relative to other downstream collaboration agents.

(6) The amount of any downstream distribution payments from a PGP 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 downstream collaboration agent relative to other downstream collaboration agents.

(7) Except for a downstream distribution payment from a PGP to a PGP member that complies with § 411.352(g) of this chapter, a downstream collaboration agent is eligible to receive a downstream distribution payment only if the downstream collaboration agent furnished an item or service 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 from which the ACO made the distribution payment to the PGP, NPPGP, or TGP that is an ACO participant.

(8) Except for a downstream distribution payment from a PGP to a PGP member that complies with § 411.352(g) of this chapter, the total amount of downstream distribution payments for a performance year paid to a downstream collaboration agent who is a physician or nonphysician practitioner and is either a PGP member or NPPGP member must not exceed 50 percent of the total Medicare-approved amounts under the PFS for items and services 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 distribution payment being distributed.

(9) 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, NPPGP, or TGP from the ACO.

(10) All downstream distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(11) 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.

(12) 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.

(13) The PGP, NPPGP, or TGP 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.

(14) The PGP, NPPGP, or TGP may not enter into a downstream distribution arrangement with any PGP member, NPPGP member, or TGP member who has—

(i) A sharing arrangement with an EPM participant; or

(ii) A distribution arrangement with the ACO that the PGP, NPPGP, or TGP is a participant in.

(15) The PGP, NPPGP, or TGP 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 value 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 a beneficiary who is an EPM beneficiary on the date of discharge from the anchor hospitalization on or after October 4, 2018, 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)(3), 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)(3)

(ii) That is in an EPM where the SNF 3-day rule waiver is not applicable under paragraph (a) of this section; or

(iii) Prior to October 4, 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 (CR) and intensive cardiac rehabilitation (ICR) incentive payment model under section 1115A of the Act.

(b) *Scope.* This subpart sets forth the following:

(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 were classified into one of seven groups based on their historic utilization of CR/ICR services. Within each group, EPM–CR and FFS–CR MSAs were randomly selected. The number of EPM–CRs selected within each group are distributed proportionately between the groups based on the assignment of the 98 EPM MSAs. The same number of FFS–MSAs were then 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 under the OPPS or to any supplier reporting place of service code 11 on the PFS claim 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 under the

OPPS or to any supplier reporting place of service code 11 on the PFS claim 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 under the OPPS or to any supplier reporting place of service code 11 on the PFS claim 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(d)) 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 calculation 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' 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' response to the FFS–CR participant's notice of calculation error, then CMS' 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. This does not apply to the limitations on review in paragraph (e) of this section.

(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 and security 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 no less frequently than 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 of this chapter.

(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 the 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 in-kind patient engagement incentives to beneficiaries in an AMI care period or CABG care period, 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) The item or service provided must be reasonably connected to medical care provided to a FFS–CR beneficiary during an AMI care period or CABG care period.

(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 during an AMI care period or CABG care 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 AMI care period or CABG care period.

(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 items or services must not be advertised or promoted except that a beneficiary may be made aware of the availability of items or services at the time the beneficiary could reasonably benefit from them.

(7) The cost of the item or service must not be shifted to another federal health care program, as defined at section 1128B(f) of the Act.

(b) *Technology provided to an FFS–CR 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 AMI care period or CABG care period.

(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 AMI care period or CABG care period.

(3) Items of technology exceeding $100 in retail value must—

(i) Remain the property of the FFS–CR participant; and

(ii) Be retrieved from the beneficiary at the end of the AMI care period or CABG care period. The FFS–CR 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 CR incentive payment model.* The following are the clinical goals of the CR incentive payment 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 treatment for AMI or CABG.

(4) Management of chronic diseases and conditions that may be affected by treatment for AMI or CABG.

(d) *Documentation of beneficiary engagement incentives.* (1) FFS–CR participants must maintain documentation of items and services furnished as a beneficiary engagement incentive 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 AMI care period or CABG care period as described in paragraph (b)(3) of this section.

(4) 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 EPM for reasons including but not limited to:

(a) CMS no longer has the funds to support the EPM; or

(b) CMS terminates the EPM 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, one of the following:

(a) CMS no longer has the funds to support the CR incentive payment model.

(b) CMS terminates the CR incentive payment 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: December 13, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: December 15, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–30746 Filed 12–20–16; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 82 Tuesday,

No. 1 January 3, 2017

Part III

Equal Employment Opportunity Commission

29 CFR Part 1614

Affirmative Action for Individuals With Disabilities in Federal Employment; Final Rule

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Part 1614

RIN 3046–AA94

Affirmative Action for Individuals With Disabilities in Federal Employment

AGENCY: Equal Employment Opportunity Commission.

ACTION: Final rule.

SUMMARY: The Equal Employment Opportunity Commission (EEOC or Commission) is issuing its final rule to amend the regulations that require federal agencies to engage in affirmative action for individuals with disabilities. These changes clarify the obligations that the Rehabilitation Act of 1973 imposes on federal agencies, as employers, that are over and above the obligation not to discriminate on the basis of disability. The regulation does not apply to the private sector or to state or local governments.

DATES: *Effective date:* This final rule will be applicable on March 6, 2017.

Applicability date: The applicability date for this final rule shall be January 3, 2018.

FOR FURTHER INFORMATION CONTACT: Christopher Kuczynski, Assistant Legal Counsel, (202) 663–4665, or Aaron Konopasky, Senior Attorney-Advisor, (202) 663–4127 (voice), or (202) 663–7026 (TTY), Office of Legal Counsel, U.S. Equal Employment Opportunity Commission. (These are not toll free numbers.) Requests for this document in an alternative format should be made to the Office of Communications and Legislative Affairs at (202) 663–4191 (voice) or (202) 663–4494 (TTY). (These are not toll free numbers.)

SUPPLEMENTARY INFORMATION:

Executive Summary

This final rule (Final Rule or Rule) amends 29 CFR 1614.203 to clarify the affirmative action obligations that Section 501 of the Rehabilitation Act of 1973 (Section 501) [1] imposes on federal agencies [2] as employers. The Rule codifies a variety of obligations currently placed on federal agencies by management directives and Executive Orders. It also adds two substantive affirmative action requirements. First, the Rule requires agencies to take specific steps that are reasonably designed to gradually increase the number of employees who have a disability as defined under Section 501, and the number of employees who have a ''targeted disability,'' which is defined for purposes of this Rule to mean a disability that is either designated as ''targeted disability or health condition'' on the Office of Personnel Management's (OPM's) Standard Form 256 (SF–256),[3] or that falls under one of the first 12 categories of disability listed in Part A of Question 5 of the EEOC's Demographic Information on Applicants form (Applicant Flow Form),[4] until they meet specific goals set by the EEOC. This is consistent with the approach taken by the Department of Labor''s Office of Federal Contract Compliance Programs in regulations issued to implement the obligation of federal contractors to engage in affirmative action for individuals with disabilities pursuant to Section 503 of the Rehabilitation Act of 1973, 29 U.S.C. 793 (Section 503).[5]

Second, the Rule requires agencies to provide personal assistance services (PAS) to employees who, because of targeted disabilities, require such assistance in order to be at work or participate in work-related travel. PAS are services that help individuals with disabilities perform activities of daily living, including, for example, assistance with removing and putting on clothing, eating, and using the restroom. Such services do not, however, include medical care, and need not be provided by someone who has medical training or qualifications.

The Commission recognizes that agencies may need some time to develop the capacity to meet these requirements. The Rule gives agencies one year to make any necessary changes in policy, staff, or other aspects of their operations. The applicability date of the Rule is thus January 3, 2018. Prior to that date, the Commission will provide extensive outreach and training to help agencies prepare to meet the new requirements.

The Commission's economic analysis estimates that the Rule will have a one-time initial cost to the federal government of approximately $145,580.40; an annual cost to the federal government of between $23,151,538.70 and $70,954,568.10; and an annual economic benefit to the federal government of approximately $6,617,619.00. The Rule is also expected to have a variety of non-monetizable qualitative and dignitary benefits for individuals with disabilities and individuals with targeted disabilities.

Background

Section 501 imposes two distinct obligations on federal agencies. First, it prohibits agencies from discriminating against individuals with disabilities pursuant to the same standards that are ''applied under title I of the Americans with Disabilities Act of 1990 . . . and the provisions of sections 501 through 504, and 510, of the Americans with Disabilities Act of 1990 . . . as such sections relate to employment.'' [6] Current EEOC regulations provide substantial guidance on these standards at 29 CFR part 1630. Additional guidance is provided in the many EEOC appellate decisions on complaints of employment discrimination brought under Section 501. These decisions are published on the EEOC's Web site, and significant decisions are compiled in a publicly available digest updated annually by the Commission's Office of Federal Operations.[7] This Final Rule does not change any of the substantive nondiscrimination requirements that

[1] 29 U.S.C. 791.

[2] Section 501 applies to ''each department, agency, and instrumentality (including the United States Postal Service and the Postal Regulatory Commission) in the executive branch and the Smithsonian Institution.'' 29 U.S.C. 791(b). For convenience, this Notice uses the term ''federal agency'' or ''agency'' to mean any federal entity covered by Section 501.

[3] Office of Pers. Mgmt., *Standard Form 256* (revised Aug., 2016), *https://www.opm.gov/forms/pdf_fill/sf256.pdf* [hereinafter *SF–256*]. Targeted disabilities include: developmental disabilities, for example, autism spectrum disorder; traumatic brain injuries; deafness or serious difficulty hearing, benefiting from, for example, American Sign Language; blindness or serious difficulty seeing even when wearing glasses; missing extremities (arm, leg, hand and/or foot); significant mobility impairments, benefitting from the utilization of a wheelchair, scooter, walker, leg brace(s) and/or other supports; partial or complete paralysis (any cause); epilepsy and other seizure disorders; intellectual disabilities; psychiatric disabilities; dwarfism; and significant disfigurement, for example, disfigurements caused by burns, wounds, accidents, or congenital disorders.

[4] EEOC, *Demographic Information on Applicants* (n.d.), *https://www.eeoc.gov/federal/upload/Applicant_Tracking_Form_2-19-2014-2.pdf* [hereinafter *Applicant Flow Form*]. The first 12 categories of disability listed in Part A of question 5 are: Deaf or serious difficulty hearing; blind or serious difficulty seeing even when wearing glasses; missing an arm, leg, hand, or foot; partial or complete paralysis (any cause); significant disfigurement (for example, severe disfigurements caused by burns, wounds, accidents, or congenital disorders); significant mobility impairment (for example, uses a wheelchair, scooter, walker or uses a leg brace to walk); significant psychiatric disorder (for example, bipolar disorder, schizophrenia, PTSD or major depression); intellectual disability (formerly described as mental retardation); developmental disability (for example, cerebral palsy or autism spectrum disorder); traumatic brain injury; dwarfism; and epilepsy or other seizure disorder.

[5] *See* 41 CFR pt. 60–741.45(a) (establishing a 7% utilization goal for employment of qualified individuals with disabilities for the contractor's entire workforce or each job group in the contractor's workforce).

[6] 29 U.S.C. 791(f).

[7] *See Digest of Equal Employment Opportunity Law,* Equal Emp't Opportunity Comm'n, *http://www.eeoc.gov/federal/digest/index.cfm* (last visited Dec. 21, 2016).

currently apply in the federal sector, as set forth in the EEOC's regulations and federal sector appellate decisions.

Second, the section requires each federal agency to maintain, update annually, and submit to the Commission an ''affirmative action program plan for the hiring, placement, and advancement of individuals with disabilities.'' It further directs the Commission to approve an affirmative action plan (Plan) if ''the Commission determines . . . that such plan provides sufficient assurances, procedures and commitments to provide adequate hiring, placement, and advancement opportunities for individuals with disabilities.'' [8]

The regulations currently implementing the Section 501 affirmative action requirement simply state that the federal government shall be a ''model employer of individuals with disabilities,'' and that federal agencies shall ''give full consideration to the hiring, placement, and advancement of qualified individuals with disabilities.'' [9] Over the years, however, the EEOC has issued various Management Directives to provide guidance on how an agency's Plan should result in the federal government being a model employer of individuals with disabilities. In addition, several Executive Orders have been issued, setting numerical objectives for hiring by the federal government of individuals with disabilities, to support the goals of Section 501.

In 1987, the Commission issued Management Directive 713 (MD–713), setting the standards by which the Commission would evaluate an agency's Plan with regard to the hiring of people with disabilities.[10] MD–713 required agencies with 1,000 or more employees to establish specific numerical objectives (goals) for employment of people with targeted disabilities, and to report the number of people with targeted disabilities employed by the agency.[11]

President Bill Clinton issued Executive Order 13163 on July 26, 2000 ''to support the goals articulated in section 501 of the Rehabilitation Act of 1973.'' [12] Under this Executive Order, each federal agency was required to prepare a plan to increase the opportunities for individuals with disabilities to be employed in the agency, and to submit the plan to OPM within 60 days from the date of the order. The Executive Order stated that ''based on current hiring patterns and anticipated increases from expanded outreach efforts and appropriate accommodations, the Federal Government, over the next 5 years, will be able to hire 100,000 qualified individuals with disabilities.'' [13] The same day, President Clinton issued Executive Order 13164, which requires federal agencies to establish written reasonable accommodation procedures, with a series of detailed requirements to be included in those written procedures.[14] Shortly thereafter, the EEOC issued *Policy Guidance on Executive Order 13164: Establishing Procedures to Facilitate the Provision of Reasonable Accommodation*.[15]

In 2003, the EEOC issued Management Directive 715 (MD–715),[16] which superseded MD–713 and is still in effect. Part B of MD–715 provides detailed standards by which the Commission judges an agency's affirmative action plan with regard to the hiring of people with disabilities. The Directive requires agencies ''to conduct an internal review and analysis of the effects of all current and proposed policies, practices, procedures and conditions that, directly or indirectly, relate to the employment of individuals with disabilities,'' and to ''collect and evaluate information and data necessary to make an informed assessment about the extent to which the agency is meeting its responsibility to provide employment opportunities for qualified applicants and employees with disabilities, especially those with targeted disabilities.'' [17] Pursuant to Executive Order 13164, MD–715 also requires agencies to have written procedures for providing reasonable accommodations, including the amount of time decision makers have to answer reasonable accommodation requests.[18] Finally, MD–715 reinforces the requirement from MD–713 that agencies with 1,000 or more employees are required ''to maintain a special recruitment program for individuals with targeted disabilities and to establish specific goals for the employment and advancement of such individuals,'' and to report the numbers of employees with targeted disabilities to the EEOC.[19]

In 2005, the EEOC issued additional guidance providing agencies with detailed practical advice for drafting and implementing reasonable accommodation procedures under Executive Order 13164,[20] and in 2008, the Commission issued a detailed question-and-answer document on promoting the employment of individuals with disabilities in the federal workforce.[21]

In July 2010, President Barack Obama issued Executive Order 13548, again setting a goal of having the federal government hire 100,000 persons with disabilities within five years.[22] The Executive Order required agencies to set their own hiring goals for persons with disabilities as defined under Section 501 and sub-goals for persons with targeted disabilities as defined by SF–256, and to report those goals to OPM. Again, policy and guidance documents were developed pursuant to this Executive Order.[23]

[8] 29 U.S.C. 791(b).

[9] 29 CFR 1614.203(a).

[10] EEOC, *Management Directive 713,* 1987 WL 768434 (Oct. 3, 1987).

[11] Management Directive 712 (MD–712) preceded MD–713 by four years. *See* EEOC, *Management Directive 712,* 1983 WL 410824 (March 29, 1983). MD–712 created documentation requirements for agencies' affirmative action plans, but did not include reporting requirements. MD–712 required agencies to focus on the employment of individuals with targeted disabilities; included detailed requirements for program administration and management, including staffing commitments and responsibilities; and required agencies with more than 1,000 employees to establish objectives for hiring people with targeted disabilities. For a general history of the EEOC's Management Directives, see Office of Fed. Operations, EEOC, *A Look at the EEOC's Office of Federal Operation's Federal Sector Programs: Past, Present, and Future,* Dig. of EEO L., Winter 2008, *http://www.eeoc.gov/federal/digest/xix-1.cfm.*

[12] *See* Executive Order No. 13163, 3 CFR 285 (2001), *http://www.gpo.gov/fdsys/pkg/FR-2000-07-28/pdf/00-19322.pdf.*

[13] *Id.*

[14] Executive Order No. 13164, 3 CFR 286 (2001), *http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2000_register&docid=fr28jy00-140.pdf.*

[15] EEOC, *Policy Guidance On Executive Order 13164: Establishing Procedures To Facilitate The Provision Of Reasonable Accommodation* (last modified Oct. 19, 2000), *http://www.eeoc.gov/policy/docs/qanda-accommodation_procedures.html* [hereinafter *13164 Guidance*].

[16] EEOC, *Management Directive 715* (Oct. 1, 2003), *http://www.eeoc.gov/federal/directives/md715.cfm* [hereinafter *MD–715*].

[17] *Id.* at B.III.

[18] *Id.* at B.V.

[19] *Id.* at B.V.

[20] EEOC, *Practical Advice on Drafting and Implementing Reasonable Accommodation Procedures under Executive Order 13164,* (July 2005), *http://www.eeoc.gov/policy/docs/implementing_accommodation.pdf.*

[21] EEOC, *Questions and Answers: Promoting Employment of Individuals with Disabilities in the Federal Workforce* (n.d.), *http://eeoc.gov/federal/qanda-employment-with-disabilities.cfm* [hereinafter *Promoting Employment*].

[22] Executive Order No. 13548, 3 CFR 168 (2010), *http://www.gpo.gov/fdsys/pkg/FR-2010-07-30/pdf/2010-18988.pdf.*

[23] Office of Pers. Mgmt., *Model Strategies for Recruitment and Hiring of People with Disabilities* (Nov. 8, 2010), *https://www.chcoc.gov/content/model-strategies-recruitment-and-hiring-people-disabilities-required-under-executive-order.* This guidance document was developed in consultation with the White House, the Department of Labor, and the EEOC.

The Rule

On May 15, 2014, the Commission published an Advance Notice of Proposed Rulemaking (ANPRM) requesting public comment on specific inquiries regarding ways to strengthen its Section 501 affirmative action regulations.[24] A total of 89 comments were received.[25] Taking the comments into account, the Commission published a Notice of Proposed Rulemaking (NPRM) proposing specific revisions to the Section 501 regulations on February 24, 2016.[26] The NPRM also asked for public input on 7 specific aspects of the proposal.[27]

The Commission received a total of 103 comments on the proposed rule, representing the opinions of 73 individuals, 52 disability advocacy organizations, 5 federal agencies, 2 federal government organizations, 3 state government organizations, 2 vocational rehabilitation organizations, and 1 group of administrative law students.[28] Twenty-one of the comments were non-responsive. The comments are available for review at the Federal eRulemaking Portal at *http://www.regulations.gov*.

The Commission has reviewed and given due consideration to all comments received during the public comment period, and now issues its Final Rule amending 29 CFR 1614.203 and 1614.601(f) to update, clarify, and put in one place the standards that the Commission will use to review and approve agency Plans. The comments resulted in numerous changes to the specific requirements proposed in the NPRM. Relevant comments and Commission responses are discussed in detail in the Section-by-Section Analysis below. The Commission also made several stylistic changes that do not affect the substantive requirements of the Rule.

Commenters also offered suggestions for additional requirements not proposed in the NPRM. In some cases, the suggested requirements were not added because the Commission lacked the requisite authority. For example, the Rule does not amend Workers' Compensation laws; revise regulations governing the hiring authority for individuals with intellectual disabilities, severe physical disabilities, or psychiatric disabilities, as set forth at 5 CFR 213.3102(u) (Schedule A hiring authority for persons with certain disabilities) by, for example, extending the trial employment period or changing the eligibility criteria; create or abolish other hiring authorities; prohibit agencies from making their own hiring decisions; or extend Section 501 obligations to state and local governments, federal contractors,[29] or businesses in the private sector generally.

The Commission also did not add a provision that either grants or denies a private right of action to enforce the affirmative action regulations, as suggested by some commenters. The Commission requested public input on the ability of individuals to seek enforcement of the requirement to provide PAS, codified at paragraph (d)(5) of the Rule as amended, in individual cases. Nonetheless, this is a matter of first impression, and the Commission believes that its procedural regulations governing complaints of discrimination in the federal sector, found at 29 CFR 1614, subpart A, are the most appropriate place to address this question. As such, this Rule takes no position on the availability of a private remedy for either the PAS obligation or the affirmative action obligations more generally.

Other requirements were not added because they concerned issues that were beyond the scope of this rulemaking. For example, the Rule does not provide that a change in supervisors is a reasonable accommodation, that inaccessible job application processes may give rise to claims of employment discrimination, or that individuals have a right to representation during the interactive process, because these suggestions pertain to Section 501's nondiscrimination requirements, which are the same as the nondiscrimination requirements of Title I[30] and certain provisions of Title V[31] of the Americans with Disabilities Act (ADA) applicable to private and state and local government employers.[32] The EEOC has regulations describing the ADA's nondiscrimination requirements at 29 CFR part 1630. For similar reasons, the Rule does not address methods of oversight established elsewhere in part 1614.

In some cases, suggested requirements were not added because they would affect matters governed by both EEOC and OPM regulations. For example, the Commission has not added requirements to the Rule designed to prevent violations of Section 501's qualification standard provisions.[33] Qualification standards are governed by EEOC's nondiscrimination regulations at 29 CFR part 1630.[34] These regulations clarify that the ADA/Section 501 qualification standard provisions require federal agencies to exempt an individual from a qualification standard, test, or other selection criterion if there is sufficient evidence that he or she cannot meet such standard, test, or criterion because of a disability, but can nevertheless perform the essential functions of the position with a reasonable accommodation (if one is required).[35] However, qualification standards are also governed by OPM regulations.[36] Similarly, the Final Rule does not address vacancy announcements; benefit programs such as return-to-work programs; or alternative models of employment such as apprenticeship programs, customized employment, and job splitting, which are also affected by OPM regulations. EEOC and OPM are working together to develop coordinated strategies on some of these issues and other matters over which both agencies have jurisdiction.

One commenter stated that the Rule should include an exemption for small agencies. However, except in the case of the workforce analysis and goal requirements imposed by paragraphs

[24] The Federal Sector's Obligation to Be a Model Employer of Individuals with Disabilities, 79 FR 27,824 (May 15, 2014) (to be codified at 29 CFR 1614.203, .601(f)).

[25] In addition to the 89 comments, the Commission received several duplicate comments.

[26] Affirmative Action for Individuals with Disabilities in the Federal Government, 81 FR 9123 (Feb. 24, 2016) (to be codified at 29 CFR 1614.203, .601(f)).

[27] *Id.* at 9130.

[28] Some comments represented the opinions of more than one entity, and some individuals submitted more than one comment.

[29] However, we note that federal contractors are subject to obligations to engage in affirmative action for individuals with disabilities under Section 503. *See* 29 U.S.C. 793(d); 41 CFR pt. 60–741.

[30] 42 U.S.C. 12101–12117.

[31] 42 U.S.C. 12201–12213.

[32] Congress incorporated all of the ADA's employment discrimination provisions in 1992. *See* Rehabilitation Act Amendments of 1992, Pub. L. 102–569, 106 Stat. 4344, 4424 (codified as amended at 29 U.S.C. 791(f)).

[33] The ADA prohibits ''using qualification standards, employment tests or other selection criteria that screen out or tend to screen out an individual with a disability or a class of individuals with disabilities,'' unless a defense applies. 42 U.S.C. 12112(b)(6), 12113(a). These provisions were made applicable to federal agencies when Congress incorporated all of the ADA's employment discrimination provisions into Section 501. *See* Rehabilitation Act Amendments, 106 Stat. at 4424.

[34] The Commission's ADA regulations were incorporated into EEOC's Section 501 regulations, via full notice and comment, after Congress incorporated the ADA's employment discrimination provisions into Section 501. *See* Federal Sector Equal Employment Opportunity, 67 FR 35,732, 35,735 (May 21, 2002) (codified at 29 CFR 1614.203(b)). Further guidance on the nondiscrimination requirements pertaining to qualification standards can be found in several cases issued through the federal sector complaint process.

[35] *See* 29 CFR 1630.10, .15(b), .15(c); 29 CFR pt. 1630, app. 1630.10, .15(b) and (c).

[36] See 5 CFR pt. 338 and authorities cited therein.

(d)(6) and (d)(7), discussed below, the commenter failed to identify any basis on which to conclude that the Rule's requirements were inappropriate for, or especially burdensome to, small agencies. For example, there is no reason to believe that small agencies cannot or should not adopt written reasonable accommodation procedures as required by paragraph (d)(3)(i) of the Final Rule. The Commission therefore has not added a general exemption.

Authority

The Commission issues this Final Rule under its Section 501 rulemaking authority. Congress expressly granted the Commission authority to issue substantive regulations under Section 501 by incorporating the federal sector enforcement provisions of Title VII of the Civil Rights Act of 1964 (Title VII) in Section 505 of the Rehabilitation Act of 1973 (Section 505).[37] The incorporated provisions provide that ''the Equal Employment Opportunity Commission . . . shall issue such rules, regulations, orders and instructions as it deems necessary and appropriate'' to carry out its federal sector responsibilities under Title VII (and, by incorporation, its federal sector responsibilities under Section 501).[38] The Commission also has express authority under Executive Order 12067 to ''issue such rules, regulations, policies, procedures or orders as it deems necessary to carry out its responsibilit[y]'' to ''provide leadership and coordination to the efforts of Federal departments and agencies to enforce all Federal statutes, Executive orders, regulations, and policies which require equal employment opportunity without regard to . . . handicap.'' [39]

As explained above, Section 501 requires federal agencies to engage in ''affirmative action'' for individuals with disabilities. However, the statute neither defines the term ''affirmative action'' nor provides detailed standards by which to determine whether an agency has met this requirement. Proper and effective enforcement of the statute thus ''necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress.'' [40] This gap, together with the Commission's ''generally conferred authority'' under Section 501, make it ''apparent . . . that Congress . . . expect[s] the agency to be able to speak [to the issue] with the force of law . . . .'' [41] The Commission thus has both the authority and the responsibility to issue regulations providing specific guidance to federal agencies on what they must do to satisfy their Section 501 obligation to engage in affirmative action for individuals with disabilities.

The Commission's prior regulations implementing the affirmative action requirement, requiring agencies to be ''model employers'' of individuals with disabilities and to give ''full consideration to the hiring, placement, and advancement'' of qualified individuals with disabilities, were promulgated pursuant to the above authority in 1982.[42] The Commission has also used its authority under Section 501 to provide subregulatory guidance to federal agencies on the contents of affirmative action programs for individuals with disabilities since 1987.[43] Now, having found that its prior regulatory and subregulatory guidance was not sufficiently advancing the employment of qualified individuals with disabilities, the Commission again exercises its authority under Section 501 to strengthen the regulations implementing the affirmative action requirement.[44] The Final Rule strengthens the regulations by—

- gathering longstanding requirements previously found in a variety of documents into a single regulation, making them easier to find and clarifying that they have the force and effect of law;
- imposing a new requirement to take specific steps that are reasonably designed to gradually increase the number of employees with disabilities and employees with targeted disabilities until they meet specific goals set by the EEOC; and
- imposing a new requirement to provide PAS to employees with targeted disabilities who need them during work hours and work-related travel.

Section-by-Section Analysis

1614.203(a) Definitions

Paragraph (a) of the proposed rule provided definitions of key terms. Many of the proposed definitions were simple abbreviations: (a)(1) provided that ''ADA'' refers to those portions of the ADA that are enforced by the Commission; [45] (a)(4) provided that ''Plan'' refers to an agency's affirmative action plan, as required under 29 U.S.C 791(b); (a)(5) provided that ''Schedule A hiring authority for persons with certain disabilities'' refers to the hiring authority for individuals with intellectual disabilities, severe physical disabilities, and psychiatric disabilities, as set forth at 5 CFR 213.3102(u); and (a)(6) provided that ''Section 501'' means Section 501 of the Rehabilitation Act, codified at 29 U.S.C. 791. The Commission received no objections to these definitions, which are retained in the Rule.[46]

Paragraph (a)(2) of the proposed rule provided that the term ''disability'' has the same meaning as set forth in 29 CFR part 1630. One commenter stated that the term should instead be defined using a ''standard set of disability identifiers'' developed pursuant to section 4302 of the Affordable Care Act.[47] Because the Rule implements Section 501, and not the Affordable Care Act, the Commission is required to adopt the definition of ''disability'' that applies under Section 501. The proposed definition of ''disability'' has therefore been retained.

Proposed paragraph (a)(8), providing that the term ''undue hardship'' has the same meaning as set forth in 29 CFR part 1630, has also been retained.[48] Undue hardship, which is both a limitation on an agency's obligation to make reasonable accommodations and to provide personal assistance services, considers the nature, extent, and cost of an accommodation or of providing personal assistance services in relation to an agency's overall resources and the

[37] *See* 29 U.S.C. 794a (incorporating 42 U.S.C. 2000e–5(e)(3), 2000e(f)–(k), 2000e(16)).

[38] 42 U.S.C. 2000e–16(b). This grant of authority to issue regulations implementing the federal sector provisions of Title VII is in addition to the more limited grant pursuant to EEOC's responsibility to enforce Title VII in the private sector. *See* 42 U.S.C. 2000e–12(a) (granting the Commission authority to issue, amend, or rescind ''suitable procedural regulations'').

[39] Executive Order No. 12067, 3 CFR, 1978 Comp., p. 206 (1978), *http://www.archives.gov/federal-register/codification/executive-order/12067.html*.

[40] *Morton* v. *Ruiz,* 415 U.S. 199, 231 (1974); *Chevron, U.S.A., Inc.* v. *Nat. Res. Def. Council, Inc.,* 467 U.S. 837, 843 (1984) (quoting *Morton,* 415 U.S. at 231).

[41] *United States* v. *Mead Corp.,* 533 U.S. 218, 229 (2001) (citing *Chevron,* 467 U.S. at 845); *see Mayo Found. for Med. Educ. & Research* v. *United States,* 562 U.S. 44, 55 (2011) (citing *Chevron,* 467 U.S. at 843).

[42] *See* Federal Sector Equal Employment Opportunity, 67 FR 35,732, 35,735 (May 21, 2002) (codified at 29 CFR 1614.203(b)).

[43] *See Management Directive 713, supra* note 10.

[44] *Cf. Assoc. Builders & Contractors, Inc.* v. *Shiu,* 773 F.3d 257, 261, 263–64 (D.C. Cir. 2014) (finding regulations that strengthened Section 503 affirmative action requirements on federal contractors valid under similar circumstances).

[45] These are title I of the ADA, 42 U.S.C. 12101 through 12117, and title V of the ADA, 42 U.S.C. 12201 through 12213, as it applies to employment.

[46] Proposed paragraphs (a)(4), (a)(5), and (a)(6) have been redesignated (a)(6), (a)(7), and (a)(8) respectively in the Final Rule.

[47] 42 U.S.C. 300kk; see generally U.S. Dep't of Health & Human Servs., *Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status* (n.d.), *https://aspe.hhs.gov/sites/default/files/pdf/76331/index.pdf*.

[48] The paragraph has been redesignated (a)(10) in the Final Rule.

impact of the accommodation or of the requirement to provide personal assistance services on the operation of the agency's business. The term is one that agencies have been familiar with since they have been required to comply with Section 501 of the Rehabilitation Act, and agency's written reasonable accommodation procedures typically explain the term's meaning and application.

Paragraph (a)(3) of the proposed rule provided that the term ''hiring authority that takes disability into account'' means any hiring authority that permits an agency to consider disability status in the selection of individuals for employment. To improve clarity, the definition has been revised to state that the term means any hiring authority that permits an agency to consider disability status ''during the hiring process.''

Paragraph (a)(7) of the proposed rule defined the term ''targeted/severe disability'' to mean disabilities specifically designated as ''targeted/severe'' on the SF–256.[49] As explained in the NPRM, disabilities that fall under this term are a subset of those that meet the definition of ''disability'' as defined under (a)(2). This subset is the focus of additional attention under several paragraphs in the Rule, discussed below. Some commenters stated that the Rule should use the term ''significant disability'' rather than ''targeted/severe disability,'' because some individuals find the term ''severe'' to be stigmatizing. One of these commenters stated further that the Rule should adopt the definition of ''significant disability'' given in Section 7 of the Rehabilitation Act of 1973.[50]

The Commission declines to use the term ''significant disability'' in place of ''targeted/severe disability.'' The term ''significant disability,'' as used by the federal government, refers to a group of disabilities that qualify an individual to receive certain government-funded services and benefits.[51] By contrast, the term ''targeted/severe disability,'' as used in the proposed rule, was intended to refer to a group of disabilities that ''have historically been used to exclude qualified individuals from employment,''[52] and therefore that, ''as a matter of policy, [have been] identified for special emphasis in affirmative action programs.''[53] We believe that use of a single term—''significant disability''—to refer both to disabilities that have historically been used to exclude qualified individuals from employment, and, at the same time, to a different group of disabilities that qualify an individual to receive certain government-funded services and benefits, is likely to cause confusion.

The Final Rule does, however, use the term ''targeted disability'' in place of ''targeted/severe disability.''[54] OPM's revised SF–256 uses the term ''targeted disabilities or serious health conditions'' rather than ''targeted/severe disabilities.'' The revision to the Rule therefore both conforms the Rule to OPM's new terminology and addresses the commenters' concern that some individuals find the term ''severe'' to be stigmatizing. In addition, the definition of the term has been widened to include disabilities that fall under one of the first 12 categories of disability listed in Part A of question 5 on the EEOC's Applicant Flow Form, which include several disabilities that have historically been used to exclude qualified individuals from employment, but that are not designated as ''targeted'' on the SF–256 (for example cerebral palsy).[55] The EEOC recognizes that it will be helpful for agencies to have an updated SF–256 that conforms to the Applicant Flow Form. The EEOC continues to work with OPM in such an effort. In the meantime, the EEOC will consider both sets of disabilities to be ''targeted'' for purposes of the Rule.

Definitions of the terms ''personal assistance services'' and ''personal assistance service provider'' have been added to the paragraph at (a)(5) and (a)(6), because several commenters expressed confusion over the meaning of the term in the proposed rule. We discuss the definition in connection with paragraph (d)(5) below.

1614.203(b) Nondiscrimination

Paragraph 1614.203(b) of the existing regulations states that Section 501 prohibits disability discrimination in employment, and that the standards used to determine whether an agency has violated the prohibition against discrimination are those applied under the ADA. The NPRM proposed minor revisions to improve clarity. The Commission received no objections to the proposed revisions, which have been retained in the Final Rule.

1614.203(c) Model Employer

This paragraph redesignates and revises paragraph 1614.203(a) of the current regulations, which provides that the federal government shall be a ''model employer'' of individuals with disabilities, and that agencies shall ''give full consideration to the hiring, placement, and advancement of individuals with disabilities.''

The NPRM did not propose any textual changes to the paragraph. However, some commenters objected to the use of the term ''placement,'' both here and throughout the regulation, because some individuals with disabilities find it offensive. Accordingly, alternate language has been incorporated here and throughout the Rule where possible. However, because Section 501 itself uses the term ''placement,''[56] the Rule retains the term where it directly references the language of the statute.

Other commenters stated that the paragraph should be revised to reflect the affirmative action requirements imposed through this rulemaking. The Commission agrees. Accordingly, the paragraph has been revised to state that ''[a]gencies shall [ ] take affirmative action to promote the recruitment, hiring, and advancement of qualified individuals with disabilities, with the goal of eliminating under-representation of individuals with disabilities in the federal workforce,'' and that agencies shall give ''full consideration to the . . . retention of qualified individuals with disabilities in the federal workforce.''

1614.203(d) Affirmative Action Plan

As provided by Section 501, this paragraph states that each agency shall adopt and implement a Plan that

[49] At the time the NPRM was published, the SF–256 used the term ''targeted/severe disability'' rather than ''targeted disability.''

[50] 29 U.S.C. 705(21) (''Except as provided in subparagraph (B) or (C), the term 'individual with a significant disability' means an individual with a disability—(i) who has a severe physical or mental impairment which seriously limits one or more functional capacities (such as mobility, communication, self-care, self-direction, interpersonal skills, work tolerance, or work skills) in terms of an employment outcome; (ii) whose vocational rehabilitation can be expected to require multiple vocational rehabilitation services over an extended period of time; and (iii) who has one or more physical or mental disabilities resulting from amputation, arthritis, autism, blindness, burn injury, cancer, cerebral palsy, cystic fibrosis, deafness, head injury, heart disease, hemiplegia, hemophilia, respiratory or pulmonary dysfunction, intellectual disability, mental illness, multiple sclerosis, muscular dystrophy, musculo-skeletal disorders, neurological disorders (including stroke and epilepsy), paraplegia, quadriplegia, and other spinal cord conditions, sickle cell anemia, specific learning disability, end-stage renal disease, or another disability or combination of disabilities determined on the basis of an assessment for determining eligibility and vocational rehabilitation needs described in subparagraphs (A) and (B) of paragraph (2) to cause comparable substantial functional limitation.'').

[51] *See, e.g.,* 29 U.S.C. 796b (''Services may be provided under [29 U.S.C. ch. 16, subch. VII, pt. A] to any individual with a significant disability, as defined in section 705(21)(B) of [title 29].'').

[52] *Promoting Employment, supra* note 21, at I.

[53] *MD–715, supra* note 16, at app. A.

[54] The definition of ''targeted disability'' appears in paragraph (a)(9) of the Final Rule.

[55] See *Applicant Flow Form, supra* note 4, at 2.

[56] *See* 29 U.S.C. 791(b).

provides sufficient assurances, procedures, and commitments to provide adequate recruitment, hiring, and advancement opportunities for individuals with disabilities at all levels of federal employment. It also sets forth the requirements that the Plan must meet in order to be approved by the Commission. The specific requirements are discussed in separate sections below.

Several commenters stated that the term ''adequate,'' as used in the statutory language quoted above, should be defined to mean ''adequate to ensure meeting the goals required under paragraph (d)(7) of this section.'' The Commission disagrees. If, on the one hand, the proposed definition was intended simply to clarify the meaning of the word, the Commission believes that the clarification is unnecessary. Section 501 requires the Commission to approve agency Plans if they ''provide[ ] sufficient assurances, procedures, and commitments to provide adequate recruitment, hiring, and advancement opportunities for individuals with disabilities at all levels of federal employment.'' By setting forth the criteria that the Commission will use to determine whether to approve a Plan in paragraph (d), the Rule effectively defines the meaning of that phrase as a whole. If, on the other hand, the definition was suggested in order to create additional criteria by which the Commission will evaluate agency Plans, the Commission disagrees with the suggestion because it would imply, contrary to paragraph (f) and to the Commission's intention, that paragraph (d) does not set forth an exhaustive list of Plan criteria.

1614.203(d)(1)(i) Disability Hiring and Advancement Program: Recruitment

Paragraph (d)(1)(i) of the proposed rule required agencies to use programs and resources that identify applicants who are eligible to be appointed under hiring authorities that take disabilities into account, examples of which include specialized training programs and databases of potential job applicants with disabilities. The paragraph also required agencies to establish and maintain contacts with organizations that specialize in the employment of individuals with disabilities, such as American Job Centers, State Vocational Rehabilitation Agencies, the Veterans' Vocational Rehabilitation and Employment Program, Centers for Independent Living, and Employment Network Service providers. In addition, the NPRM asked whether the Rule should require agencies to maintain a file or database of individuals who have been determined to be eligible for appointment under a hiring authority that takes disability into account, but who were not hired, and, if so, whether inclusion in the database should be voluntary.

A significant number of commenters stated that recruitment of individuals with targeted disabilities should receive additional emphasis in the paragraph. Consistent with the federal government's policy of giving targeted disabilities ''special emphasis in affirmative action programs,'' [57] paragraph (d)(1)(i) has been amended to require agencies to use programs and resources that identify job applicants with disabilities, ''including individuals with targeted disabilities,'' who are eligible for appointment under a special hiring authority, and to establish and maintain contacts with organizations that specialize in providing assistance to individuals with disabilities, ''including individuals with targeted disabilities,'' in securing and maintaining employment.

Some commenters stated that agencies should be required to use all of the programs and resources, and to maintain contact with all of the disability organizations, given as examples in the paragraph. Some stated that use of additional programs and resources, such as internship programs and community message boards, and contact with additional disability organizations, such as state Protection and Advocacy organizations, Ticket to Work networks, supported and customized employment providers, college or university career centers that cater to individuals with disabilities, and local education authorities, should also be mandatory.

The Commission is not persuaded that every agency will benefit from the same set of programs, resources, and disability organizations in their efforts to recruit individuals with disabilities and individuals with targeted disabilities. The particular programs, resources, and disability organizations referenced in the paragraph have therefore been kept as examples. Because there is no need to make the list of examples exhaustive, most of the suggested additions were not included in the final paragraph, though they certainly may be appropriate resources to assist agencies in meeting their affirmative action obligations. However, because it was a particularly common suggestion, internship programs were added as examples of programs or resources that can be used to identify individuals who may be appointed under hiring authorities that take disability into account.

Some commenters stated that, instead of requiring agencies to ''maintain contacts'' with organizations that specialize in the employment of individuals with disabilities, the Commission should require agencies to establish and maintain ''linkage agreements or other formal arrangements'' with such organizations. The paragraph has been revised to state that the required contacts may include formal agreements, but does not make formal agreements mandatory. The EEOC lacks the information necessary to determine, for example, how many formal agreements each agency should have, what each party to the agreement should be obligated to do, and what should happen if a party fails to meet an obligation in the agreement. Further, the Commission suspects that different approaches may be appropriate for different agencies.

Many commenters responding to the proposal to require a file or database of individuals who have been determined to be eligible for appointment under a hiring authority that takes disability into account but who have not been hired generally favored some version of the proposal, but there was disagreement regarding the location of the database. For example, several commenters stated that the file/database needs to be government-wide in order to be effective. Other commenters stated that the databases should be required, but they would be more effective if each agency maintained its own database of individuals with disabilities who had already evidenced interest in the agency.

Upon further consideration, however, the Commission has concluded that agencies should be encouraged to maintain such databases, rather than making such databases mandatory for every agency. Databases containing the résumés of applicants eligible for appointment under the Schedule A hiring authority for individuals with certain disabilities, and similar resources, will greatly assist agencies in locating and hiring qualified job applicants with disabilities and targeted disabilities. Such databases will be of significant help as agencies seek to meet their targets with regarding to hiring such individuals.

The Commission therefore retains ''databases of potential job applicants with disabilities'' as an example of programs and resources that identify such applicants in paragraph (d)(1)(i)(A) of the Rule, and encourages agencies to develop new databases or augment existing résumé databases to fulfill these

[57] *MD–715, supra* note 16, at app. A.

functions. Should an agency decide to maintain such a database, the Commission advises the agency to include individuals in the database on a voluntary basis only, and to retain in the database only such information as is necessary to determine an applicant's identity, qualifications, and eligibility for appointment under a hiring authority that takes disability into account. Medical information about an individual's specific disability should not be included. The Commission is willing to provide technical assistance to any agency with regard to maintaining a database consistent with all applicable privacy [58] and record retention [59] laws and regulations.

1614.203(d)(1)(ii) Disability Hiring and Advancement Program: Application Process

Paragraph (d)(1)(ii) of the proposed rule required agencies to ensure that they have sufficient staff to handle any disability-related issues that arise during the application and selection processes. It also required the agency to provide such staff with training, support, and other resources sufficient to enable them to (A) answer any disability-related questions from members of the public regarding the application and hiring processes; (B) provide job applicants with necessary reasonable accommodations; (C) accept applications for appointment under hiring authorities that take disability into account; (D) determine whether individuals who have applied for appointment under a hiring authority that takes disability into account are eligible for such appointment; (E) forward the application of an individual who has applied for appointment to a particular position under a hiring authority that takes disability into account and who is eligible to the relevant hiring officials, and explain to those officials how and when the individual may be appointed; and (F) oversee any other disability-related hiring programs. Proposed paragraphs (d)(1)(ii)(D) and (d)(1)(ii)(E) were combined into a single paragraph (d)(1)(ii)(E) in the Final Rule, in order to clarify that agencies are not required to determine whether an individual is eligible for appointment under a hiring authority that takes disability into account unless such individual is being considered for a particular position.

Some commenters stated that the paragraph should be more specific as to who should perform the duties described above. Commenters suggested, for example, that only employees who focus on disability-related issues full time, employees who themselves have disabilities, or employees who are not under the supervision of the office of human resources should perform the duties. One commenter stated that the paragraph should specify the number of staff members who are assigned to these duties.

The Commission believes that agencies should be afforded some flexibility in how the duties are carried out and declines to adopt a one-size-fits-all approach. Some small agencies, for example, may not need an employee who works on disability-related issues on a full-time basis, and the proper number of employees required to handle duties related to the hiring of individuals with disabilities will vary depending on an agency's size and structure. Additionally, we see no reason to conclude categorically that employees who handle issues related to applications from individuals with disabilities should not be under the supervision of an agency's human resources office, though we caution that a human resources specialist assigned to handle applications for a particular job may not necessarily have the necessary expertise to handle requests for reasonable accommodation, questions about hiring authorities that take disability into account, and other questions from job applicants with disabilities. Finally, the Commission does not believe that employees with disabilities are necessarily the only individuals capable of effectively handling duties related to the hiring of other individuals with disabilities, and embodying such an assumption in the Final Rule may actually work to encourage the segregation of individuals with disabilities into specific job categories.

Some commenters stated that the paragraph should require agencies to provide relevant staff members with accurate information on reasonable accommodation, the Schedule A hiring authority for persons with certain disabilities, the affirmative action requirements imposed under this rulemaking, and other disability-related issues. Because the paragraph already requires agencies to provide ''sufficient training, support, and other resources to carry out'' the tasks listed above, the Commission concludes that no additional language is necessary.

1614.203(d)(1)(iii) Disability Hiring and Advancement Program: Advancement

This paragraph of the proposed rule required agencies to take specific steps to ensure that current employees with disabilities have sufficient opportunities for advancement, such as engaging in efforts to ensure that employees with disabilities are informed of and have opportunities to enroll in relevant training, developing and maintaining mentoring programs, and administering exit interviews that address the recruitment, hiring, inclusion, and advancement of individuals with disabilities.

Some commenters stated that all of the specific steps referenced in the paragraph should be mandatory. Others stated that they should be made more specific, by, for example, requiring agencies to hire dedicated ''disability advancement staff''; approach all employees with disabilities when training opportunities arise; give all notices of training opportunities ''promptly'' to individuals with disabilities in accessible formats; hire full-time assistive technology experts, and make use of the programs, resources, and disability organizations referenced in paragraph (d)(1)(i) to facilitate advancement.[60] Again, the Commission is not persuaded that every agency will benefit from the same strategies for improving advancement opportunities for individuals with disabilities and individuals with targeted disabilities. The Rule has therefore retained the original examples.

Some commenters stated that the paragraph should contain prohibitions against disability discrimination. For example, commenters stated that the paragraph should require agencies to make reasonable accommodations available to participants in mentoring

[58] Résumés, like all records that are personally identifiable and contained in a system of records, are subject to the confidentiality requirements of the Privacy Act. *See* 5 U.S.C. 552a. Privacy Act requirements regarding résumés that are submitted by applicants to federal agencies, including those submitted by applicants for appointment under the Schedule A hiring authority for individuals with certain disabilities, are specifically addressed by the Office of Personnel Management's Government-Wide Systems of Records Notice, OPM/GOVT–5, Recruiting, Examining, and Placement Records. *See* Privacy Act of 1974, System of Records, 71 FR 35,351 (June 19, 2006); Privacy Act of 1974; Routine Use Implementation; System of Records, 80 FR 74,815 (Nov. 30, 2015).

[59] Federal record retention requirements are overseen by the National Archives and Records Administration (NARA). *See, e.g., Records Management,* Nat'l Archives & Recs. Admin., *https://www.archives.gov/records-mgmt/* (last visited Dec. 21, 2016).

[60] As an alternative, the same commenter suggested that the paragraph should be revised to require ''extra,'' ''concentrated,'' or ''specialized'' efforts to ensure that employees with disabilities are aware of training opportunities. Because the Commission does not know how the additional language would change the obligations imposed by the paragraph, the alternative suggestion was not considered.

programs, that individuals with disabilities must be afforded equal opportunities to gain work experience, and that individuals appointed under the Schedule A hiring authority for persons with certain disabilities should be afforded supervision similar to that given other employees.[61] As explained above, the Commission believes that it is inappropriate to provide new guidance on nondiscrimination obligations applicable to federal agencies, as well as to private and state and local government employers, in a regulation that applies only to the affirmative action obligations of federal agencies.

Some commenters stated that the paragraph should require review of all adverse actions taken against individuals with disabilities by, for example, the head of the agency or a neutral, non-agency party. Federal employees already possess several means of subjecting adverse actions to further review. Depending on the issues involved, employees may make use of existing internal mechanisms including alternative dispute resolution, if available; file complaints of employment discrimination pursuant to 29 CFR 1614.106; file appeals with the Merit Systems Protection Board; and file appeals with the U.S. Office of Special Counsel.[62] The Commission has been given no reason to believe that an additional layer of review would improve either the accuracy or the speed with which reviews are carried out. Indeed, because an additional layer of review would not toll existing time frames for filing complaints of discrimination, it is quite likely that such a requirement would significantly burden agencies while resulting in little if any impact on the number of discrimination complaints filed, or worse, cause confusion for employees with disabilities that could result in late filing of complaints. The commenters' suggestion therefore was not incorporated into the Rule.

1614.203(d)(2) Disability Anti-Harassment Policy

Paragraph (d)(2) of the proposed rule required agencies to state expressly in their anti-harassment policies that disability-based harassment is prohibited. The Commission received no comments objecting to the requirement. It therefore has been retained in the Final Rule.

Some commenters stated that the paragraph should also require agencies to provide training on the disability-based harassment policy. The Commission is not persuaded that the addition is necessary. Agencies routinely provide training on their anti-harassment policies. If, as required under this paragraph, an agency's policy expressly states that disability-based harassment is prohibited, the training should naturally address the topic. The Commission notes that Commissioners Chai R. Feldblum and Victoria A. Lipnic recently published a report on how agencies and other employers can improve efforts to prevent harassment that discusses disability-based harassment throughout, and that includes a section specifically on the prevalence of disability-based harassment.[63]

1614.203(d)(3)(i) Reasonable Accommodation: Procedures

Proposed paragraph (d)(3)(i) required agencies to make reasonable accommodation procedures available to job applicants and employees in both written and accessible formats. It also required the procedures to address a minimum of 20 specific topics, including expedited processing, interim accommodations, reasonable accommodation requests, confidentiality, processing deadlines, the process for filing complaints pursuant to 29 CFR 1614.106, and notice of denied requests.

Commenters did not object to the proposal to make reasonable accommodation procedures available in written and accessible formats. One commenter stated that the paragraph should require the procedures to be available online. Recognizing the central importance of online access in the modern workplace, the paragraph now provides that ''[t]he Plan shall require the agency to . . . post on its public Web site, and make available to all job applicants and employees in written and accessible formats, reasonable accommodation procedures. . . .''

Some commenters suggested adding a statement that ''accessible formats'' include American Sign Language (ASL). The requirement to make reasonable accommodation procedures available in written ''and accessible formats'' was drafted so as not to require the accessible format to be ''written,'' and to provide job applicants with maximum flexibility to request a type of accessible format that meets his or her particular needs. The language is sufficiently general that it should be interpreted to encompass ASL, as well as documents in Braille or large print, documents in an electronic format that can be read by screen reading software, an individual who can read the document aloud, and other types of accessible formats.

Most of the public comments addressing this paragraph concerned 4 of the 20 required topics—

• *(d)(3)(i)(B) (redesignated (d)(3)(i)(B) and (d)(3)(i)(C)[64]): Reassignment.* The proposed paragraph required the procedures to explain that the agency will consider reassignment to a position for which the employee is qualified, and not just permission to compete for such a position, as a reasonable accommodation if no other reasonable accommodation would permit the employee to perform the essential functions of his or her current position. It also required the procedures to explain how and where officials should conduct searches for vacant positions when considering reassignment as a reasonable accommodation. The Commission has revised the paragraph to clarify that agencies need only consider reassignment ''to a vacant position'' as a reasonable accommodation, consistent with 29 CFR 1630.2(o)(2)(ii).

Several commenters stated that the paragraph should clarify that the ''reassignment rule applies to nondiscrimination obligations,'' *i.e.,* that failure to provide reassignment as a reasonable accommodation may give rise to liability for employment discrimination. Because each of the 20 required topics pertain to the obligation to provide reasonable accommodations, which is a nondiscrimination obligation,[65] they all in some sense express principles that ''apply to nondiscrimination obligations.'' The Commission therefore disagrees that this paragraph in particular should include

[61] One commenter stated that the Rule should prohibit individuals appointed under the Schedule A hiring authority for people with certain disabilities from filing discrimination complaints. Because this requirement does not implement principles of affirmative action, it has not been included.

[62] *See generally Employee Rights & Appeals: Alternative Dispute Resolution,* Office of Pers. Mgmt., *https://www.opm.gov/policy-data-oversight/employee-relations/employee-rights-appeals/#url=Alternative-Dispute-Resolution* (last visited Dec. 21, 2016) (discussing alternative dispute resolution); *Employee Rights & Appeals: Appeals,* Office of Pers. Mgmt., *https://www.opm.gov/policy-data-oversight/employee-relations/employee-rights-appeals/#url=Appeals* (last visited Dec. 21, 2016) (discussing the right to file a complaint of discrimination under the 1614 process and to file appeals with the Merit Systems Protection Board and U.S. Office of Special Counsel).

[63] *See* Chai R. Feldblum & Victoria A. Lipnic, EEOC, *Report of the Co-Chairs of the Select Task Force on the Study of Harassment in the Workplace* 12–13 (2016), *https://www.eeoc.gov/eeoc/task_force/harassment/upload/report.pdf.*

[64] For reasons of clarity, the proposed paragraph was split into 2 paragraphs in the Final Rule.

[65] 42 U.S.C. 12112(b)(5)(A); 29 CFR 1630.9; 29 CFR pt. 1630, app. 1630.9, .9(e).

the suggested statement. However, in response to the commenters' concerns, the proposed paragraph has been revised to state that reassignment ''is'' a reasonable accommodation, and that such reassignment ''must'' be considered if the agency determines that no other reasonable accommodation would permit the employee to perform the essential functions of his or her current position.

One commenter stated that the paragraph should clarify that only employees, and not job applicants, may require reassignment as a reasonable accommodation. Because the paragraph requires an agency's procedures to state that it will consider reassignment when the ''employee'' can no longer perform the essential functions of his or her ''current position,'' no further clarification is required.

One commenter stated that the paragraph should require agencies to develop and maintain a database of vacant positions within the agency, and to require that agency officials use the database when considering whether to provide reassignment as a reasonable accommodation. The Commission believes that the addition is unnecessary, as long as an agency ''[n]otif[ies] supervisors and other relevant agency employees how and where they are to conduct searches for available vacancies when considering reassignment as a reasonable accommodation'' as required under revised paragraph (d)(3)(i)(C).

• *(d)(3)(i)(I) (redesignated (d)(3)(i)(J)): Requests for supplemental medical documentation.* The proposed paragraph required the procedures to explain the agency's right to request relevant supplemental medical information if the information submitted by the requester is insufficient. The Commission has revised the paragraph to clarify that ''insufficient'' means ''insufficient for the purposes specified in paragraph (d)(3)(i)(I) of this section'' (referring to the agency's right to require documentation sufficient to ''explain the nature of the individual's disability, his or her need for reasonable accommodation, and how the requested accommodation, if any, will assist the individual to apply for a job, perform the essential functions of the job, or enjoy the benefits and privileges of the workplace'').

One commenter stated that the paragraph should cap the number of times an agency may request supplemental documentation. As explained in the NPRM, current anti-discrimination law already prohibits agencies from requesting more documentation than is necessary to establish the existence of a disability and the need for accommodation.[66] To the extent that the proposed cap would further restrict agencies, it would have the effect of denying them documentation that may be necessary to carry out the interactive process, potentially resulting in denials of needed accommodations. Therefore, the Commission has declined to impose a cap on the number of agency requests for documentation to support an accommodation request.

• *(d)(3)(i)(L) (redesignated (d)(3)(i)(M) and (d)(3)(i)(O)[67]): Deadlines.* The proposed paragraph required the procedures to designate a maximum amount of time, absent extenuating circumstances, that the agency has to either provide a requested accommodation or deny the request. It also required the procedures to explain that the time limit begins to run when the accommodation is first requested, and that, where a particular reasonable accommodation can be provided in less than the maximum amount of time allowed, failure to respond promptly may result in a violation of the Rehabilitation Act.

One commenter stated that the Commission should eliminate the time limit requirement. The suggestion runs counter to longstanding federal policy. Executive Order 13164 states that each agency's procedures must ''[d]esignate a time period during which reasonable accommodation requests will be granted or denied, absent extenuating circumstances.''[68] As instructed by Executive Order 13164, the Commission provided further clarification of the requirement in guidance, which is still in effect.[69]

Some commenters stated that the paragraph should require the procedures to provide additional information on the types of extenuating circumstances that would justify a delay in providing a reasonable accommodation. Commenters stated, for example, that the procedures should list all possible extenuating circumstances, should provide that an inability to secure funding is not an extenuating circumstance, should state that a delay is justified ''[a]s long as both parties are actively engaged in the interactive process,'' or should state that a requester's failure to engage in the interactive process, for example by failing to provide necessary documentation, constitutes an extenuating circumstance.

Extenuating circumstances are, by definition, factors that cannot ''reasonably have been anticipated or avoided in advance of the request for accommodation.''[70] Thus, it is not possible to specify all such circumstances in a regulation. In addition, some agencies may define certain acts or omissions during the interactive process as ''extenuating circumstances,'' while others may not. For example, the inability to provide equipment needed as a reasonable accommodation because a vendor has suddenly and unexpectedly gone out of business might be an extenuating circumstance for a small agency making a purchase of the equipment for the first time, but not for a large agency that has extensive experience with providing reasonable accommodations.

The Commission therefore believes that it is not possible to create a definitive list of what constitute extenuating circumstances. However, a new paragraph has been added at (d)(3)(i)(N) clarifying the Commission's longstanding position that ''the agency will not be expected to adhere to its usual timelines if an individual's health professional fails to provide needed documentation in a timely manner.''[71]

• *(d)(3)(i)(N) (redesignated (d)(3)(i)(P)): Interim accommodations.* The proposed paragraph required the agency's procedures to explain that, where a reasonable accommodation cannot be provided immediately, the agency must provide an interim accommodation whenever possible.

One commenter stated that the paragraph should not require an agency's procedures to state an interim accommodation ''must'' be provided ''whenever possible,'' but rather that the agency will ''seek to'' provide interim accommodations during a delay. Another commenter stated that the procedures should not require the agency to provide interim accommodations if the existence of a disability, the need for accommodation, and the effectiveness of the proposed accommodation have not been established.

The Commission disagrees that agencies should only be required to ''seek to'' provide an interim accommodation when there is a delay in providing a preferred accommodation. Interim accommodations may be necessary in order to avoid, for example, a worsening of symptoms, exacerbation

[66] *See, e.g., 13164 Guidance, supra* note 15.

[67] For reasons of clarity, the paragraph on deadlines in the proposed rule was split into 2 paragraphs in the Final Rule.

[68] Executive Order No. 13164, *supra* note 14.

[69] *See 13164 Guidance, supra* note 15.

[70] *Id.*

[71] *See id.*

of a medical condition, or pain. They therefore may play a crucial role in preserving the requesting individual's ability to work. The Commission also disagrees that interim accommodations should only be required once the existence of a disability, the need for accommodation, and the effectiveness of a proposed accommodation have been established. The term ''establish'' connotes a formal finding. There may be reasons why an agency does not make a formal finding even though it is reasonably likely that the requesting individual is entitled to a reasonable accommodation, such as where a disability is obvious even though the appropriate accommodation has not been established.

For the foregoing reasons, the paragraph has been amended to require an interim accommodation that allows the requesting individual to perform some or all of the essential functions of his or her job when ''all the facts and circumstances known to the agency make it reasonably likely that [the] individual will be entitled to a reasonable accommodation, . . . [and] it is possible to do so without imposing undue hardship on the agency.''

Other commenters stated that agencies should be required to address topics in addition to the 20 proposed in the NPRM in their reasonable accommodation procedures. For example, commenters stated that the procedures should be required to explain that employees and applicants do not need to use ''magic words'' in order to begin the interactive process; that reasonable accommodations may be available to help applicants meet qualification standards; that the interactive process is ''ongoing''; and that employees and job applicants have an obligation to participate in the interactive process. None of the requirements were added because they are implicit in existing EEOC requirements. For example, the requirement to explain that employees and applicants do not need to use ''magic words'' in order to begin the interactive process is implicit in the existing requirement to ''[p]rovide guidance to supervisors on how to recognize requests for reasonable accommodation'' at (b)(i)(3)(G). Moreover, the list of 20 topics is only intended to set a minimum; agencies are free to address additional topics in the procedures if they wish to do so.

The Commission made an unrequested change to proposed paragraph (d)(3)(i)(G) (redesignated (d)(3)(i)(H) in the Final Rule), clarifying that decision makers should communicate with individuals who have requested a reasonable accommodation early in the interactive process ''and throughout the process.'' The revision does not represent a change in Commission policy.

1614.203(d)(3)(ii) Reasonable Accommodation: Cost of Accommodations

Paragraph (d)(3)(ii) of the proposed rule required agencies to inform all employees who are authorized to grant or deny requests for reasonable accommodation that, pursuant to the regulations implementing the undue hardship defense at 29 CFR part 1630, all available resources are considered when determining whether a denial of reasonable accommodation based on cost is appropriate. As a clarification, this portion of the paragraph has been revised to state that all available resources are considered, ''excluding those designated by statute for a specific purpose that does not include reasonable accommodation.'' The paragraph also required the agency to ensure that relevant decision-makers are informed about various external resources that may be used in providing reasonable accommodations, including, for example, a centralized fund specifically created by the agency for providing reasonable accommodations, the Department of Defense Computer and Electronic Accommodations Program (CAP),[72] and agency funds that, although not designated specifically for providing reasonable accommodations, may be used for that purpose. The purpose of the paragraph was to ensure that sufficient funds are available for more costly accommodations when necessary.

Many commenters stated that the paragraph should require a centralized fund. In the NPRM, the Commission stated that it did not require a centralized fund due to practical concerns regarding the precise manner in which an agency's appropriated funds are held, requested, and disbursed, and due to the fact that centralized funding does not ensure that sufficient funds are provided for costly accommodations where, for example, the fund is too small or relevant decision-makers do not know how to access the fund. The commenters argued that these concerns could be overcome by, for example, requiring agencies to base the size of the fund on costs in previous years and instructing relevant personnel how to access the fund.

The EEOC has supported the use of a centralized fund to pay for reasonable accommodation.[73] We think that a centralized fund is one of the best and easiest ways to ensure that requests for reasonable accommodation are not denied for reasons of cost, and that individuals with disabilities are not excluded from employment due to the anticipated cost of a reasonable accommodation, if the resources available to the agency as a whole would enable it to provide one without undue hardship.

However, the Commission is not persuaded that a centralized fund is the only way to achieve this objective. For example, centralized contracting vehicles may be an effective alternative. The paragraph has thus been amended to require agencies to take specific steps—which may include adoption of a centralized fund—to achieve these goals. The paragraph further states that such steps must be reasonably designed to, at a minimum—

- ensure that anyone who is authorized to grant or deny requests for reasonable accommodation or to make hiring decisions is aware that, pursuant to the regulations implementing the undue hardship defense at 29 CFR part 1630, all resources available to the agency as a whole, excluding those designated by statute for a specific purpose that does not include reasonable accommodation, are considered when determining whether a denial of reasonable accommodation based on cost is lawful; and
- ensure that anyone authorized to grant or deny requests for reasonable accommodation or to make hiring decisions is aware of, and knows how to arrange for the use of, agency resources available to provide the accommodation, including any centralized fund the agency may have for that purpose.

The revised paragraph requires agencies to adopt systems that perform the same valuable functions of centralized funds, while providing them with flexibility to work within existing budgetary schemes.

1614.203(d)(3)(iii) Reasonable Accommodation: Notification of Basis for Denial

Paragraph (d)(3)(iii) of the proposed rule required agencies to provide a job applicant or employee who is denied a reasonable accommodations with a written notice that explains the reason

[72] *See generally* Computer/Electronic Accommodations Program, *http://www.cap.mil* (last visited Aug. 3, 2015).

[73] *See, e.g.,* EEOC, *Instructions to Federal Agencies for EEO MD–715* I (last updated July 20, 2004), *http://www.eeoc.gov/federal/directives/715instruct/section1.html* (''The Model EEO Program and Agency Self-Assessment Checklist'').

for the denial, notifies the applicant or employee of any available internal appeal or informal dispute resolution processes, provides instructions on how to file a complaint of discrimination pursuant to 29 CFR 1614.106, and explains that, pursuant to 29 CFR 1614.105, the right to file a complaint will be lost unless the job applicant or employee initiates contact with an EEO Counselor within 45 days of the denial regardless of whether he or she participates in an informal dispute resolution process. The paragraph has been amended to clarify that the notice must be made available in accessible formats.

One commenter stated that agencies should also be required to provide notices to individuals when they first request reasonable accommodations, stating that they may file complaints of discrimination if the agency fails to make a decision on or before a ''date certain.'' The same commenter stated that agencies should also provide notices whenever they determine that extenuating circumstances justify a delay in provision of an accommodation.

The intended purpose of the suggested notices appears to be to (a) inform job applicants and employees who request reasonable accommodations that, absent extenuating circumstances, the agency must either provide a reasonable accommodation or deny the request within a certain number of days; (b) ensure that requesting individuals are aware of any alleged extenuating circumstances that justify a delay in providing a reasonable accommodation; and (c) inform requesters that they have the right to file complaints of discrimination if the agency fails to meet its deadlines absent extenuating circumstances. Reasonable accommodation procedures that comply with paragraph (d)(3)(i) should already satisfy these objectives: (d)(3)(i)(M) requires the procedures to designate the maximum amount of time the agency has, absent extenuating circumstances, to either provide a requested accommodation or deny the request; (d)(3)(i)(S) requires the agency to notify requesters of any alleged extenuating circumstances that justify a delay; and (d)(3)(i)(T) requires the agency to explain the requester's right to file a complaint. The additional notices are therefore unnecessary.

1614.203(d)(4) Accessibility of Facilities and Technology

Paragraph (d)(4) of the proposed rule required agencies to provide all employees with contact information for individuals who are responsible for ensuring agency compliance with Section 508 of the Rehabilitation Act (Section 508),[74] which requires all electronic and information technology purchased, maintained, or used by the agency to be readily accessible to and usable by people with disabilities, and for individuals who are responsible for ensuring agency compliance with the Architectural Barriers Act of 1968 (ABA),[75] which requires the agency to ensure that its facilities are physically accessible to people with disabilities. It also required agencies to provide clear instructions on how to file complaints alleging violations of those laws, and to assist individuals with filing complaints against another federal agency when an investigation has shown that such other agency is responsible for the alleged violation. The paragraph does not require the agency to provide legal advice, or to represent individuals in complaints against other agencies; it merely requires agencies to provide contact information. The paragraph has been modified to clarify that the information must be available in accessible formats, and that it should be available online.

Some commenters stated that the paragraph should require agencies to provide the information to new hires ''immediately.'' The paragraph requires agencies to provide the information to ''all'' employees. Because ''all'' employees include newly hired employees, no change was required.

Some commenters stated that the paragraph should require agencies to inform employees of their substantive rights under Section 508 and the ABA, in addition to their enforcement rights under those laws. Because employees may be equally unaware of their substantive rights and their enforcement rights under Section 508 and the ABA, the revised paragraph requires agencies to provide employees with information on both. Again, the paragraph does not require agencies to provide legal advice or represent the individual. Agencies may satisfy this requirement by providing Internet links to existing resources on Section 508 and the ABA.

Other commenters stated that the requirement to ''assist'' individuals with filing complaints against other agencies was unclear, and that, to the extent that it was intended to require agencies to act as advocates for, or advisors to, individuals in actions against other agencies, it should be struck. The paragraph was not intended to require agencies to act as advocates for employees in actions against other agencies. The paragraph has been modified to clarify that agencies are only required to provide information on where to file a complaint against another agency when an investigation shows that such other agency is responsible for an alleged violation.

1614.203(d)(5) Personal Services Allowing Employees To Participate in the Workplace

Currently, agencies are required to provide certain job-related services to individuals with disabilities as reasonable accommodations if doing so would enable them to apply for a job, perform job functions, or enjoy the benefits and privileges of employment, absent undue hardship. For example, an agency may be required to provide sign language interpreters, readers, assistance with note taking or photocopying, or permission to use a job coach as a reasonable accommodation.[76] However, provision of PAS that are needed on the job, such as assistance with eating or using the restroom, is not considered a reasonable accommodation under the ADA or as a matter of nondiscrimination under Section 501.

The NPRM proposed to place this obligation on agencies as an affirmative action requirement under Section 501. Paragraph (d)(5) of the proposed rule required agencies to provide PAS, such as assistance with removing and putting on clothing, eating, and using the restroom, to employees who need them because of a disability during work hours and job-related travel, unless doing so would impose undue hardship. It further provided that agencies are permitted to assign PAS providers to more than one individual with a disability, and to require them to do non-PAS tasks as time permits. In addition, the NPRM requested public input on (a) whether the description of PAS in the proposed paragraph was adequate; (b) whether the requirement to provide PAS should be kept in the Final Rule; (c) whether individuals who provide PAS should be assigned to particular individuals or, instead, asked to provide services to multiple individuals as needed; and (d) whether the agency should be allowed to assign other tasks to PAS providers when no personal assistance is needed.

Many commenters responding to the question of whether the NPRM's description of PAS was adequate complained that the description was vague. Commenters offered various suggestions for making the description more precise—some stated that it

[74] 29 U.S.C. 794d.

[75] 42 U.S.C. 4151–4157.

[76] *See* 29 CFR pt. 1630, app. 1630.9.

should include additional examples, one stated that it should exclude medical services, one stated that the list of examples should be exhaustive, and two stated that the paragraph should incorporate language used in the definition of PAS given elsewhere in the Rehabilitation Act.[77]

The Commission has chosen the last option. The term ''personal assistance services,'' as it is used in the disability community, expresses an open-ended concept. It is therefore not possible to provide an exhaustive list of examples, and addition of a few examples will necessarily fail to capture the full meaning. New paragraph (a)(5) thus provides that the term ''personal assistance services'' means ''assistance with performing activities of daily living that an individual would typically perform if he or she did not have a disability, and that is not otherwise required as a reasonable accommodation, including, for example, assistance with removing and putting on clothing, eating, and using the restroom.'' New paragraph (a)(4) defines the related term ''personal assistance service provider'' to mean ''an employee or independent contractor whose primary job functions include provision of personal assistance services.''

Comments on whether the PAS requirement should be kept in the Final Rule were mixed. Many disability advocacy organizations and individuals strongly favored the requirement, emphasizing that a lack of PAS in the workplace poses a major barrier to employment for some individuals with disabilities. Other commenters objected. Some argued that the associated costs would be too high. Some argued that the Commission lacks the authority to impose the requirement. Others objected that compliance with the requirement would be extremely difficult or impossible because, for example, it would require agencies to violate appropriations and antideficiency laws; require them to coordinate with local nursing boards; lead to the depletion of reasonable accommodation funds; result in reduced hiring of individuals with disabilities; conflict with merit systems principles and veterans' preference rules, at least to the extent that it would require agencies to hire providers chosen by the individuals who need them; require agencies to provide services in a variety of locations; or lead to the hiring and retention of unqualified employees.

The Final Rule retains the requirement to provide PAS during work hours[78] and job-related travel, absent undue hardship, and further clarifies in revised paragraph (d)(5)(iii) that agencies may not take adverse actions against job applicants and employees on the basis of their need, or perceived need, for PAS. Public comments from advocacy organizations and individuals confirm that lack of PAS in the workplace and/or the fear of losing PAS provided by means-tested assistance programs are stubborn and persistent barriers to employment for individuals with certain disabilities. For many individuals with targeted disabilities such as paralysis or cerebral palsy, full participation in the workplace is impossible without PAS.

The Commission is not persuaded by the objections raised by commenters. First, the issue of cost is addressed in the section on Executive Orders 13563 and 12866 below. Second, we disagree that the Commission lacks authority to impose the requirement. As explained above, the Commission has Section 501 rulemaking authority under Section 505 and Executive Order 12067, and, having found that its prior regulatory and subregulatory guidance was not sufficiently advancing the employment of qualified individuals with disabilities, here exercises its authority to strengthen the regulations implementing the Section 501 affirmative action requirement.[79] Because public comments confirm that a lack of PAS in the workplace is a persistent barrier to employment for individuals with certain significant disabilities, one of the ways in which the regulation is being strengthened is by requiring agencies to provide PAS to individuals who need them during work hours and job-related travel, absent undue hardship.

Third, as to the arguments that compliance would be extremely difficult or impossible, the Commission notes as it did in the preamble to the proposed rule that several federal agencies currently provide PAS on a voluntary basis, and have been doing so for decades without any of the negative consequences imagined by commenters.[80]

Responses to the question of whether PAS providers should be assigned to single individuals or to multiple individuals were mixed. Some stated that providers should be assigned to single individuals because (a) PAS are often required on very short notice, (b) receipt of PAS from multiple providers is likely to make the individual with a disability feel uncomfortable, and (c) services are improved if the provider is familiar with the individual's needs. Others stated that agencies should be given maximum flexibility. Commenters were more uniformly in favor of allowing agencies to assign non-PAS tasks to PAS providers, as long as the PAS-related assignments were given higher priority. One commenter disagreed, arguing that assignment of both PAS and non-PAS tasks to a single individual would create practical problems in contracting, creation of position descriptions, and performance assessment.

In both respects, the Final Rule grants flexibility to agencies in revised paragraph (d)(5)(ii). Again the Commission looks to actual practice for guidance. Federal agencies have used a variety of models for providing PAS to equal effect. The Commission, for example, has hired federal employees to provide PAS to individuals with disabilities on a one-to-one basis, whereas the Department of Labor has contracted for a pool of qualified personnel to provide PAS and other services to multiple employees.[81] Moreover, if an agency finds that a

[77] *See* 29 U.S.C. 705(28) (''The term 'personal assistance services' means a range of services, provided by one or more persons, designed to assist an individual with a disability to perform daily living activities on or off the job that the individual would typically perform if the individual did not have a disability. Such services shall be designed to increase the individual's control in life and ability to perform everyday activities on or off the job.'').

[78] Work hours include time that an employee is teleworking, whether the telework is part of an agency telework program available to all employees or is being provided as a reasonable accommodation. The Commission sees no legal reason to treat the provision of PAS for workers who are teleworking any differently from the provision of other services by individuals as a reasonable accommodations, such as sign language interpreters and readers. Determinations of whether PAS can be provided to an employee who is teleworking without undue hardship should be made on a case-by-case basis, as are decisions about reasonable accommodations.

[79] *See supra* notes 37–44 and accompanying text.

[80] The Commission provides personal assistant services to employees with disabilities who require them. The Department of Labor, the Department of Transportation, and the Department of Justice's Civil Rights Division also provide workplace PAS for employees with disabilities. *See* Department of Labor statement of work on providing personal assistance services as a reasonable accommodation for qualified Department of Labor employees with disabilities (2014) [hereinafter DOL statement] (on file with the Commission); Dep't of Transp., *Disability Resource Center Services Handbook* (Nov. 2014), *http://www.transportation.gov/individuals/disability/disability-resource-center-drc-services-handbook* (providing guidance to the Department of Transportation on meeting its obligations regarding the retention and promotion of individuals with disabilities by providing personal assistance and other services); Civil Rights Div., U.S. Dep't of Justice, *Reasonable Accommodation Manual* A.2.5 (n.d.) (on file with the Commission) (providing that the Civil Rights Division will provide part-time personal care attendants at work or on official travel when necessary and otherwise reasonable).

[81] DOL statement, *supra* note 80.

particular approach is impracticable or does not meet employees' needs, the paragraph permits the agency to adopt an alternative approach.

Other comments on the requirement raised the following issues:

• *Eligibility.* Some stated that an agency should only be required to provide PAS to individuals who are qualified to perform their jobs. Although the Commission does not believe that the proposed paragraph provided otherwise, it has been revised to state that agencies are required to provide PAS only if they ''would, together with any reasonable accommodations required under [29 CFR] part 1630 . . ., enable the employee to perform the essential functions of his or her position.'' [82]

Other commenters stated that an agency should only be required to provide PAS to individuals who have targeted disabilities. As discussed in the NPRM, the Commission believes that individuals who do not have targeted disabilities will not require PAS in order to participate in the workplace.[83] The paragraph has therefore been revised in the manner suggested.

• *Additional services.* Some commenters stated that the paragraph should require agencies to provide additional services to employees with disabilities, including help with getting to and from work, identifying transportation options and accessing transportation, assistance with becoming familiar with surroundings, and ''informational and navigational awareness, as well as lightweight communication.'' The commenters did not, however, cite to any studies or other objective sources establishing that such services would significantly improve employment of individuals with disabilities, or to any data on which to base an estimate of the economic impact of the requirement. The Commission has not incorporated these suggestions.

A significant number of commenters stated that the Rule should require agencies to permit employees with disabilities to use job coaches and other forms of supported employment paid for by outside sources. The Commission strongly endorses the use of supported employment. Indeed, permission to use a job coach or other forms of supported employment is a reasonable accommodation that may be required if such a person needs those services to perform the essential functions of a position and if providing those services does not impose an undue hardship on the agency.[84] As explained above, however, the Commission believes that it would be inappropriate to provide guidance on nondiscrimination requirements applicable to federal agencies, as well as to private and state and local government employers, in a regulation that applies to the affirmative action obligations of federal agencies.

• *Undue hardship exception.* One commenter stated that agencies should not be required to establish undue hardship in order to deny a request for PAS, because, given the fact that they typically have very large budgets, agencies ''will have very limited ability to deny such requests . . . regardless of the nature of the request.'' The commenter did not suggest an alternative standard.

The Commission disagrees with the commenter's characterization. First, the paragraph does not require agencies to provide PAS to individuals who request them ''regardless of the nature of the request.'' The paragraph only requires agencies to provide personal assistants, who will assist the employee with eating, using the restroom, and similar activities to individuals who need them because of a targeted disability; it does not require agencies to provide services that the individual does not need in order to participate in the workplace, or services that are needed for reasons other than disability. Second, agencies may be able to establish undue hardship for reasons other than cost.[85]

• *Selection and evaluation of personal assistance service provider.* Some commenters stated that the paragraph should require PAS providers to meet certain qualification standards, such as those imposed by OPM for all government employees and specific standards based on experience and training. Others stated that an agency should be required to consult with individuals who receive PAS during their providers' performance reviews.

These requirements were not incorporated into the Rule because they primarily concern OPM functions. EEOC is not in the best position to determine what qualifications PAS providers have to possess, and we do not wish to limit unduly the choices of employees who may want to work with a PAS provider who may not necessarily possess specific certifications or credentials. This is similar to the approach the Commission has taken under the ADA with respect to sign language interpreters and readers provided as reasonable accommodations. However, the revised paragraph does provide that PAS must be provided by a personal assistance service provider, meaning an employee or independent contractor whose primary job functions include provision of personal assistance services at (d)(5)(ii).

Some commenters stated that the paragraph should require agencies to consider the preferences of individuals with disabilities when selecting their PAS providers. The Commission agrees and notes that this is the same principle that applies when an employer is choosing from among available accommodations.[86] New paragraph (d)(5)(iv) requires agencies, when selecting someone to provide personal assistance services to a single individual, to give primary consideration to the individual's preferences to the extent permitted by law.

• *Process for requesting PAS.* Some commenters stated that the paragraph should require agencies to have written procedures for processing PAS requests, similar to the reasonable accommodation procedures required under paragraph (d)(4). Some stated more specifically that agencies should be permitted to require medical documentation, be required to use a centralized fund, or be required to consult with vocational rehabilitation agencies during the process.

The Commission agrees that agencies should have procedures for processing requests for PAS. Paragraph (d)(5)(v) of the Final Rule requires agencies to adopt such procedures, and to make them available online and in written and accessible formats. Because the intent of the Rule is to require agencies to treat PAS requests like requests for reasonable accommodation, the paragraph further provides that agencies may satisfy the requirement by stating in their reasonable accommodation procedures that the process for requesting personal assistance services, the process for determining whether such services are required, and the agency's right to deny such requests when provision of the services would pose an undue hardship, are the same as for reasonable accommodations.

[82] 29 CFR 1630.203(5)(i)(B), as amended.

[83] Affirmative Action for Individuals with Disabilities in the Federal Government, 81 FR 9123, 9134 n.101 (Feb. 24, 2016) (to be codified at 29 CFR 1614.203, .601(f)).

[84] *See* 29 CFR pt. 1630, app. 1630.9.

[85] EEOC, *Enforcement Guidance: Reasonable Accommodation and Undue Hardship Under the Americans with Disabilities Act* (2002), *https://www.eeoc.gov/policy/docs/accommodation.html#undue.*

[86] *See* 29 CFR pt. 1630, app. 1630.9.

1614.203(d)(6) and 1614.203(d)(7)(i) Utilization analysis and goals

Paragraph (d)(7)(i) of the proposed rule required agencies to adopt the goal of achieving a 12% representation rate for people with disabilities at the GS–11 level [87] and above, including the Senior Executive Service (SES); [88] a 12% representation rate for people with disabilities at the GS–10 level and below; a 2% representation rate for individuals with targeted disabilities at the GS–11 level and above, including the SES; and a 2% representation rate for people with targeted disabilities at the GS–10 level and below. Paragraph (d)(6) required agencies to perform the workforce analysis necessary to determine whether these goals have been met annually, based on SF–256 records, records of requests for reasonable accommodation, and records of appointments under hiring authorities that take disability into account. In addition, the NPRM asked for public input on whether the proposed goals were appropriate, and whether there are any data showing that the goals should be raised or lowered.

The Commission received a small number of comments requesting clarification of the proposed goals. One commenter asked whether the 2% goals were intended to be sub-goals of the 12% goals, *i.e.,* whether the individuals who are counted as individuals with targeted disabilities for purposes of determining whether a 2% goal has been met may also be counted as individuals with disabilities for purposes of determining whether a 12% goal has been met.

The 2% goals are intended to be sub-goals. Disabilities that fall under the term ''targeted disability'' are a subset of those that fall under the term ''disability'' as defined under Section 501. Thus, any employee who has a targeted disability, and who therefore counts toward a 2% goal for individuals with targeted disabilities, will necessarily have a condition that meets the Section 501 definition of ''disability,'' and will therefore also count toward the 12% goal for individuals with disabilities.

Another commenter asked whether the fact that the NPRM proposed a 12% goal for individuals with disabilities at the GS–11 level and above, and a 12% goal for individuals with disabilities at the GS–10 level and below, meant that it proposed a 24% overall goal for individuals with disabilities. Similarly, the commenter wondered whether the 2% goals ''combined'' to create a 4% overall goal for individuals with targeted disabilities. Because each 12% and each 2% goal applies to a different segment of the workforce, the Rule does not impose goals of 24% and 4% overall.[89]

A small number of commenters stated that the goals should not be retained in the Final Rule because the proposed methods of measuring agencies' representation rates—SF–256 records, reasonable accommodation records, and documentation relating to appointment of individuals under hiring authorities that take disability into account—are inaccurate. SF–256 data, according to commenters, are especially likely to underestimate representation rates for individuals with disabilities and individuals with targeted disabilities because many employees are reluctant to disclose disabilities using this form. Some stated that a greater number of employees would self-disclose if, for example, the form did not ask the individual to indicate his or her specific type of disability, or if it included questions on topics other than disability.

The Commission acknowledged in the NPRM that SF–256 data are likely to underestimate representation rates for individuals with disabilities and individuals with targeted disabilities, and, for that reason, used prior SF–256 data as a starting point when it developed the goals.[90] As discussed, SF–256 data themselves (together with other data that agencies are permitted to use under (d)(6)) indicate that the federal government as a whole has achieved representation rates that are close to 12% for individuals with disabilities and 2% for individuals with targeted disabilities; actual representation rates may be much larger. The Commission also reminds agencies that they have the discretion to periodically request employees to respond to voluntary surveys updating their SF–256 information. If accompanied by an explanation of why self-reporting is important, resurveying can enhance data accuracy. The Commission therefore is not persuaded that the proposed goals are overly burdensome due to problems of measurement.

However, the Commission does acknowledge commenters' assertions that there may be ways to improve the accuracy of self-reported data, for example by asking individuals to indicate whether they have disabilities or targeted disabilities without asking for more detailed information. The Commission is not able to amend the SF–256, as suggested by some commenters, because OPM controls the content of the SF–256. Nor can the Commission require OPM to establish an ''authoritative'' system for tracking disability information, as suggested by another commenter.

Instead, the Final Rule allows, but does not require, agencies to collect disability information using forms other than the SF–256. Paragraph (d)(6)(ii)(A) has thus been amended to allow agencies to classify individuals for purposes of the workforce analysis based on ''[t]he individual's self-identification as an individual with a disability or an individual with a targeted disability on a form, including but not limited to the Office of Personnel Management's Standard Form 256, which states that the information collected will be kept confidential and used only for statistical purposes, and that completion of the form is voluntary.'' [91] The paragraph permits agencies to design their own forms or use existing forms as appropriate. For example, agencies are permitted to use the approach taken in EEOC's Applicant Flow Form. This form asks, among other things, whether the individual has a non-targeted disability. It does not, however, require the individual to identify which non-targeted disability he or she has.[92] The Final Rule also

[87] Most federal employees are part of the General Schedule (GS) pay system. The General Schedule has fifteen grades—GS–1 (lowest) to GS–15 (highest). *See generally General Schedule Classification and Pay,* Office of Pers. Mgmt., *http://www.opm.gov/policy-data-oversight/pay-leave/pay-systems/general-schedule/* (last visited Dec. 21, 2016).

[88] High-level leadership positions in the federal government are occupied by members of the SES. SES members have a different pay scale than employees who are part of the GS pay system. *See generally Senior Executive Service: Leading America's Workforce,* Office of Pers. Mgmt., *http://www.opm.gov/policy-data-oversight/senior-executive-service/* (last visited Dec. 21, 2016).

[89] Where X represents the total number of employees on the GS and SES scales and Y represents the total number of employees employed at the GS–10 level and below, $0.02(Y) + 0.02(X - Y) = 0.02(X)$; $0.12(Y) + 0.12(X - Y) = 0.12(X)$.

[90] Affirmative Action for Individuals with Disabilities in the Federal Government, 81 FR 9123, 9128–29 (Feb. 24, 2016) (to be codified at 29 CFR 1614.203, .601(f)).

[91] The other records discussed in this paragraph will also be kept confidential, because they are subject to the Privacy Act. *See* 5 U.S.C. 552a. Additionally, records relating to reasonable accommodation are subject to the ADA's confidentiality requirements, as incorporated. *See* 42 U.S.C. 12112(d)(4)(A) (imposing the requirements); 29 U.S.C. 791(f) (incorporating the requirements into Section 501); 29 CFR 1630.14(c) (implementing the requirements); 29 CFR pt. 1630, app. 1630.14(c) (discussing the requirements); 29 CFR 1614.203(b) (incorporating the ADA regulations at 29 CFR pt. 1630 into the Section 501 regulations).

[92] *Applicant Flow Form, supra* note 4, at 3.

makes conforming amendments to 29 CFR 1614.601(f) (discussed below).[93]

One commenter argued that the goals should be eliminated for agencies that have limited opportunities to use the Schedule A hiring authority for persons with certain disabilities, and for small agencies that typically draw from a small applicant pool. The commenter also argued that small agencies should be exempted because it is sometimes possible to determine which employees within the agency have a disability based solely on aggregate data, which, according to the commenter, may result in ''per se violations of [the confidentiality requirements of] the Rehabilitation Act.''

The Final Rule does not include exemptions for agencies that have limited opportunities to use the Schedule A hiring authority for persons with certain disabilities or for small agencies. The Commission believes that all agencies are able to take steps to improve employment opportunities for individuals with disabilities, including targeted disabilities. Agencies that have limited opportunities to use the Schedule A hiring authority for persons with certain disabilities may still, for example, take steps to improve the application process as required under (d)(1)(ii); adopt advancement programs as required under (d)(1)(iii), and take other actions recommended under (d)(7)(ii) to the extent permitted by law. Agencies that typically draw from a small applicant pool may take steps to expand the pool, as required under (d)(1)(i). These and other steps specified throughout paragraph (d) are all that the Rule requires of an agency that fails to achieve a goal—paragraph (f)(2) (discussed below) provides that ''failure to achieve a goal set forth in paragraph (d)(7) of the Rule, by itself, is not grounds for disapproval unless the Plan fails to require the agency to take specific steps that are reasonably designed to achieve the goal.''

The Commission does not see how compliance with the goal requirements could lead to ''per se violations of the Rehabilitation Act.'' The commenter appears to have assumed that the Rule requires agencies to make detailed, grade-level-by-grade-level disability information available to the public. It does not. The Rule only requires agencies to publish representation rates for people with disabilities and people with targeted disabilities in two broadly defined groups. Moreover, nothing in the Rule requires an individual with a disability to self-identify as such; if an individual does not wish to disclose his or her disability status, he or she need not fill out the SF–256 or similar forms.

One commenter stated that agencies should be allowed to set their own goals. After the ANPRM public comment period, the Commission decided to adopt government-wide goals in the proposed rule.[94] The commenter did not provide any basis on which to overturn that decision. Upon further consideration, the Commission has determined that the proposed government-wide approach continues to be the most appropriate one.

Most commenters responding to the question of whether the proposed goals were appropriate stated that they were too low. These commenters generally argued that, because existing representation rates for individuals with disabilities and individuals with targeted disabilities are already close to 12% and 2% respectively, the proposed goals would merely ''maintain the status quo.''[95]

The Commission disagrees that the proposed goals would merely ''maintain the status quo.'' Although it is true that the federal government as a whole has achieved representation rates of close to 12% and 2%, many individual agencies have not.[96] For these agencies, meeting the goals would represent significant improvement. Further, because the goals apply at both higher and lower levels of employment, agencies that employ a disproportionately high number of individuals with disabilities in lower paying positions would also see significant improvement by meeting the goals. As noted in the NPRM, the representation rates for individuals with disabilities and individuals with targeted disabilities are significantly lower at the GS–11 level and above than at the GS–10 level and below.[97]

Additionally, the commenters failed to identify any data on which the Commission could reasonably base higher goals. Many commenters simply picked numbers without justification. Some commenters stated that the Commission should ''look to those agencies that have done the best job of employing people with disabilities, as well as workforce data'' to set the goals, but provided no explanation as to how this could reasonably be done, and instead chose goals that did not appear to be connected either with agency benchmarks or with workforce data.[98] One commenter stated that the goals should be based on census data. However, the census definition of ''disability'' matches neither the Section 501 definition of ''disability'' nor the definition of ''targeted disability'' under paragraph (a).[99] Census data, therefore, are inapposite. Because commenters failed to identify any reasonable alternatives, and because the Commission believes that the 12% and 2% goals are based on the best available data, the Final Rule retains goals of 12% for individuals with disabilities and 2% for individuals with targeted disabilities.

Some commenters stated that the goals should be extended to employees who are on neither the GS nor the SES scale. We agree. However, to avoid the difficulties inherent in establishing ''equivalencies'' across differing pay

[93] One commenter stated that current regulations at 29 CFR part 1630 should also be amended, because those regulations generally prohibit agencies from asking disability-related questions, as would be required under (d)(6). The Commission disagrees. The anti-discrimination regulations permit agencies (and employers generally) to ask disability-related questions for purposes of engaging in affirmative action for individuals with disabilities. *Cf. Assoc. Builders & Contractors, Inc.* v. *Shiu,* 30 F. Supp. 3d 25, 37–38 (D.D.C. 2014) (holding that the ADA does not prohibit federal contractors from inviting job applicants to self-identify as individuals with disabilities pursuant to regulations implementing the affirmative action requirement imposed on federal contractors by Section 503), *aff'd,* 773 F.3d 257 (D.C. Cir. 2014); Letter from Peggy R. Mastroianni, Legal Counsel, EEOC, to Patricia A Shiu, Director, Office of Fed. Contract Compliance Programs, Dep't of Labor (Aug. 8, 2013), *http://www.dol.gov/ofccp/regs/compliance/section503.htm* (follow ''EEOC Opinion on the Invitation to Self-Identify'' hyperlink) (discussing job applicants).

[94] *See* Affirmative Action for Individuals with Disabilities in the Federal Government, 81 FR at 9128.

[95] For example, commenters cited a recent OPM report finding that 14.64% of federal employees have reportable disabilities, 18.8% of federal employees at the GS–10 level and below have disabilities, 12.6% of federal employees at the GS–11 level and above have disabilities, 1.18% of federal employees have targeted disabilities, 1.91% of federal employees at the GS–10 level and below have targeted disabilities, and 0.8% of federal employees at the GS–11 level and above have targeted disabilities, *see* Office of Pers. Mgmt., *Report on the Employment of Individuals with Disabilities in the Federal Executive Branch: Fiscal Year 2014,* 25 (Oct. 9, 2015), *https://www.opm.gov/policy-data-oversight/diversity-and-inclusion/reports/disability-report-fy2014.pdf* [hereinafter *2014 Report*], and a recent survey indicating that 13.5% of federal employees have disabilities, *Governmentwide Unweighted Results: Demographic, Items 85–98,* Office of Pers. Mgmt., *http://www.fedview.opm.gov/2014/Reports/ResponsePCT.asp?AGY=ALL&SECT=8* (last visited Dec. 8, 2016).

[96] *See, e.g., 2014 Report, supra* note 95, at 10.

[97] *See id.* at 25.

[98] These commenters recommended goals of ''at least'' 15% for people with disabilities and 4% for people with targeted disabilities.

[99] The ACS collects disability data by asking a series of questions such as whether, due to a physical, mental, or emotional problem, the person has ''serious difficulty'' hearing, seeing (even with glasses), remembering, concentrating, or making decisions, walking or climbing stairs, bathing or dressing, and/or doing errands alone. *See American Community Survey (ACS),* U.S. Census Bureau, *https://www.census.gov/people/disability/methodology/acs.html* (last visited Dec. 21, 2016).

scales, the Commission has decided to classify non-GS employees using a simple pay cutoff. The revised paragraph thus requires agencies to adopt 12% and 2% goals for ''employees at the GS–11 level and above, together with employees who are not paid under the General Schedule but who have salaries equal to or greater than employees at the GS–11, step 1 [100] level in the Washington, DC locality'' [101] and ''employees at the GS–10 level and below, together with employees who are not paid under the General Schedule but who have salaries less than employees at the GS–11, step 1 level in the Washington, DC locality.'' Express reference to the SES was removed from the paragraph because SES employees are included in the category of ''employees who are not paid under the General Schedule but who have salaries equal to or greater than employees at the GS–11, step 1 level in the Washington, DC locality.''

Some commenters stated that the Rule should impose separate goals for each individual grade level, or for each individual job series and grade level. The Commission does not believe that the additional burden on agencies of meeting such goals would substantially promote the hiring, retention, and advancement of individuals with disabilities and individuals with targeted disabilities. For example, we see no reason to require agencies to have the same percentage of individuals with disabilities at both the GS–4 and GS–5 levels, and we are unsure what inference should be drawn from the fact that an agency employs a disproportionately low number of individuals at the GS–12 level, for example, but not at the GS–13 level. Of course, significant disparities in the distribution of individuals with disabilities or individuals with targeted disabilities within the pay grouping may raise concerns. For example, an agency that meets goals for the employment of people with targeted disabilities in both pay groupings, but that employs most such individuals at the GS–1 through GS–4 and GS–11 through GS–12 levels, is probably insufficiently attentive to its obligations to provide advancement opportunities. However, absent evidence at this time that agencies would attempt to circumvent their affirmative action obligations in this way, the Rule continues to group employees according to whether they are employed at higher or lower levels, rather than according to individual grade level and job series, for purposes of meeting the (d)(7)(i) goals.

Two commenters stated that federal jobs ''limit[ing] advancement, or segregat[ing] federal workers on the basis of disability (including segregation into separate work areas or separate lines of advancement)'' should not count toward achievement of the goals. We assume that the commenters are referring to positions that ''limit, segregate, or classify a job applicant or employee in a way that adversely affects his or her employment opportunities or status on the basis of disability'' in violation of Section 501's nondiscrimination requirements.[102] Although we agree with the general principle that an agency should not benefit from employing individuals with disabilities if the agency also discriminates against them, we believe that the appropriate response in these cases is to challenge the discriminatory behavior under 29 CFR 1614.106.

Some commenters stated that the Rule should establish a deadline for achieving the goals. The Commission disagrees. As noted in the NPRM, there are many reasons why it may take some agencies more time than others to meet the utilization goals, such as budgetary constraints (including hiring freezes), the number of additional individuals with targeted disabilities that would have to be hired to achieve the goals, and the nature of certain jobs within an agency's workforce that may include valid physical standards that individuals with certain disabilities may not be able to meet.

Some commenters stated that the paragraph should require agencies to adopt other types of goals in addition to, or instead of, representation rate goals—

• *Hiring and promotion goals.* Some commenters stated that certain percentages of each agency's new hires should be, and certain percentages of each agency's promotions should be given to, individuals with disabilities and individuals with targeted disabilities. As applied to agencies that underperform with respect to employment of individuals with disabilities and individuals with targeted disabilities, hiring and retention goals do not impose more stringent requirements than the corresponding representation rate goals. They were therefore not added.

• *Retention rate goals.* One commenter stated that agencies should be required to adopt the goal of having a retention rate for employees who were appointed under the Schedule A hiring authority for persons with certain disabilities that is equal to or greater than the retention rate for other employees. The Commission lacks any data establishing what the retention rate for individuals who were appointed under the Schedule A hiring authority for persons with certain disabilities should be. Further, a function of paragraphs (d)(8)(iv) and (d)(8)(v), requiring agencies to keep detailed records on individuals who were appointed under the Schedule A hiring authority for persons with certain disabilities, and paragraph (d)(1)(iii), requiring agencies to report data regarding such individuals, is to ensure that both individuals within the agency and the Commission will be alerted if the agency is experiencing problems with retention. The Commission concludes that a separate goal is unnecessary.

• *Goals for utilization of supported employment.* Some commenters stated that the Rule should impose goals for hiring and employment of individuals receiving supported employment services. The commenter cited no evidence that such goals would eliminate a significant barrier to employment for a large number of individuals with disabilities, and neither stated what percentage the goal should be nor provided any data on which to base the goal. However, in light of the commenters' observation that there is an evidence base showing that supported employment services are an effective way to maintain employment for many individuals with disabilities, provision of such services has been added as an example of a strategy that an agency may use to increase the number of employees with disabilities and targeted disabilities in paragraph (d)(7)(ii), discussed below.

1614.203(d)(7)(ii) Progression Toward Goals

Proposed paragraph (d)(7)(ii) required agencies that fail to meet one or more goals required under paragraph (d)(7)(i) to take specific steps that are reasonably designed to gradually increase the number of employees with disabilities and targeted disabilities, examples of

[100] Pay rates for employees at a given GS level depend on the within-grade level, or ''step,'' of the employee, which ranges between one and ten, and on the geographic location of the employee. *See generally General Schedule Classification and Pay, supra* note 87.

[101] The rate of pay for employees on the GS and SES scales is determined by adding a ''locality adjustment'' to a base rate. *See generally Pay & Leave: Salaries & Wages,* Office of Pers. Mgmt., *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2016/general-schedule/* (last visited Dec. 21, 2016) (discussing alternative dispute resolution). Washington, DC is currently in the ''Washington-Baltimore-Northern Virginia, DC–MD–VA–WV–PA region.'' *Id.* The Rule refers to the ''Washington, DC locality'' in the event that the locality is renamed or defined differently in the future.

[102] 42 U.S.C. 12112(b)(1); 29 CFR 1630.5.

which included increased use of hiring authorities that take disability into account; consideration of disability or targeted disability status as a positive factor in hiring, promotion, or assignment decisions, to the extent permitted by law; additional outreach and recruitment efforts; adoption of training, internship, and mentoring programs for individuals with disabilities; and disability-related training for all employees. Agencies interested in the last example are encouraged to review the components of effective harassment prevention training set forth in the report issued by Commissioners Feldblum and Lipnic in June 2016.[103] For reasons indicated in the section immediately above, ''[i]ncreased efforts to hire and retain individuals who require supported employment because of a disability, who have retained the services of a job coach at their own expense or at the expense of a third party, and who may be given permission to use the job coach during work hours as a reasonable accommodation without imposing undue hardship on the agency'' has been added as an example.

One commenter asked whether the paragraph requires agencies that do not meet the goals to hire individuals with disabilities or individuals with targeted disabilities who are not qualified for the job, or who are less qualified than other candidates. It does not. Hiring authorities that take disability into account do not provide agencies with a means of hiring individuals who are unqualified, and agencies are not required to hire individuals who are unqualified in order to, for example, provide disability-related training for all employees, engage in additional outreach and recruitment efforts, or adopt training, internship, or mentoring programs for individuals with disabilities.

Some commenters stated that agencies should always be required to consider disability status and targeted disability status as positive factors in hiring, promotion, and employment decisions, regardless of whether the agency has failed to meet a goal. Other commenters stated that certain kinds of disability-related training, such as awareness and anti-stigma training, should also be mandatory. The purpose of these efforts is to address problems of underrepresentation. To the extent that an agency is meeting its (d)(7)(i) goals, the Commission is without reason to believe that such efforts are necessary.

[103] *See* Chai R. Feldblum & Victoria A. Lipnic, *supra* note 63.

1614.203(d)(8) Recordkeeping

This paragraph of the Final Rule requires that each agency keep, and make available to the Commission upon request,[104] records of: (i) The number of job applications received from individuals with disabilities, and the number of individuals with disabilities who were hired by the agency; (ii) the number of job applications received from individuals with targeted disabilities, and the number of individuals with targeted disabilities who were hired by the agency; (iii) all rescissions of conditional job offers, demotions, and terminations taken against applicants or employees as a result of medical examinations or inquiries; (iv) all agency employees hired under the Schedule A hiring authority for persons with certain disabilities, and each such employee's date of hire, entering grade level, probationary status, and current grade level; (v) the number of employees appointed under the Schedule A hiring authority for persons with certain disabilities who have been converted to career or career-conditional appointments in the competitive service each year, and the number of such employees who were terminated prior to being converted to a career or career-conditional appointment in the competitive service each year; and (vi) details regarding all requests for reasonable accommodation the agency receives. Aside from minor stylistic and terminological differences, it is identical to paragraph (d)(8) of the proposed rule.[105]

One federal agency stated that the paragraph should not require agencies to keep records of all reasonable accommodation requests because, in the agency's opinion, it is more efficient to handle some requests ''informally.'' The commenter's position runs counter to longstanding federal policy. Executive Order 13164 instructs agencies to ensure that their systems of recordkeeping ''track the processing of requests for reasonable accommodation,''[106] and guidance on the Executive Order provides that the records must (among other things) allow the agency to identify ''the number and types of reasonable accommodations that have been requested in the application process and whether those requests have been granted or denied; . . . the number and types of reasonable accommodation for each job, by agency component, that have been approved, and the number and types that have been denied; . . . [and] the amount of time taken to process each request for reasonable accommodation . . . .''[107] Such records are a necessary component of an agency's efforts to ensure that the agency is processing requests for reasonable accommodation in accordance with the nondiscrimination requirements of Section 501.

One commenter suggested that the paragraph should require agencies to develop systems that make their employment data available to vocational rehabilitation agencies ''in real time.'' The commenter failed to clarify how such a system would work, but, to the extent that it would grant non-agency access to agency personnel files, it is likely to create significant problems of privacy and data security.

1614.203(e) Reporting

The paragraph requires each agency to submit to the Commission, on an annual basis, a report that contains a copy of its Plan; the results of its two most recent workforce analyses performed pursuant to paragraph (d)(6) of the Rule showing the percentages of individuals with disabilities and individuals with targeted disabilities in both of the specified pay groups; the number of individuals appointed under the Schedule A hiring authority for persons with certain disabilities during the previous year; the total number of employees whose employment at the agency began by appointment under the Schedule A hiring authority for persons with certain disabilities; and an explanation of any changes that were made to the Plan since the prior submission. The paragraph also requires agencies to make all information submitted to the Commission pursuant to this requirement available to the public by, at a minimum, posting a copy of the submission on its public Web site and providing a means by which members of the public may request copies of the submission in accessible formats. Aside from minor stylistic differences, it is identical to paragraph (e) of the proposed rule.

[104] The records will be subject to all applicable record retention requirements, including the record retention requirements overseen by NARA. *See, e.g., Records Management, supra* note 59.

[105] The records required under this paragraph are subject to the confidentiality requirements of the Privacy Act. *See* 5 U.S.C. 552a. Records relating to reasonable accommodation are also subject to the confidentiality requirements imposed by the ADA, as incorporated. *See* 42 U.S.C. 12112(d)(4)(A) (imposing the requirements); 29 U.S.C. 791(f) (incorporating the requirements into Section 501); 29 CFR 1630.14(c) (implementing the requirements); 29 CFR pt. 1630, app. 1630.14(c) (discussing the requirements); 29 CFR 1614.203(b) (incorporating the implementing regulations into the regulations implementing Section 501).

[106] Executive Order No. 13164, *supra* note 14.

[107] *See 13164 Guidance, supra* note 15.

Several commenters stated that the proposed reporting requirements overlapped with those of MD–715, and therefore that, in order to avoid redundancies, MD–715 should be amended. As stated in the NPRM, the Commission intends to modify the requirements of MD–715 after final promulgation of this Rule to eliminate redundancies.

Some commenters stated that the paragraph should require agencies to report (and, if not already required to do so, keep records of) additional information, including, for example, the number of individuals appointed under the Schedule A hiring authority for persons with certain disabilities who were subjected to removal or offered voluntary resignation; the representation rates for individuals with disabilities and individuals with targeted disabilities broken down by grade level; a list of the disability organizations with which the agency maintains partnerships; the retention and performance rates for employees with disabilities and employees with targeted disabilities; the numbers of employees classified as having disabilities on the basis of conditions that developed pre-hire, that developed post-hire, or were service-related; and the number of individuals appointed under each veterans' authority who identified themselves as having a targeted disability. The Commission is not persuaded that it is necessary to report information at this level of detail in order to determine whether an agency has satisfied its Section 501 obligation to engage in affirmative action for individuals with disabilities.

1614.203(f) Standards for Approval and Disapproval of Plans

Paragraph (f) of the proposed rule provided that the Commission will (1) approve an agency Plan if it determines that the Plan, as implemented, meets the requirements set forth in paragraph (d) of the rule, and (2) disapprove a Plan if it determines that it, as implemented, does not meet those requirements. The paragraph further clarified that failure to achieve a goal set forth in paragraph (d)(8)(i), by itself, is not grounds for disapproval unless the Plan fails to require the agency to take specific steps that are reasonably designed to achieve the goal in the future. Having received no objections, the Commission adopts the paragraph in the Final Rule unchanged.

1614.601(f) EEO Group Statistics

Section 1614.601 requires each agency to establish a system to collect and maintain accurate demographic information about its employees, and paragraph 1614.601(f) specifies how agencies are to gather disability data. As explained above, paragraphs (d)(6)(ii) and (d)(6)(iii) specify how agencies are to gather disability data for purposes of the workforce analyses required under (d)(6)(i). In order to avoid any conflict between sections 1614.203 and 1614.601, paragraph 1614.601(f) has been amended to provide that ''[d]ata on disabilities shall be collected using a method permitted under § 1614.203(d)(6)(ii) and § 1614.203(d)(6)(iii).'' The revised paragraph imposes no new obligations on federal agencies.

Executive Order 12866 [108] and Executive Order 13563 [109] (Regulatory Planning and Review)

This Rule has been drafted and reviewed in accordance with Executive Order 12866 and Executive Order 13563. This Rule has been designated a ''significant regulatory action'' under section 3(f) of Executive Order 12866. Accordingly, the proposed rule has been reviewed by the Office of Management and Budget.

Executive Order 12866 directs agencies to submit a regulatory impact analysis for those regulatory actions that are ''economically significant'' within the meaning of section 3(f)(1).[110] A regulatory action is economically significant under section 3(f)(1) if it is anticipated (1) to ''[h]ave an annual effect on the economy of $100 million or more,'' or (2) to ''adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.'' [111] Executive Order 13563 reaffirms the principles established by Executive Order 12866, and further emphasizes the need to reduce regulatory burden to the extent feasible and permitted by law.[112] It directs agencies to propose or adopt a regulation only upon a reasoned determination that its benefits justify its cost (recognizing that some benefits and costs are difficult to quantify); to tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives; and to select, from among alternative regulatory approaches, including the alternative of not regulating, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages, distributive impacts, and equity).

As explained above, the Commission has concluded that the existing practice of explaining Section 501's affirmative action obligations through management directives and sub-regulatory guidance,[113] and not through regulation,[114] has failed to sufficiently advance the employment of qualified individuals with disabilities. Detailed regulations are necessary in order to ensure that the obligations have, and are recognized to have, the force of law. Moreover, the Rule will make it easier for agencies to learn about their affirmative action obligations by presenting them all in one place, rather than in a range of documents, none of which are comprehensive.

EEOC has conducted an economic analysis of this Final Rule in accordance with EO 12866 and EO 13563. The analysis, revised in response to public comments and in light of the revisions discussed above, is presented below.

Except where noted, we assume that work required under the Rule will be performed by GS–12 step 5 level employees in the Washington-Baltimore-Northern Virginia, DC–MD–VA–WV–PA region.[115] The compensation rate for such employees,

[108] Executive Order No. 12866, 3 CFR 638 (1993), *http://www.whitehouse.gov/sites/default/files/omb/inforeg/eo12866.pdf.*

[109] Executive Order No. 13563, 3 CFR 215 (2011), *http://www.whitehouse.gov/sites/default/files/omb/inforeg/eo12866/eo13563_01182011.pdf.*

[110] Executive Order 12866 refers to ''those matters identified as, or determined by the Administrator of [the Office of Information and Regulatory Affairs] to be, a significant regulatory action within the scope of section 3(f)(1).'' Executive Order No. 12866, *supra* note 108. The Office of Management and Budget states that ''Executive Order 12866 requires agencies to conduct a regulatory analysis for economically significant regulatory actions as defined by Section 3(f)(1).'' Office of Mgmt. & Budget, *Circular A–4* (Sept., 2003), *http://www.whitehouse.gov/omb/circulars_a004_a-4.*

[111] Executive Order No. 12866, *supra* note 108.

[112] Executive Order No. 13563, *supra* note 109.

[113] *See supra* notes 10–23 and accompanying text.

[114] Prior paragraph 1614.203(a) stated only that the federal government shall be a ''model employer of individuals with disabilities,'' and that federal agencies shall ''give full consideration to the hiring, placement, and advancement of qualified individuals with disabilities.''

[115] In the NPRM, the Commission assumed that some of the required tasks would be performed by employees at the GS–14 level. On reflection, we believe that they are more likely to be performed by employees at the GS–12 level. The Commission realizes that not all of these tasks will be performed by GS–12 step 5 level employees in the Washington-Baltimore-Northern Virginia, DC–MD–VA–WV–PA region; the assumption is made purely for purposes of the economic analysis.

adjusted to include benefits, is $66.78 per hour [116] or $143,968.85 per year.[117]

Provisions Imposing No Additional Burden

The NPRM stated that many of the requirements in the proposed rule would have no economic effect, because they did not impose new requirements or burdens on federal agencies—

- Proposed paragraph (a), which set forth definitions of key terms, imposed no substantive requirements.
- Proposed paragraph (b), which provided that Section 501 prohibits discrimination on the basis of disability, and that the standards for determining whether Section 501 has been violated in a complaint alleging employment discrimination are the same standards applied under the ADA, merely revised paragraph (b) in the current regulations for clarity.
- Proposed paragraph (c), which required agencies to be model employers of individuals with disabilities, was identical to paragraph (a) of the current regulations.
- The requirement to adopt an affirmative action plan, in proposed paragraph (d), is imposed by Section 501.[118]
- Proposed paragraph (d)(1)(iii), which required agencies to take steps to ensure that individuals with disabilities have sufficient advancement opportunities, provided guidance on how to fulfill existing requirements rather than imposing new ones.[119]
- The requirements of proposed paragraphs (d)(3)(i) (requiring written reasonable accommodation procedures) and (d)(3)(iii) (requiring agencies to provide individuals who have been denied a reasonable accommodation with written notice of the reasons for the denial) were taken from MD–715, Executive Order 13164, and existing agency guidance.[120]
- The recordkeeping requirements of proposed paragraph (d)(8), with the exception of the requirements imposed by (d)(8)(iii) and (d)(8)(iv) (discussed below), were taken from MD–715.[121]
- The requirement to submit a Plan to the Commission for approval on an annual basis, found in proposed paragraph (e)(1), is imposed by Section 501.[122]

The Commission received no objections to this aspect of the economic analysis, and none of the revisions made to these paragraphs impose additional requirements or burdens on federal agencies.

One-Time Costs

The NPRM stated that the following aspects of the proposed rule, all of which required agencies to make certain information more readily available, imposed one-time compliance costs on federal agencies—

- Proposed paragraph (d)(2) required agencies to clarify in their harassment policies that disability-based harassment is prohibited.
- Proposed paragraph (d)(3)(ii) required agencies to inform all employees who are authorized to grant or deny requests for reasonable accommodation that all resources available to the agency as a whole are considered when determining whether a denial of reasonable accommodation based on cost is lawful.
- Proposed paragraph (d)(4) required agencies to make certain contact information available to employees.
- Proposed paragraph (e)(2) required agencies to make their Plans available to the public.

The Commission estimated that agencies would need to spend approximately 5 hours performing these tasks, updating policies, and checking for compliance. The Commission received no objections to this estimate in the public comments. Revisions to these paragraphs, however, led us to adjust the estimate—

- Proposed paragraph (d)(3)(ii) has been revised to require agencies to inform all employees who are authorized to make hiring decisions, in addition to employees authorized to grant or deny requests for reasonable accommodation, that all resources available to the agency as a whole, excluding those designated by statute for a specific purpose that does not include reasonable accommodation, are considered when determining whether a denial of reasonable accommodation based on cost is lawful.
- Proposed paragraph (d)(3)(ii) has also been revised to require agencies to ensure that anyone authorized to grant or deny requests for reasonable accommodation or to make hiring decisions is aware of, and knows how to arrange for the use of, agency resources available to provide the accommodation.
- Proposed paragraph (d)(4) has been revised to require agencies to make information on substantive Section 508 and ABA rights available to employees, in addition to contact information.

To account for the additional requirements, the Commission has doubled the estimate of the time needed to perform the necessary tasks, from 5 to 10 hours. Multiplying by the number of agencies covered by the Rule (218) [123] and by the hourly compensation rate of $66.78 yields a total estimated cost of $145,580.40.

Paragraph (d)(1)(ii)

The NPRM stated that proposed paragraph (d)(1)(ii), requiring agencies to have sufficient staff to answer disability-related questions from members of the public, process requests for reasonable accommodations made by job applicants, accept and process applications for appointment under hiring authorities that take disability into account, and oversee any other disability-related hiring programs, would impose recurring costs on federal agencies. The Commission provided both a high and a low estimate. To calculate the high estimate, we assumed that each covered agency would need to hire at least one new employee to assist the existing agency staff in performing the required tasks. To calculate the low estimate, we assumed that approximately 10% of agencies, or 22 agencies, would need to hire a new employee. Using the updated annual

[116] *See* Office of Pers. Mgmt., *Salary Table 2016–DCB: Hourly Basic (B) Rates by Grade and Step, Hourly Overtime (O) Rates by Grade and Step* (Jan. 2016), *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2016/DCB_h.pdf* (providing hourly monetary compensation rates). To adjust for the cost of benefits, we divided the annual salary by 0.61. *See* Congressional Budget Office, *Comparing the Compensation of Federal and Private-Sector Employees* 9 (Jan. 2012), *https://www.cbo.gov/sites/default/files/01-30-FedPay_0.pdf* [hereinafter *Comparing Compensation]* (reporting that the cost of providing benefits to federal workers averages between $15.50 and $24.70 per hour).

[117] *See* Office of Pers. Mgmt., *Salary Table 2016–DCB: Annual Rates by Grade and Step* (Jan. 2016), *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2016/DCB.pdf* [hereinafter *Annual Rates*] (providing annual monetary compensation rates). To adjust for the cost of benefits, we divided the annual salary by 0.61. *See Comparing Compensation, supra* note 116, at 9 (reporting that benefits account for 39% of the cost of total compensation for federal workers).

[118] 29 U.S.C. 791(b).

[119] *See, e.g.,* 29 CFR 1614.102(a)(10), (a)(11), (a)(13), (b)(1); *Promoting Employment, supra* note 21; *13164 Guidance, supra* note 15; *MD–715, supra* note 16. Indeed, the Commission anticipated that the additional guidance contained in the proposed rule, in the form of helpful examples and suggestions, would reduce agency burden by making it easier to satisfy the existing requirements. However, because the Commission did not have any data upon which to base an estimate of time saved, it did not quantify the benefit.

[120] *See MD–715, supra* note 16; Executive Order No. 13164, *supra* note 14; *13164 Guidance, supra* note 15.

[121] *See MD–715, supra* note 16.

[122] 29 U.S.C. 791(b).

[123] The number of agencies covered by the requirements of MD–715 varies from year to year. The number of agencies covered in Fiscal Year 2014 was 218.

compensation rate of $143,968.85, we multiply by the total number of covered agencies (218) to arrive at a high estimate of $31,385,209.30 per year, and by 22 to arrive at a low estimate of $3,167,314.70 per year.

Paragraph (d)(5)

The NPRM stated that proposed paragraph (d)(5), requiring agencies to provide PAS to employees who need them because of a disability, would impose costs because some current federal employees require PAS.[124] The Commission was aware of only one study measuring the number of employed individuals who require personal services at work because of a disability (2003 study), finding that 1.1% of individuals with disabilities, as that term was defined, required ''a personal assistant to help with job-related activities.'' [125] We thus estimated that 1.1% of current federal employees with targeted disabilities would require PAS.[126]

One commenter stated that this estimate was far too low, and that the proposed paragraph would require federal agencies to provide PAS to ''multitudes'' of federal employees. The Commission disagrees. It is simply not true that ''multitudes'' of current federal employees are unable to eat, use the restroom, or perform similar tasks without assistance. The Commission reminds readers that (d)(5) does not require agencies to assist employees by, for example, typing or reading work materials aloud for someone who requires these services because of a disability, because those types of job-related services are already required as reasonable accommodations absent undue hardship. (Of course, an agency would not be required to provide these specific accommodations if an alternative would be both less expensive and equally effective.) The paragraph also does not require agencies to hire an assistant to perform essential functions of the individual's job, or to perform tasks that the individual can perform on his or her own.

As explained in the NPRM, the Commission suspects that the actual number of current federal employees who will receive PAS pursuant to (d)(5) is close to zero. A federal employee who requires PAS to remain in the workplace, but does not receive PAS from his or her agency, generally would need to pay for such services out-of-pocket. An individual who has no income, by contrast, typically relies on public benefits to pay for PAS. One study has found that an individual would need to earn approximately $40,000.00 per year simply to break even.[127]

Nevertheless, because the Commission lacks any additional data, we continue to assume for purposes of the analysis that 1.1% of current federal employees with targeted disabilities require PAS. There are approximately 19,536 individuals with targeted disabilities in the federal workforce.[128] Multiplying that number by 0.011 yields an estimated total of 215 current federal employees who require PAS. The Commission is aware of 16 current employees who are already given PAS by their agencies. Because provision of PAS to these individuals would not represent new costs, we exclude these individuals from the analysis, leaving an estimated 199 current employees who will receive PAS as a result of (d)(5).

Even though the proposed paragraph allowed agencies to assign PAS providers to multiple individuals, and to perform additional duties, the Commission assumed in the NPRM that agencies would provide each individual with the equivalent of a full-time PAS provider.[129] We provided both a high and a low estimate of associated costs. To calculate the low estimate, we assumed that agencies would contract with vendors to provide each individual with PAS for the equivalent of full-time hours at the minimum hourly rate for federal contractors ($10.10).[130] To calculate the high estimate, the Commission assumed that agencies would hire a PAS provider for each individual at the GS–5 level.

One commenter stated that the estimates were far too low. The commenter further stated that, to generate the low-end estimate, the Commission should assume that agencies will hire PAS providers at the GS–6 level, which, according to the commenter, is a level appropriate for practical nurses.

The commenter's assertions are out of step with all available evidence. PAS providers earn, on average, an amount per hour that is approximately equal to the federal minimum wage,[131] and an amount per year that is significantly lower than the annual salary of a GS–5 level employee.[132] We therefore retain the prior assumptions. To generate the low estimate, we multiply $10.10 by the equivalent of full-time hours (2,080 hours per year), yielding an estimated annual per-person cost of $20,800.00. Multiplying by the number of covered agencies yields a total estimated cost for providing PAS to current federal employees of $4,180,592.00 per year. To generate the high estimate, we multiply the annual salary of a GS–5, step 5 level employee in the Washington-Baltimore-

[124] Paragraph (d)(5) is also expected to impose costs arising from the need to provide PAS to individuals who are hired because of the Rule. These costs are discussed in the section on paragraph (d)(7) below.

[125] *See* Craig Zwerling, et al., *Workplace Accommodations for People with Disabilities: National Health Interview Survey Disability Supplement, 1994–1995,* 45 J. Occupational & Envtl. Med. 517, 519 (2003). For purposes of the study, an individual had a disability if he or she had ''difficulty with [activities of daily living] (bathing, dressing, eating, getting in or out of bed or chair, or using the toilet); difficulty with [instrumental activities of daily living] (preparing own meals, shopping for personal items, using the telephone, doing heavy work around the house, or doing light work around the house); functional limitations (lifting 10 pounds, walking up 10 steps, walking a quarter mile, standing for 20 minutes, bending down from a standing position, reaching over the head, using the fingers to grasp or handle something, or holding a pen or pencil); difficulty seeing (even with their glasses); difficulty hearing (even with a hearing aid); reported mental health or cognitive diagnoses (Down's Syndrome, mental retardation, schizophrenia, delusional disorders, bipolar disorder, major depression, severe personality disorder, alcohol abuse, drug abuse, other mental or emotional conditions); or reported use of a cane, crutches, walker, wheelchair. Or scooter to get around.'' *Id.* at 518.

[126] The group of individuals included in the study, *see supra* note 125, more closely matches the definition of ''targeted disability'' than the definition of ''disability'' under paragraph (a). As noted throughout, the Section 501 definition of ''disability'' is very broad.

[127] *See* Douglas Klayman, et al., Soc. Dynamics, LLC, *Funding Options for Personal Assistance Services* 17 (2009), *www.dol.gov/odep/research/FundingOptionsPersonalAssistanceServices(PAS).pdf.*

[128] *See 2014 Report, supra* note 95, at 25.

[129] Because individuals who require personal assistance services generally do not require them continuously throughout the workday, the cost of providing such services to a single individual will represent a fraction of this figure. *See, e.g.,* Tatiana I. Solovieva et al., *Cost of Workplace Accommodations for Individuals with Disabilities: With or Without Personal Assistance Services,* 2 Disability & Health J. 196, 201 (2009) (reporting that the median annual cost of accommodations for individuals who need personal assistance services is $8,000.00).

[130] *See* Executive Order No. 13658, 79 FR 9851 (Feb. 12, 2014), *http://www.gpo.gov/fdsys/pkg/FR-2014-02-20/pdf/2014-03805.pdf.*

[131] *See, e.g., Personal Assistant Career,* MyMajors, *http://www.mymajors.com/career/personal-assistant/salary/* (last visited Dec. 21, 2016) (reporting that PAS providers have an average hourly wage of $10.20); Douglas Klayman, et al., *supra* note 127, at 16 (finding that the average hourly wage was $9.11); Denetta L. Dowler et al., *Personal Assistance Services in the Workplace: A Literature Review,* 4 Disability & Health J. 201, 206 (2011) (finding that the average hourly wages of between $8.18 and $12.00); Tatiana I. Solovieva et al., *Personal Assistance Services (PAS) for Individuals with Disabilities: Self-Care at the Workplace,* 36 Work 339, 341 (2010) (reporting an average hourly wage of $8.34).

[132] PAS providers have an average annual income of $21,210.00. *See, e.g., Personal Assistant Career, supra* note 131. A GS–5 step 5 level employee in the Washington-Baltimore-Northern Virginia, DC-MD-VA-WV-PA region earns $39,967.00—a full 88% more. *See Annual Rates, supra* note 117.

Northern Virginia, DC-MD-VA-WV-PA region ($65,519.67, adjusted to include benefits) [133] by the number of covered agencies, for a total estimated cost of $13,038,414.33 per year.

In calculating both the high- and low-end costs of providing PAS, the Commission did not include the cost of having PAS providers accompany employees on work-related travel. First, we believe that whether an agency is required to provide PAS or not, it would have the obligation to pay the cost of a PAS provider to travel with an employee as a reasonable accommodation.[134] Additionally, the Commission lacks any reliable data on which to base such an estimate, since there is no way of knowing how many employees who require PAS would be hired into jobs that require travel and how often travel would be required.

Paragraph (d)(6)

In the NPRM, the Commission asserted that proposed paragraph (d)(6), requiring agencies to gather workforce data, imposed no new costs on agencies because they are already required to gather such data under MD–715.[135] However, paragraph (d)(6)(ii)(A) has been amended to allow agencies to develop novel ways of gathering voluntary self-report data if the SF–256 does not meet their needs. We estimate that 50 agencies will gather voluntary self-identification data using a form other than the SF–256, and that each agency will spend 10 hours per year administering the survey, for a total of 500 additional burden hours. Multiplying by the hourly compensation rate of $66.78, we conclude that paragraph (d)(6) will have a total annual cost of approximately $33,390.00.

Paragraph (d)(7)

The NPRM noted that 3 aspects of proposed paragraph (d)(7), requiring agencies to adopt employment goals for individuals with disabilities and individuals with targeted disabilities, were likely to impose recurring costs. First, to determine whether the goals have been met, agencies would need to determine how many individuals with disabilities are employed at each GS and SES level. The NPRM stated that the associated costs would be minimal because agencies could simply request the information from OPM.[136] The Commission estimated that each agency would spend 2 hours performing the required tasks, for an estimated total of 436 burden hours.

Again, revisions to the Rule require us to adjust the estimate. In addition to the information described above, agencies that have employees who are on neither the GS nor the SES pay scale will need to determine how many such employees—

- are individuals with disabilities and have salaries equal to or greater than an employee at the GS–11 step 1 level in the Washington, DC locality;
- are individuals with targeted disabilities and have salaries equal to or greater than employees at the GS–11 step 1 level in the Washington, DC locality;
- are individuals with disabilities and have salaries less than employees at the GS–11 step 1 level in the Washington, DC locality; and
- are individuals with targeted disabilities and have salaries less than employees at the GS–11 step 1 level in the Washington, DC locality.

There are approximately 114 agencies that have employees on non-GS, non-SES pay scales. The Commission estimates that each such agency will spend 2 hours collecting the required information, for a total of 228 additional burden hours. Adding the previous estimate yields an overall estimate of 664 burden hours arising from the obligation to determine whether the employment goals have been met. Multiplying by the hourly compensation rate $66.78 yields a total estimated annual cost of $44,341.92.

Second, the NPRM stated that because paragraph (d)(7)(i) encourages federal agencies to hire individuals with disabilities, it may impose ongoing costs by increasing the number of federal employees who need a reasonable accommodation. We first considered the number of additional employees who would require a reasonable accommodation. Based on OPM data, the Commission estimated that the federal government as a whole would need to hire approximately 384 individuals with targeted disabilities at the GS–10 level or below, and approximately 10,381 individuals with targeted disabilities at the GS–11 level or above (including the SES), to meet the goals.

Because the goals have been revised to cover employees who are on neither the GS nor the SES pay scale, the estimate has been revised— [137]

- Agencies will need to hire approximately 1,594 additional individuals with targeted disabilities to meet the 2% goal for individuals who are either at the GS–10 level or below or who are not paid under the General Schedule and who have salaries that are less than that of an employee at the GS–11 step 1 level in the Washington, DC locality.[138]
- Agencies will need to hire approximately 15,385 additional individuals with targeted disabilities to meet the 2% goal for individuals who are either at the GS–11 level or above or who are not paid under the General Schedule and who have salaries equal to or greater than that of an employee at the GS–11 step 1 level in the Washington, DC locality.
- Agencies will need to hire approximately 4,262 additional individuals with disabilities to meet the 12% goal for individuals who are either at the GS–11 level or above or who are not paid under the General Schedule and who have salaries equal to or greater than that of an employee at the GS–11 step 1 level in the Washington, DC locality.

As in the NPRM, we assume that each new hire will require a reasonable accommodation,[139] and estimate the

[133] *See supra* note 117.

[134] *See* 29 CFR pt. 1630, app. 1630.2(o) (stating that it may be a reasonable accommodation for an employer to provide ''a travel attendant to act as a sighted guide to assist a blind employee on occasional business trips''). Additionally, federal regulations specifically provide for the reimbursement of travel expenses for family members or other attendants needed by an employee with a disability to make work-related travel possible. *See* 41 CFR 301–12, –13, –70.

[135] MD–715 requires agencies to conduct annual internal reviews of their policies, practices, and procedures to determine whether they provide sufficient employment opportunities to qualified applicants and employees with disabilities, especially those with targeted disabilities. As part of this analysis, agencies must determine the numerical representation and distribution of applicants and employees with disabilities and targeted disabilities. *See MD–715, supra* note 16, at B.III. MD–715 also requires agencies to determine whether they are meeting obligations imposed by Title VII, 42 U.S.C. 2000e—2000e–17, on an annual basis. *See id.* at A. Those requirements are not relevant to this rulemaking.

[136] *See, e.g., 2014 Report, supra* note 95, at 25.

[137] *See id.* Because OPM reports only limited data regarding federal employees who are on neither the GS nor the SES pay scale, the Commission assumed for purposes of this analysis that employees, employees with disabilities, and employees with targeted disabilities are distributed between higher and lower levels of employment in roughly the same proportions as employees on the GS and SES scales. We also note that, based on an initial review of 2015 data, the number of new hires required to reach the goals would likely be lower than estimated above, resulting in lower costs overall. *See* Office of Pers. Mgmt., *Report on the Employment of Individuals with Disabilities in the Federal Executive Branch: Fiscal Year 2015,* 27 (2015), *https://www.opm.gov/policy-data-oversight/diversity-and-inclusion/reports/disability-report-fy2015.pdf.*

[138] The regulation does not require agencies to create positions or vacancies for persons with targeted disabilities; agencies may place individuals with targeted disabilities into existing vacancies.

[139] As noted in the NPRM, this is almost certainly an overestimate, because many individuals with disabilities do not require an accommodation. *See*

cost of each accommodation to be $500.00 per year.[140] Multiplying by the total number of estimated new hires (21,241) yields an estimated cost of $10,620,500.00 per year arising from the need to provide reasonable accommodations to new hires.

Third, the NPRM stated that proposed paragraph (d)(7)(i) would impose ongoing costs by encouraging agencies to hire employees who are entitled to PAS under paragraph (d)(5). We assumed that the percentage of individuals who require PAS among new hires with targeted disabilities would reflect the percentage of individuals requiring PAS among individuals who have targeted disabilities, are unemployed, and are looking for work. Based on the 2003 study, and on a 2006 study that investigated the prevalence of reported ''self-care difficulties'' among employed and unemployed individuals with disabilities,[141] we estimated that between 1.1% and 2% of individuals who have targeted disabilities, are unemployed, and looking for work require PAS. However, because neither study assessed the need for PAS among unemployed individuals,[142] we noted at the time that the estimates may be both under- and over-inclusive.

The Commission has refined its approach. We again assume that the percentage of individuals requiring PAS among new hires with targeted disabilities will reflect the percentage of those requiring PAS among individuals who have targeted disabilities, are unemployed, and looking for work. To determine the latter percentage, we first attempt to determine the number of individuals who have targeted disabilities, are unemployed, and are looking for work. We then attempt to determine the number of individuals who have targeted disabilities, are unemployed, are looking for work, and who require PAS. Finally, we compare the two numbers to arrive at a percentage.

To determine the number of individuals who have targeted disabilities, are unemployed, and are looking for work, we rely on census data. As discussed above, the census definition of ''disability'' matches neither the definition of ''disability'' nor the definition of ''targeted disability'' under paragraph (a). However, the census data are the best available to the Commission at this time. Further, because the census definition requires ''serious difficulty'' with an activity such as seeing or walking, it is likely that most people who meet the census definition have a targeted disability.[143] We therefore rely on census data to conclude for purposes of the economic analysis that there are approximately 1,282,377 individuals who have targeted disabilities, are unemployed, and are looking for work.[144]

To determine the number of individuals who have targeted disabilities, are unemployed, are looking for work, and who require PAS, we first note that there are approximately 1,257,000 individuals employed as personal assistance service providers throughout the country.[145] Assuming that each provider is assigned to a single individual, there are approximately 1,257,000 individuals who require PAS nationally, presumably because of a targeted disability.[146] Not all of these individuals are unemployed and looking for work, however—some are already employed, some are retired, some are below working age, and some do not participate in the workforce for other reasons.

The Commission is not aware of any data showing how many individuals who require PAS because of a targeted disability are unemployed and looking for work. To arrive at an approximation, we assume that the workforce participation and unemployment rates for such individuals reflect those of individuals who have disabilities that result in self-care difficulty more generally.[147] Research shows that roughly 8% of these individuals participate in the workforce (are either employed or unemployed and looking for work),[148] and that their unemployment rate is approximately 18.14%.[149] Thus, roughly 18.14% of 8%, or 1.4512%, of individuals with disabilities resulting in self-care difficulty are unemployed and looking for work. Applying this percentage to the estimated number of individuals who require PAS because of a targeted disability (1,257,000), we find that there are approximately 18,242 individuals who have a targeted disability, are unemployed, are looking for work, and who require PAS nationally.

Comparing the estimated number of individuals who have targeted disabilities, are unemployed, are looking for work, and who require PAS (18,242) to the estimated total number of individuals who have targeted disabilities, are unemployed, and are looking for work (1,282,377), we find that the former group represents 1.42% of the latter. Assuming, as discussed above, that this relationship will be

Job Accommodation Network, *Workplace Accommodations: Low Cost, High Impact* 3 (updated Sept. 1, 2014), *http://askjan.org/media/downloads/LowCostHighImpact.pdf.*

[140] *See id.* (finding that, if an accommodation has a cost, it will typically be approximately $500.00). This is also almost certainly an overestimate, because many individuals with disabilities do not require an accommodation; if an accommodation is required, it is likely to have no cost; and if it does have a cost, the cost does not necessarily recur. *See id.*

[141] Susan Stoddard et al., *Personal Assistance Services as a Workplace Accommodation,* 27 Work 363, 364 (2006).

[142] As explained, the 2003 study assesses the need for PAS among employed individuals with disabilities, and the 2006 study assesses the prevalence of reported self-care difficulties among unemployed individuals with disabilities.

[143] *See supra* note 99.

[144] *See Employment Status by Disability Status and Type (2014),* U.S. Census Bureau, *http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ACS_14_1YR_B18120&prodType=table* (last visited Dec. 21, 2016) (reporting that 1,282,377 individuals who meet the census definition of ''disability'' are noninstitutionalized, between the ages of 18 and 64, unemployed, and looking for work). Use of the census data will lead to an overestimate of costs. As noted in the NPRM, some individuals with targeted disabilities, such as individuals with epilepsy or certain psychiatric disabilities, likely do not fall into the census definition. Therefore, the census data are likely to underestimate the total number of individuals with targeted disabilities who are unemployed and looking for work, thereby making the proportion of such individuals needing PAS seem artificially large.

[145] *Personal Assistant Career, supra* note 131.

[146] We recognize that some individuals with disabilities may receive PAS from family members, rather than from persons who work as personal assistance service providers. We have no data, however, about how many such individuals receive PAS exclusively from family members, and consequently, whether and to what extent 1,257,000 individuals who require PAS underestimates the actual number. We believe that any difference would be small, however, since individuals who receive PAS from family members likely also receive PAS from individuals who are PAS providers.

[147] We suspect that the workforce participation rate for individuals who require PAS is significantly lower than the workforce participation rate for individuals who have disabilities that result in self-care difficulty. But again, because the Commission lacks more specific data, and also because lower workforce participation rates may be offset by higher unemployment rates for individuals who require PAS, we believe that the data on individuals who have disabilities that result in self-care difficulty are adequate for purposes of this analysis.

[148] Am. Insts. for Research, *One Size Does Not Fit All: A New Look at the Labor Force Participation of People with Disabilities* 4 (2015), *http://www.air.org/sites/default/files/downloads/report/Labor-Force-Participation-People-with-Disabilities-Yin-Sept-2015.pdf.*

[149] In 2014, the number of employed individuals who had disabilities that resulted in self-care difficulty was 548,700, and the number who were unemployed and looking for work was 121,600. The total number of such individuals who participated in the workforce in 2014 was therefore 670,300. The 121,600 who were unemployed and looking for work represent 18.14% of this total. All of these figures were obtained using the data retrieval tool at Cornell Univ., *American Community Survey (ACS) Employment Statistics,* Disability Statistics, *https://www.disabilitystatistics.org/reports/acs.cfm?statistic=3* (last visited July 7, 2016).

reflected in the estimated 16,979 new hires who have targeted disabilities, we conclude that 241 new hires will require PAS.

To generate an estimate of the associated costs, we rely on the estimated per-person costs for providing PAS calculated in the section on paragraph (d)(5) above. Multiplying 241 by the low estimate of the associated costs ($21,008.00) yields a total estimated cost of $5,062,928.00 per year, and multiplying by the high estimate of the associated costs ($65,519.67) yields a total estimated cost of $15,790,240.47 per year.

In summary, the estimated annual costs arising from paragraph (d)(7) will be $44,341.92 (the estimated cost of determining whether goals have been met) plus $10,620,500.00 (the estimated cost of providing reasonable accommodations to individuals hired pursuant to the goals) plus between $5,062,928.00 and $15,790,240.47 (the estimated cost of providing PAS to individuals hired pursuant to the goals), for a total estimated annual cost of between $15,727,769.92 and $26,455,082.39.

Paragraphs (d)(8)(iii) and (d)(8)(iv)

The requirements of proposed paragraphs (d)(8)(iii) and (d)(8)(iv)—to keep records of all employees hired under the Schedule A hiring authority for persons with certain disabilities, to calculate the number of such employees who have been converted to career or career-conditional appointment, and to calculate the number of such employees who have been terminated prior to conversion—were adopted unchanged in the Final Rule. The NPRM estimated that it would take each agency 2 hours to gather the required data, to perform the required calculations, and to create and maintain the associated records. Multiplying by the number of covered agencies yielded an overall estimate of 436 burden hours per year.

One commenter stated that the estimate is too low for small agencies that do not have ''automated [human resources (HR)] systems.'' The commenter did not state how many such agencies there are. For purposes of this analysis, the Commission estimates for purposes of this analysis that 20 agencies lack an automated HR system.

The commenter also did not provide an estimate of the amount of time that such agencies would need to perform the required tasks, except to say that the ''guidepost . . . is the amount of time it takes to manually prepare the MD–715 report.'' We disagree that it would take agencies the same amount of time to meet the requirements of (d)(8)(iii) and (d)(8)(iv) as it would take them to prepare an entire MD–715 report. The commenter is reminded that, to the extent paragraph (d)(8) requires agencies to maintain the same records that are required under MD–715, it imposes no new burden. The (d)(8) requirements exceed those of MD–715 only insofar as they require records relating to the Schedule A hiring authority for persons with certain disabilities. We also note that the associated burden is likely to be proportional to the size of the agency—if an agency is small enough that it lacks an automated HR system, it is not likely to have appointed an overwhelmingly large number of individuals under the Schedule A hiring authority for persons with certain disabilities.

Nevertheless, the Commission estimates for purposes of this analysis that each of the estimated 20 agencies lacking automated HR systems will need to spend an additional 10 hours performing the required tasks, for a total of 200 additional burden hours. Adding this to the previous estimate yields a total estimate of 636 burden hours. Multiplying by the hourly compensation rate of $66.78 yields a total estimated cost for paragraphs (d)(8)(iii) and (d)(8)(iv) of $42,472.08 per year.

Economic Benefits

As stated in the NPRM, the Rule is also expected to have positive economic effects by bringing a greater number of individuals with disabilities into the workforce.[150] Because individuals who require PAS throughout the day and who are looking for work most likely rely on government benefits to meet the significant cost of hiring a personal assistant, the NPRM assumed that each individual who receives PAS from an agency would otherwise have relied on Social Security and Supplemental Security Income benefits to pay for those services. Research indicated that, for every individual with a disability who transitions from receipt of benefits to gainful employment, the federal government saves approximately $19,380.00 in paid benefits, and gains approximately $8,079.00 in tax revenue, on an annual basis,[151] for a total annual benefit of $27,459.00 per individual. The Commission received no objections to this analysis. Multiplying by the revised estimate of the number of new hires who are expected to require PAS (241) yields a total estimated economic benefit of $6,617,619.00 per year.

Non-Economic Effects

The NPRM also noted that, in addition to economic effects, the proposed rule would have a variety of qualitative and dignitary benefits, all of which further values identified in Executive Order 13563 such as equity, human dignity, and fairness. Most significantly, the NPRM stated that the rule would increase the number of hiring and advancement opportunities available to individuals with disabilities by making them better aware of federal job openings. Research demonstrates that employment is an important determinant of both perceived quality of life and health status among individuals with disabilities.[152] In addition, the NPRM stated that the proposed rule would have qualitative and dignitary benefits, including—

- promotion of human dignity and self-respect, and diminished feelings of exclusion and humiliation;
- reduced prevalence of disability-based stereotypes and associated stigma;
- increased diversity, understanding, and fairness in the workplace; and
- improved interactions with coworkers and workplace morale.

All of these considerations apply equally well to the Final Rule. The Rule is also expected to prevent disability-based employment discrimination by making job applicants, employees, and agency management better aware of the protections against discrimination provided by Section 501.

Summary

In summary, the Commission estimates that the Rule as a whole will have a one-time initial cost to the federal government of approximately $145,580.40, an annual cost to the federal government of between $23,151,538.70 and $70,954,568.10, and an annual economic benefit to the federal government of $6,617,619.00. The Rule is also expected to have a variety of non-monetizable qualitative and dignitary benefits for individuals with disabilities and individuals with targeted disabilities.

Regulatory Flexibility Act

The Commission certifies under 5 U.S.C. 605(b) that this Rule will not have a significant economic impact on

[150] *See, e.g.,* Jean P. Hall, et al., *Employment as a Health Determinant for Working-Age, Dually-Eligible People with Disabilities,* 6 Disability & Health J. 100 (2013) (finding that employment of individuals with disabilities is associated with lower per-person, per-month Medicaid expenditures).

[151] *See* Douglas Klayman, *et al., supra* note 127, at 17.

[152] *See, e.g.,* Jean P. Hall, *et al., supra* note 150, at 100 (finding that, among individuals who are eligible for both Medicaid and Medicare, paid employment is associated with significantly better quality of life, self-reported health status, and health behaviors).

a substantial number of small entities, because it applies exclusively to employees and agencies of the federal government. For this reason, a regulatory flexibility analysis is not required.

Unfunded Mandates Reform Act of 1995

This Final Rule will not result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This action pertains to agency management, personnel and organization and does not substantially affect the rights or obligations of non-agency parties and, accordingly, is not a ''rule'' as that term is used by the Congressional Review Act (Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996. Therefore, the reporting requirement of 5 U.S.C. 801 does not apply.

List of Subjects in 29 CFR Part 1614

Administrative practice and procedure, Age discrimination, Equal employment opportunity, Government employees, Individuals with disabilities, Race discrimination, Religious discrimination, Sex discrimination.

For the reasons set forth in the preamble, the Equal Employment Opportunity Commission amends 29 CFR part 1614 as follows:

PART 1614—FEDERAL SECTOR EQUAL EMPLOYMENT OPPORTUNITY

■ 1. The authority citation for part 1614 continues to read as follows:

Authority: 29 U.S.C. 206(d), 633a, 791 and 794a; 42 U.S.C. 2000e–16 and 2000FF–6(e); E.O. 10577, 3 CFR, 1954–1958 Comp., p. 218; E.O. 11222, 3 CFR, 1964–1965 Comp., p. 306; E.O. 11478, 3 CFR, 1969 Comp., p. 133; E.O. 12106, 3 CFR, 1978 Comp., p. 263; Reorg. Plan No. 1 of 1978, 3 CFR, 1978 Comp., p. 321.

■ 2. Revise § 1614.203 to read as follows:

§ 1614.203 Rehabilitation Act.

(a) *Definitions.* The following definitions apply for purposes of this section:

(1) The term *ADA* means title I of the Americans with Disabilities Act of 1990, as amended (42 U.S.C. 12101 through 12117), title V of the Americans with Disabilities Act, as amended (42 U.S.C. 12201 through 12213), as it applies to employment, and the regulations of the Equal Employment Opportunity Commission implementing titles I and V of the ADA at part 1630 of this chapter.

(2) The term *disability* means disability as defined under § 1630.2(g) through (l) of this chapter.

(3) The term *hiring authority that takes disability into account* means a hiring authority that permits an agency to consider disability status during the hiring process, including the hiring authority for individuals with intellectual disabilities, severe physical disabilities, or psychiatric disabilities, as set forth at 5 CFR 213.3102(u); the Veterans' Recruitment Appointment authority, as set forth at 5 CFR part 307; and the 30% or More Disabled Veteran authority, as set forth at 5 CFR 316.302(b)(4), 316.402(b)(4).

(4) The term *personal assistance service provider* means an employee or independent contractor whose primary job functions include provision of personal assistance services.

(5) The term *personal assistance services* means assistance with performing activities of daily living that an individual would typically perform if he or she did not have a disability, and that is not otherwise required as a reasonable accommodation, including, for example, assistance with removing and putting on clothing, eating, and using the restroom.

(6) The term *Plan* means an affirmative action plan for the hiring, placement, and advancement of individuals with disabilities, as required under 29 U.S.C. 791(b).

(7) The term *Schedule A hiring authority for persons with certain disabilities* means the hiring authority for individuals with intellectual disabilities, severe physical disabilities, or psychiatric disabilities, as set forth at 5 CFR 213.3102(u).

(8) The term *Section 501* means section 501 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 791).

(9) The term *targeted disability* means a disability that is designated as a ''targeted disability or health condition'' on the Office of Personnel Management's Standard Form 256 or that falls under one of the first 12 categories of disability listed in Part A of question 5 of the Equal Employment Opportunity Commission's Demographic Information on Applicants form.

(10) The term *undue hardship* has the meaning set forth in part 1630 of this chapter.

(b) *Nondiscrimination.* Federal agencies shall not discriminate on the basis of disability in regard to the hiring, advancement or discharge of employees, employee compensation, job training, or other terms, conditions, and privileges of employment. The standards used to determine whether Section 501 has been violated in a complaint alleging employment discrimination under this part shall be the standards applied under the ADA.

(c) *Model employer.* The Federal Government shall be a model employer of individuals with disabilities. Agencies shall give full consideration to the hiring, advancement, and retention of qualified individuals with disabilities in the federal workforce. Agencies shall also take affirmative action to promote the recruitment, hiring, and advancement of qualified individuals with disabilities, with the goal of eliminating under-representation of individuals with disabilities in the federal workforce.

(d) *Affirmative action plan.* Pursuant to 29 U.S.C. 791, each agency shall adopt and implement a Plan that provides sufficient assurances, procedures, and commitments to provide adequate hiring, placement, and advancement opportunities for individuals with disabilities at all levels of federal employment. An agency fails to satisfy this requirement unless it has adopted and implemented a Plan that meets the following criteria:

(1) *Disability hiring and advancement program*—(i) *Recruitment.* The Plan shall require the agency to take specific steps to ensure that a broad range of individuals with disabilities, including individuals with targeted disabilities, will be aware of and be encouraged to apply for job vacancies when eligible. Such steps shall include, at a minimum—

(A) Use of programs and resources that identify job applicants with disabilities, including individuals with targeted disabilities, who are eligible to be appointed under a hiring authority that takes disability into account, consistent with applicable OPM regulations, examples of which could include programs that provide the qualifications necessary for particular positions within the agency to individuals with disabilities, databases of individuals with disabilities who previously applied to the agency but were not hired for the positions they applied for, and training and internship programs that lead directly to employment for individuals with disabilities; and

(B) Establishment and maintenance of contacts (which may include formal agreements) with organizations that specialize in providing assistance to individuals with disabilities, including

individuals with targeted disabilities, in securing and maintaining employment, such as American Job Centers, State Vocational Rehabilitation Agencies, the Veterans' Vocational Rehabilitation and Employment Program, Centers for Independent Living, and Employment Network service providers.

(ii) *Application process.* The Plan shall ensure that the agency has designated sufficient staff to handle any disability-related issues that arise during the application and selection processes, and shall require the agency to provide such individuals with sufficient training, support, and other resources to carry out their responsibilities under this section. Such responsibilities shall include, at a minimum—

(A) Ensuring that disability-related questions from members of the public regarding the agency's application and selection processes are answered promptly and correctly, including questions about reasonable accommodations needed by job applicants during the application and selection processes and questions about how individuals may apply for appointment under hiring authorities that take disability into account;

(B) Processing requests for reasonable accommodations needed by job applicants during the application and placement processes, and ensuring that the agency provides such accommodations when required to do so under the standards set forth in part 1630 of this chapter;

(C) Accepting applications for appointment under hiring authorities that take disability into account, consistent with applicable OPM regulations;

(D) If an individual has applied for appointment to a particular position under a hiring authority that takes disability into account, determining whether the individual is eligible for appointment under such authority, and, if so, forwarding the individual's application to the relevant hiring officials with an explanation of how and when the individual may be appointed, consistent with all applicable laws;

(E) Overseeing any other agency programs designed to increase hiring of individuals with disabilities.

(iii) *Advancement program.* The Plan shall require the agency to take specific steps to ensure that current employees with disabilities have sufficient opportunities for advancement. Such steps may include, for example—

(A) Efforts to ensure that employees with disabilities are informed of and have opportunities to enroll in relevant training, including management training when eligible;

(B) Development or maintenance of a mentoring program for employees with disabilities; and

(C) Administration of exit interviews that include questions on how the agency could improve the recruitment, hiring, inclusion, and advancement of individuals with disabilities.

(2) *Disability anti-harassment policy.* The Plan shall require the agency to state specifically in its anti-harassment policy that harassment based on disability is prohibited, and to include in its training materials examples of the types of conduct that would constitute disability-based harassment.

(3) *Reasonable accommodation*—(i) *Procedures.* The Plan shall require the agency to adopt, post on its public Web site, and make available to all job applicants and employees in written and accessible formats, reasonable accommodation procedures that are easy to understand and that, at a minimum—

(A) Explain relevant terms such as ''reasonable accommodation,'' ''disability,'' ''interactive process,'' ''qualified,'' and ''undue hardship,'' consistent with applicable statutory and regulatory definitions, using examples where appropriate;

(B) Explain that reassignment to a vacant position for which an employee is qualified, and not just permission to compete for such position, is a reasonable accommodation, and that the agency must consider providing reassignment to a vacant position as a reasonable accommodation when it determines that no other reasonable accommodation will permit an employee with a disability to perform the essential functions of his or her current position;

(C) Notify supervisors and other relevant agency employees how and where they are to conduct searches for available vacancies when considering reassignment as a reasonable accommodation;

(D) Explain that an individual may request a reasonable accommodation orally or in writing at any time, need not fill out any specific form in order for the interactive process to begin, and need not have a particular accommodation in mind before making a request, and that the request may be made to a supervisor or manager in the individual's chain of command, the office designated by the agency to oversee the reasonable accommodation process, any agency employee connected with the application process, or any other individual designated by the agency to accept such requests;

(E) Include any forms the agency uses in connection with a reasonable accommodation request as attachments, and indicate that such forms are available in alternative formats that are accessible to people with disabilities;

(F) Describe the agency's process for determining whether to provide a reasonable accommodation, including the interactive process, and provide contact information for the individual or program office from whom requesters will receive a final decision;

(G) Provide guidance to supervisors on how to recognize requests for reasonable accommodation;

(H) Require that decision makers communicate, early in the interactive process and periodically throughout the process, with individuals who have requested a reasonable accommodation;

(I) Explain when the agency may require an individual who requests a reasonable accommodation to provide medical information that is sufficient to explain the nature of the individual's disability, his or her need for reasonable accommodation, and how the requested accommodation, if any, will assist the individual to apply for a job, perform the essential functions of a job, or enjoy the benefits and privileges of the workplace;

(J) Explain the agency's right to request relevant supplemental medical information if the information submitted by the requester is insufficient for the purposes specified in paragraph (d)(3)(i)(I) of this section;

(K) Explain the agency's right to have medical information reviewed by a medical expert of the agency's choosing at the agency's expense;

(L) Explain the agency's obligation to keep medical information confidential, in accordance with applicable laws and regulations, and the limited circumstances under which such information may be disclosed;

(M) Designate the maximum amount of time the agency has, absent extenuating circumstances, to either provide a requested accommodation or deny the request, and explain that the time limit begins to run when the accommodation is first requested;

(N) Explain that the agency will not be expected to adhere to its usual timelines if an individual's health professional fails to provide needed documentation in a timely manner;

(O) Explain that, where a particular reasonable accommodation can be provided in less than the maximum amount of time permitted under paragraph (d)(3)(i)(M) of this section, failure to provide the accommodation in a prompt manner may result in a violation of the Rehabilitation Act;

(P) Provide for expedited processing of requests for reasonable accommodations that are needed sooner than the maximum allowable time frame permitted under paragraph (d)(3)(i)(M) of this section;

(Q) Explain that, when all the facts and circumstances known to the agency make it reasonably likely that an individual will be entitled to a reasonable accommodation, but the accommodation cannot be provided immediately, the agency shall provide an interim accommodation that allows the individual to perform some or all of the essential functions of his or her job, if it is possible to do so without imposing undue hardship on the agency;

(R) Inform applicants and employees how they may track the processing of requests for reasonable accommodation;

(S) Explain that, where there is a delay in either processing a request for or providing a reasonable accommodation, the agency must notify the individual of the reason for the delay, including any extenuating circumstances that justify the delay;

(T) Explain that individuals who have been denied reasonable accommodations have the right to file complaints pursuant to 29 CFR 1614.106;

(U) Encourage the use of voluntary informal dispute resolution processes that individuals may use to obtain prompt reconsideration of denied requests for reasonable accommodation;

(V) Provide that the agency shall give the requester a notice consistent with the requirements of paragraph (d)(3)(iii) of this section at the time a request for reasonable accommodation is denied; and

(W) Provide information on how to access additional information regarding reasonable accommodation, including, at a minimum, Commission guidance and technical assistance documents.

(ii) *Cost of accommodations.* The Plan shall require the agency to take specific steps to ensure that requests for reasonable accommodation are not denied for reasons of cost, and that individuals with disabilities are not excluded from employment due to the anticipated cost of a reasonable accommodation, if the resources available to the agency as a whole, excluding those designated by statute for a specific purpose that does not include reasonable accommodation, would enable it to provide an effective reasonable accommodation without undue hardship. Such steps shall be reasonably designed to, at a minimum—

(A) Ensure that anyone who is authorized to grant or deny requests for reasonable accommodation or to make hiring decisions is aware that, pursuant to the regulations implementing the undue hardship defense at 29 CFR part 1630, all resources available to the agency as a whole, excluding those designated by statute for a specific purpose that does not include reasonable accommodation, are considered when determining whether a denial of reasonable accommodation based on cost is lawful; and

(B) Ensure that anyone authorized to grant or deny requests for reasonable accommodation or to make hiring decisions is aware of, and knows how to arrange for the use of, agency resources available to provide the accommodation, including any centralized fund the agency may have for that purpose.

(iii) *Notification of basis for denial.* The Plan shall require the agency to provide a job applicant or employee who is denied a reasonable accommodation with a written notice at the time of the denial, in an accessible format when requested, that—

(A) Explains the reasons for the denial and notifies the job applicant or employee of any available internal appeal or informal dispute resolution processes;

(B) Informs the job applicant or employee of the right to challenge the denial by filing a complaint of discrimination under this part;

(C) Provides instructions on how to file such a complaint; and

(D) Explains that, pursuant to 29 CFR 1614.105, the right to file a complaint will be lost unless the job applicant or employee initiates contact with an EEO Counselor within 45 days of the denial, regardless of whether the applicant or employee participates in an informal dispute resolution process.

(4) *Accessibility of facilities and technology*—(i) *Notice of rights.* The Plan shall require the agency to adopt, post on its public Web site, and make available to all employees in written and accessible formats, a notice that—

(A) Explains their rights under Section 508 of the Rehabilitation Act of 1973, 29 U.S.C. 794d, concerning the accessibility of agency technology, and the Architectural Barriers Act, 42 U.S.C. 4151 through 4157, concerning the accessibility of agency building and facilities;

(B) Provides contact information for an agency employee who is responsible for ensuring the physical accessibility of the agency's facilities under the Architectural Barriers Act of 1968, and an agency employee who is responsible for ensuring that the electronic and information technology purchased, maintained, or used by the agency is readily accessible to, and usable by, individuals with disabilities, as required by Section 508 of the Rehabilitation Act of 1973; and

(C) Provides instructions on how to file complaints alleging violations of the accessibility requirements of the Architectural Barriers Act of 1968 and Section 508 of the Rehabilitation Act of 1973.

(ii) *Assistance with filing complaints at other agencies.* If an agency's investigation of a complaint filed under Section 508 of the Rehabilitation Act of 1973 or the Architectural Barriers Act of 1968 shows that a different entity is responsible for the alleged violation, the Plan shall require the agency to inform the individual who filed the complaint where he or she may file a complaint against the other entity, if possible.

(5) *Personal assistance services allowing employees to participate in the workplace*— (i) *Obligation to provide personal assistance services.* The Plan shall require the agency to provide an employee with, in addition to professional services required as a reasonable accommodation under the standards set forth in part 1630 of this chapter, personal assistance services during work hours and job-related travel if—

(A) The employee requires such services because of a targeted disability;

(B) Provision of such services would, together with any reasonable accommodations required under the standards set forth in part 1630 of this chapter, enable the employee to perform the essential functions of his or her position; and

(C) Provision of such services would not impose undue hardship on the agency.

(ii) *Service providers.* The Plan shall state that personal assistance services required under paragraph (d)(5)(i) of this section must be performed by a personal assistance service provider. The Plan may permit the agency to require personal assistance service providers to provide personal assistance services to more than one individual. The Plan may also permit the agency to require personal assistance service providers to perform tasks unrelated to personal assistance services, but only to the extent that doing so does not result in failure to provide personal assistance services required under paragraph (d)(5)(i) of this section in a timely manner.

(iii) *No adverse action.* The Plan shall prohibit the agency from taking adverse actions against job applicants or employees based on their need for, or

perceived need for, personal assistance services.

(iv) *Selection of personal assistance service providers.* The Plan shall require the agency, when selecting someone who will provide personal assistance services to a single individual, to give primary consideration to the individual's preferences to the extent permitted by law.

(v) *Written procedures.* The Plan shall require the agency to adopt, post on its public Web site, and make available to all job applicants and employees in written and accessible formats, procedures for processing requests for personal assistance services. An agency may satisfy this requirement by stating, in the procedures required under paragraph (d)(3)(i) of this section, that the process for requesting personal assistance services, the process for determining whether such services are required, and the agency's right to deny such requests when provision of the services would pose an undue hardship, are the same as for reasonable accommodations.

(6) *Utilization analysis*—(i) *Current utilization.* The Plan shall require the agency to perform a workforce analysis annually to determine the percentage of its employees at each grade and salary level who have disabilities, and the percentage of its employees at each grade and salary level who have targeted disabilities.

(ii) *Source of data.* For purposes of the analysis required under paragraph (d)(6)(i) of this section, an employee may be classified as an individual with a disability or an individual with a targeted disability on the basis of—

(A) The individual's self-identification as an individual with a disability or an individual with a targeted disability on a form, including but not limited to the Office of Personnel Management's Standard Form 256, which states that the information collected will be kept confidential and used only for statistical purposes, and that completion of the form is voluntary;

(B) Records relating to the individual's appointment under a hiring authority that takes disability into account, if applicable; and

(C) Records relating to the individual's requests for reasonable accommodation, if any.

(iii) *Data accuracy.* The Plan shall require the agency to take steps to ensure that data collected pursuant to paragraph (d)(6)(i) of this section are accurate.

(7) *Goals*—(i) *Adoption.* The Plan shall commit the agency to the goal of ensuring that—

(A) No less than 12% of employees at the GS–11 level and above, together with employees who are not paid under the General Schedule but who have salaries equal to or greater than employees at the GS–11, step 1 level in the Washington, DC locality, are individuals with disabilities;

(B) No less than 12% of employees at the GS–10 level and below, together with employees who are not paid under the General Schedule but who have salaries less than employees at the GS–11, step 1 level in the Washington, DC locality, are individuals with disabilities;

(C) No less than 2% of employees at the GS–11 level and above, together with employees who are not paid under the General Schedule but who have salaries equal to or greater than employees at the GS–11, step 1 level in the Washington, DC locality, are individuals with targeted disabilities; and

(D) No less than 2% of employees at the GS–10 level and below, together with employees who are not paid under the General Schedule but who have salaries less than employees at the GS–11, step 1 level in the Washington, DC locality, are individuals with targeted disabilities.

(ii) *Progression toward goals.* The Plan shall require the agency to take specific steps that are reasonably designed to gradually increase the number of persons with disabilities or targeted disabilities employed at the agency until it meets the goals established pursuant to paragraph (d)(7)(i) of this section. Examples of such steps include, but are not limited to—

(A) Increased use of hiring authorities that take disability into account to hire or promote individuals with disabilities or targeted disabilities, as applicable;

(B) To the extent permitted by applicable laws, consideration of disability or targeted disability status as a positive factor in hiring, promotion, or assignment decisions;

(C) Disability-related training and education campaigns for all employees in the agency;

(D) Additional outreach or recruitment efforts;

(E) Increased efforts to hire and retain individuals who require supported employment because of a disability, who have retained the services of a job coach at their own expense or at the expense of a third party, and who may be given permission to use the job coach during work hours as a reasonable accommodation without imposing undue hardship on the agency; and

(F) Adoption of training, mentoring, or internship programs for individuals with disabilities.

(8) *Recordkeeping.* The Plan shall require the agency to keep records that it may use to determine whether it is complying with the nondiscrimination and affirmative action requirements imposed under Section 501, and to make such records available to the Commission upon the Commission's request, including, at a minimum, records of—

(i) The number of job applications received from individuals with disabilities, and the number of individuals with disabilities who were hired by the agency;

(ii) The number of job applications received from individuals with targeted disabilities, and the number of individuals with targeted disabilities who were hired by the agency;

(iii) All rescissions of conditional job offers, demotions, and terminations taken against applicants or employees as a result of medical examinations or inquiries;

(iv) All agency employees hired under the Schedule A hiring authority for persons with certain disabilities, and each such employee's date of hire, entering grade level, probationary status, and current grade level;

(v) The number of employees appointed under the Schedule A hiring authority for persons with certain disabilities who have been converted to career or career-conditional appointments in the competitive service, and the number of such employees who were terminated prior to being converted to a career or career-conditional appointment in the competitive service; and

(vi) Details about each request for reasonable accommodation including, at a minimum—

(A) The specific reasonable accommodation requested, if any;

(B) The job (occupational series, grade level, and agency component) sought by the requesting applicant or held by the requesting employee;

(C) Whether the accommodation was needed to apply for a job, perform the essential functions of a job, or enjoy the benefits and privileges of employment;

(D) Whether the request was granted (which may include an accommodation different from the one requested) or denied;

(E) The identity of the deciding official;

(F) If denied, the basis for such denial; and

(G) The number of days taken to process the request.

(e) *Reporting*—(1) *Submission to the Commission.* On an annual basis, each federal agency shall submit to the Commission for approval, at such time and in such manner as the Commission deems appropriate—

(i) A copy of its current Plan;

(ii) The results of the two most recent workforce analyses performed pursuant to paragraph (d)(6) of this section showing the percentage of employees with disabilities and employees with targeted disabilities in each of the designated pay groups;

(iii) The number of individuals appointed to positions within the agency under the Schedule A hiring authority for persons with certain disabilities during the previous year, and the total number of employees whose employment at the agency began by appointment under the Schedule A hiring authority for persons with certain disabilities; and

(iv) A list of changes made to the Plan since the prior submission, if any, and an explanation of why those changes were made.

(2) *Availability to the public.* Each agency shall make the information submitted to the Commission pursuant to paragraph (e)(1) of this section available to the public by, at a minimum, posting a copy of the submission on its public Web site and providing a means by which members of the public may request copies of the submission in accessible formats.

(f) *Commission approval and disapproval*—(1) *Basis for approval.* If the Commission determines that an agency has adopted and implemented a Plan that meets the requirements set forth in paragraph (d) of this section, the Commission shall approve the Plan.

(2) *Basis for disapproval.* If the Commission determines that an agency has failed to adopt and implement a Plan that meets the requirements set forth in paragraph (d) of this section, the Commission shall disapprove the Plan as required by 29 U.S.C. 791(b). Failure to achieve a goal set forth in paragraph (d)(7)(i) of this section, by itself, is not grounds for disapproval unless the Plan fails to require the agency to take specific steps that are reasonably designed to achieve the goal.

■ 3. Amend § 1614.601 by revising paragraph (f) to read as follows:

§ 1614.601 EEO group statistics.

* * * * *

(f) Data on disabilities shall be collected using a method permitted under § 1614.203(d)(6)(ii) and § 1614.203(d)(6)(iii).

* * * * *

Dated: December 21, 2016.

For the Commission.

Peggy R. Mastroianni,

Legal Counsel.

[FR Doc. 2016–31397 Filed 12–30–16; 8:45 am]

BILLING CODE 6570–01–P

FEDERAL REGISTER

Vol. 82 Tuesday,

No. 1 January 3, 2017

Part IV

Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Part 217

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to Waterfront Construction; Proposed Rule

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 217

[Docket No. 160830798–6798–01]

RIN 0648–BG32

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to Waterfront Construction

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS has received a request from the U.S. Navy (Navy) for authorization to take marine mammals incidental to conducting waterfront construction at Naval Submarine Base Kings Bay, GA, over the course of five years (2017–2022). As required by the Marine Mammal Protection Act (MMPA), NMFS is proposing regulations to govern that take, and requests comments on the proposed regulations.

DATES: Comments and information must be received no later than February 2, 2017.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2016–0161, by any of the following methods:

• *Electronic submission:* Submit all electronic public comments via the federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2016-0161,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.

• *Mail:* Submit written comments to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910.

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

FOR FURTHER INFORMATION CONTACT: Ben Laws, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Availability

A copy of Navy's application and any supporting documents, as well as a list of the references cited in this document, may be obtained online at: *www.nmfs.noaa.gov/pr/permits/incidental/construction.htm.* In case of problems accessing these documents, please call the contact listed above (see **FOR FURTHER INFORMATION CONTACT**).

National Environmental Policy Act (NEPA)

The Navy is preparing an Environmental Assessment (EA) to consider the direct, indirect and cumulative effects to the human environment resulting from the waterfront construction activities. NMFS has reviewed the draft EA and believes it is appropriate to adopt the EA in order to assess the impacts to the human environment of issuance of regulations and subsequent Letters of Authorization (LOAs) to the Navy and subsequently sign our own FONSI. Information in the Navy's application, the Navy's EA, and this notice collectively provide the environmental information related to proposed issuance of these regulations for public review and comment. All documents are available at the aforementioned Web site. We will review all comments submitted in response to this notice as we complete the NEPA processes, including a final decision of whether to adopt the Navy's EA and sign a FONSI, prior to a final decision on the incidental take authorization request.

Purpose and Need for Regulatory Action

This proposed rule, to be issued under the authority of the Marine Mammal Protection Act (MMPA) (16 U.S.C. 1361 *et seq.*), would establish a framework for authorizing the take of marine mammals incidental to the Navy's waterfront construction activities at Naval Submarine Base Kings Bay, GA (NSB Kings Bay). The Navy proposes to repair (including direct repairs and repairs by component replacement) in-water structures at NSB Kings Bay, construct a new Transit Protection System Operational Support Facility, and extend the existing Layberth Pier in order to (1) address critical damage and mission and safety requirements, (2) limit further deterioration and increase the useful life of the structures, and (3) upgrade infrastructure to meet requirements of new submarine technology. Construction will include use of impact and vibratory pile driving, including installation and removal of steel, concrete, composite, and timber piles.

We received an application from the Navy requesting five-year regulations and authorization to take bottlenose dolphins. Take would occur by Level B harassment incidental to impact and vibratory pile installation and removal. The regulations would be valid from 2017 to 2022. Please see the ''Background'' section below for definitions of harassment.

Legal Authority for the Proposed Action

Section 101(a)(5)(A) of the MMPA (16 U.S.C. 1371(a)(5)(A)) directs the Secretary of Commerce to allow, upon request, the incidental, but not intentional taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region for up to five years if, after notice and public comment, the agency makes certain findings and issues regulations that set forth permissible methods of taking pursuant to that activity, as well as monitoring and reporting requirements. Section 101(a)(5)(A) of the MMPA and the implementing regulations at 50 CFR part 216, subpart I provide the legal basis for issuing this proposed rule containing five-year regulations, and for any subsequent LOAs. As directed by this legal authority, this proposed rule contains mitigation, monitoring, and reporting requirements.

Summary of Major Provisions Within the Proposed Rule

Following is a summary of the major provisions of this proposed rule regarding Navy waterfront construction activities. We have preliminarily determined that the Navy's adherence to the proposed mitigation, monitoring, and reporting measures described below would achieve the least practicable adverse impact on the affected marine mammals. These measures include:

• Required monitoring of the waterfront construction areas to detect the presence of marine mammals before beginning construction activities.

• Shutdown of construction activities under certain circumstances to avoid injury of marine mammals.

• Soft start for impact pile driving to allow marine mammals the opportunity

to leave the area prior to beginning impact pile driving at full power.

Background

Paragraphs 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1371 (a)(5)(A) and (D)) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.''

Except with respect to certain activities not pertinent here, section 3 of the MMPA (16 U.S.C. 1362) defines ''harassment'' as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Summary of Request

On January 19, 2016, we received an adequate and complete request from Navy for authorization to take marine mammals incidental to waterfront construction activities. We received an initial draft of the request on August 27, 2015, followed by revised drafts on November 6 and December 2, 2015. On February 17, 2016 (81 FR 8048), we published a notice of receipt of Navy's application in the **Federal Register**, requesting comments and information related to the request for 30 days. We did not receive any comments. The Navy provided an interim revised draft incorporating minor revisions on March 8, 2016.

The Navy proposes to repair in-water structures at NSB Kings Bay, as well as to construct new facilities and modify existing facilities. These repairs, upgrades, and new construction would include use of impact and vibratory pile driving, including installation and removal of steel, concrete, composite, and timber piles. Hereafter (unless otherwise specified or detailed) we use the term ''pile driving'' to refer to both pile installation and pile removal. The use of both vibratory and impact pile driving is expected to produce underwater sound at levels that have the potential to result in behavioral harassment of marine mammals. Only the bottlenose dolphin (*Tursiops truncatus truncatus*) is expected to be present. The requested regulations would be valid for five years, from July 12, 2017, through July 11, 2022.

Description of the Specified Activity

Overview

NSB Kings Bay is the Navy's east coast home port for ballistic missile nuclear submarines supporting the Trident II (D–5) missile. NSB Kings Bay manages, maintains, and operates Trident ballistic missile (SSBN) and guided missile (SSGN) submarines, Trident II D–5 and Tomahawk Land Attack Missiles and systems, and infrastructure and quality of life facilities and programs. In 2010, the Navy found that conditions of water-based support facilities varied widely from good to seriously deteriorated. Continuous monitoring of these conditions by Navy at NSB Kings Bay has confirmed the advanced deterioration and critical nature of some issues that pose operational and safety risks. Additionally, other areas of initial deterioration were identified which require remedy in order to maintain the useful life of existing structures. Damage observed includes deteriorated concrete piles, pile caps, and deck components (cracked, spalled, delaminated, exposed/corroded internal reinforcing steel structures); marine pest (marine wood borer) damage on wooden piles; broken or unmaintained mooring fittings; and corrosion on steel piles and pile caps. In some cases, it is more cost effective to demolish older structures that are deteriorated and not well configured to fit existing and upcoming assets and replace them with new structures that are specifically designed to meet new mission requirements.

To ensure the Navy can continue its mission of supporting the Fleet Ballistic Missile System and Trident Submarine Program, the Navy proposes to repair (including direct repairs and repairs by component replacement) in-water structures at NSB Kings Bay, construct a new Transit Protection System Operational Support Facility, and extend the existing Layberth Pier. These repairs, upgrades, and new construction would (1) address critical damage and mission and safety requirements, (2) limit further deterioration and increase the useful life of the structures, and (3) upgrade infrastructure to meet requirements of new submarine technology. Construction will include use of impact and vibratory pile driving, including installation and removal of steel, concrete, composite, and timber piles. The specified activity is comprised of six distinct projects, four of which are comprised of multiple smaller projects. These projects and components are summarized in Table 1. Please see Figure 1–2 in the Navy's application for locations of facilities referred to in Table 1.

TABLE 1—SUMMARY OF PROPOSED WATERFRONT CONSTRUCTION PROJECTS

Project ID	Descriptor	Summary
Project 1: Port Operations Waterfront Facilities Repair		
1A	Tug Pier	Repair concrete structural piles, pile caps, utility cover grates, headwall, mooring support and hardware, and deck undersides; replace wooden fender piles with concrete piles; and modify the fender system on the south side of access pier.
1B	General Access Pier Crab Island	Install new guide piles, and repair brow and handrails.

TABLE 1—SUMMARY OF PROPOSED WATERFRONT CONSTRUCTION PROJECTS—Continued

Project ID	Descriptor	Summary
Project 2: Unspecified Minor Construction Layberth Fender Pile Modification		
2	Unspecified Minor Construction Layberth Fender Pile Modification P661 Project.	Install additional fender piles to shorten the distance between existing piles and provide the required support for hydro-pneumatic fenders.
Project 3: Waterfront Repair and Replacement Maintenance Program		
3A	Explosive Handling Wharf #2 Pier w/Capstans (7).	Repair high-density polyethylene (HDPE) fender pile wraps, sacrificial anodes attached to the steel fender piles, steel safety ladders and treated timber bracing; repair or replace various pile caps, piles, and mooring foundations; and clean and repaint mooring fittings and two steel guide pipe piles on the diver's float.
3B	(Dry Dock) Interface Wharf	Replace timber fender bearing strips and wales, repair concrete deck, bullrail, edge beams, and mooring foundations; and repair, paint and recoat cathodic protection on the steel H-pile fender system and sheet pile.
3C	Refit Wharf #1	Replace various pile caps, piles, and the outboard edge beam; and repair, clean, and paint several mooring fittings.
3D	Refit Wharf #2	Replace or repair various pile caps, piles, outboard edge beams, and mooring foundations; and reattach underdeck lighting conduit and clean and repaint various mooring fittings.
3E	Refit Wharf #3	Replace or repair various pile caps, piles, the outboard edge beams, and mooring foundations; and clean and repaint various mooring fittings.
3F	Warping Wharf w/Capstan (4)	Repair HDPE fender pile wraps; replace or repair various pile caps, piles, and mooring foundations; and clean and repaint mooring fittings.
3G	Tug Pier	Replace timber fender piles with guide piles and small boat access floats; paint mooring fittings; and repair concrete pile caps, concrete piles, concrete underdeck, and storm drain.
Project 4: Transit Protection System (TPS) Pier and Off-Shore Supply Vessel Berthing Modification Project		
4A	New TPS Pier	Construct a new pier with full hotel service capability including power; potable water; fire protection; sewage connections; Ship Overboard Drainage collection; fuel; and telephone, cable, and Local Area Network services.
4B	Small Craft Berth Site VI	Once the new TPS pier is constructed, floating berthing slips would be constructed and provided with full hotel service capability. The berthing pier would consist of a pile supported reinforced concrete structure with floating sections. This project includes the installation of two 5,000-gallon above ground storage tanks and provides two associated truck off-loading connections and fuel dispensing units.
Project 5: Trident Refit Facility Waterfront Facilities Repair, Magnetic Silencing Facility with Crane		
5	Magnetic Silencing Facility with Cranes (Trident Refit Facility Waterfront Facilities Repair).	Replace timber fender piles, restraining chains, aluminum utility tray, and concrete pile utility guide bracket; and repair wooden hand rails and the cracked concrete deck underside.
Project 6: Demolition of the Transit Protection System Pier and Layberth North Trestle		
6A	Demolition of TPS Pier	Remove the tip of the existing TPS Pier.
6B	Demolition of Layberth North Trestle	Demolish the North Layberth Trestle.

Dates and Duration

The specified activity may occur at any time during the five-year period of validity of the proposed regulations. Planned dates of individual projects and project components are shown in Table 2, however, project dates may shift. In-water construction activities would occur during daylight hours, defined here as one hour post-sunrise to one hour prior to sunset.

Specified Geographical Region

NSB Kings Bay is located in southeastern Georgia, approximately four miles inland (straight line distance) from the Atlantic Ocean, and approximately eight miles north of the Georgia-Florida border, along the western shore of Cumberland Sound (see Figure 2–1 in the Navy's application). NSB Kings Bay is an approximately 16,000 acre installation including the land areas and adjacent water areas along Kings Bay and Cumberland Sound between Marianna Creek to the north and Mill Creek to the south, and is restricted from general public access.

This estuarine environment receives salt water input from ocean waters through tidal exchange, and fresh water input from rivers, tributaries, and stormwater outfalls. The large tidal range and strong currents result in tidally mixed waters that are refreshed on a daily basis. Please see section 2 of the Navy's application for more information.

Detailed Description of Activities

The Navy plans to remove deteriorated timber, concrete, and steel piles and replace them with concrete, composite, and steel piles. New construction would involve installation of steel, concrete, and composite piles. Aspects of construction activities other than pile driving are not anticipated to have the potential to result in incidental take of marine mammals because they are either above water or do not produce levels of underwater sound with likely potential to result in marine mammal disturbance. Therefore, we do not discuss elements of construction

activity other than pile driving. No concurrent pile driving would occur. Project specific pile totals are given in Table 2.

A vibratory hammer would be used for all pile removal work. If use of the vibratory hammer is not feasible for pile installation (*i.e.,* with steel piles), a Delmag Pile Hammer D62–22 or equivalent impact hammer would be used. The Delmag Pile Hammer D62–22 is a single acting diesel impact hammer with energy capacity of 76,899–153,799 foot-pounds. The most effective and efficient method of pile installation available would be implemented for each project. The method fitting these criteria may vary based on specific project requirements and local conditions. In some areas of Kings Bay a limestone layer can be found relatively close to the substrate/water interface. This type of layer requires impact driving because vibratory installation will not drive the piles to a sufficient depth. Impact driving, while generally producing higher levels of sound also minimizes the net amount of active driving time, thus reducing the amount of time during which marine mammals may be exposed to noise. Impact or vibratory pile driving could occur on any day, but would not occur simultaneously.

TABLE 2—PILE DRIVING SUMMARY

ID	Project start (fiscal year)	Water depth (ft)	Pile size (in)	Pile type	Total number		Installation method	Estimated number of strikes per pile	Total maximum in-water work days
					Installed	Removed			
1A	2017	24	18	Concrete	148	0	Impact	60	30
			24	Concrete	18	0	Impact	70	4
			16	Timber	0	159	n/a	n/a	31
1B	2017	15	16	Composite	2	0	Vibratory	n/a	1
			16	Timber	0	2	n/a	n/a	1
2	2017	46	14	Steel (H)	55	0	Impact	80	7
3A	2017	46	24	Steel	2	2	Impact	70	2
	2022		24	Concrete	3	3	Impact	75	2
			24	Steel	10	10	Impact	70	7
3B	2021	46	14	Steel (H)	99	99	Impact	60	15
3C	2018	46	24	Steel	6	0	Impact	70	1
			30	Steel	0	6	n/a	n/a	1
3D	2017	46	24	Steel	6	0	Impact	70	1
			30	Steel	0	6	n/a	n/a	1
3E	2018	46	24	Steel	6	0	Impact	70	1
			30	Steel	0	6	n/a	n/a	1
3F	2021	46	30	Steel	8	8	Impact	70	4
3G	2022	30	14	Steel (H)	77	77	Impact	60	16
4A	2020	35	24	Concrete	165	0	Impact	200	55
			18	Concrete	50	0	Impact	80	17
			24	Concrete	0	121	n/a	n/a	8
4B	2020	35	24	Steel	30	30	Impact	100	8
5	2017	46	18	Composite	18	0	Vibratory	n/a	3
			16	Timber	0	18	n/a	n/a	3
6A	2022	46	24	Concrete	0	649	n/a	n/a	41
6B	2022	46	24	Concrete	0	121	n/a	n/a	6

Vibratory hammers, which can be used to either install or extract a pile, contain a system of counter-rotating eccentric weights powered by hydraulic motors, and are designed in such a way that horizontal vibrations cancel out, while vertical vibrations are transmitted into the pile. The pile driving machine is lifted and positioned over the pile by means of an excavator or crane, and is fastened to the pile by a clamp and/or bolts. The vibrations produced cause liquefaction of the substrate surrounding the pile, enabling the pile to be extracted or driven into the ground using the weight of the pile plus the hammer. Impact hammers use a rising and falling piston to repeatedly strike a pile and drive it into the ground. Impact or vibratory driving could occur on any work day during the period of validity of these proposed regulations.

Steel piles are typically vibratory-driven for their initial embedment depths or to refusal and finished with an impact hammer for proofing or until the pile meets structural requirements, as necessary. Proofing involves striking a driven pile with an impact hammer to verify that it provides the required load-bearing capacity, as indicated by the number of hammer blows per foot of pile advancement. Non-steel piles are typically impact-driven for their entire embedment depth, in part because non-steel piles are often displacement piles (as opposed to pipe piles) and require some impact to allow substrate penetration.

Table 3 shows total piles planned for installation (I) and removal (R) by pile type and size in total and per year. Note that no pile driving is planned for fiscal year (FY) 2019. Below we provide further detail specific to individual projects and project components. For additional detail, please see Table 1 and section 1 of the Navy's application. As noted previously, all pile removal would be accomplished using a vibratory hammer and all impact driving would be accomplished using a Delmag Pile Hammer D62–22 or equivalent impact hammer.

TABLE 3—PILE TOTALS BY TYPE AND YEAR

Pile type	Size (in)	FY2017		FY2018		FY2020		FY2021		FY2022		Totals	
		I	R	I	R	I	R	I	R	I	R	I	R
Composite	16	2	0	0	0	0	0	0	0	0	0	2	0
	18	18	0	0	0	0	0	0	0	0	0	18	0
Concrete	18	148	0	0	0	50	0	0	0	0	0	198	0
	24	18	0	0	0	165	121	0	0	3	773	186	894
Steel (H)	14	55	0	0	0	0	0	99	99	77	77	231	176
Steel	24	8	2	12	0	30	30	0	0	10	10	60	42
	30	0	6	0	12	0	0	8	8	0	0	8	26
Timber	16	0	179	0	0	0	0	0	0	0	0	0	179
Totals		249	187	12	12	245	151	107	107	90	860	703	1,317

Project 1A: Tug Pier—The Navy plans to remove deteriorated timber fender piles and replace them with concrete piles. It is anticipated that 5 to 16 piles would be removed or installed per day with a total of up to 65 days of in-water work.

Project 1B: General Access Pier Crab Island—Timber guide piles at this pier are damaged and would be replaced by fiberglass reinforced plastic composite guide piles. Extraction and installation would both be performed using a vibratory hammer. It is anticipated that an average of two piles would be installed or removed per day for approximately two days of in-water work.

Project 2: Unspecified Minor Construction, Layberth Pier—The Navy plans to install additional steel H-piles to reduce the existing gaps between fender piles, which are considered too wide to adequately support the necessary fender system. No existing piles would need to be removed. It is anticipated that an average of eight piles would be installed per day for approximately seven days of in-water work.

The Waterfront Pile Repair and Replacement Maintenance Program (*i.e.,* Project 3) consists of repairing and/or replacing structurally unsound piles along the waterfront restricted area. This project includes multiple individual projects as follows:

Project 3A: Explosives Handling Wharf #2 Pier with Capstans—Upgrading Explosives Handling Wharf #2 would require the installation of two new steel piles and the removal of two guide piles in FY17. Additionally, three concrete piles and ten steel piles would be removed and subsequently replaced in 2022. It is anticipated that two piles would be installed or removed per day for a total of approximately 11 days of in-water work in FY17 and FY22.

Project 3B: (Dry Dock) Interface Wharf—Numerous fender piles are in an advanced state of deterioration. Repairing the Interface Wharf would require the installation of new steel H-piles and removal of existing steel H-piles. It is anticipated that an average of 14 piles would be removed or installed per day for approximately 15 days of in-water work.

Projects 3C–E: Refit Wharfs 1–3—All three Refit Wharfs are in disrepair and present a safety risk to the personnel and heavy equipment utilizing the piers. In each case, proposed repair work would involve the removal of existing fender piles and replacement with new steel piles. It is anticipated that an average of six piles would be removed or installed per day for approximately two days of in-water work for each of the three projects.

Project 3F: Warping Wharf with Capstan—Repairing deterioration of the existing Warping Wharf would require the installation of new steel piles and the removal of eight existing fender piles. It is anticipated that an average of five piles would be removed or installed per day for approximately four days of in-water work.

Project 3G: Tug Pier—The same location subject to Project 1A, Project 3G represents anticipated future work at the Tug Pier (scheduled for FY22). A large quantity of steel fender piles would be removed and replaced. It is anticipated that an average of ten piles would be removed or installed per day for approximately sixteen days of in-water work.

Project 4 (Transit Protection System (TPS) Off-Shore Supply Vessel Berthing Modification Project) involves the construction of a new pier associated with TPS functions and the modification of the existing berthing pier on the north trestle.

Project 4A: New Facility—The construction of the new pier would require the installation of new square concrete piles and removal of existing concrete piles. It is anticipated that 16 to 22 piles would be removed and 3 to 12 piles would be installed per day for approximately 80 days of in-water work.

Project 4B: Small Craft Berth Site—The existing berthing pier on the north trestle would be relocated to align with the new pier associated with the proposed TPS Operational Facility and modified as needed. These modifications would require installation of new steel piles and the removal existing piles. It is anticipated that an average of eight piles would be installed or removed per day for approximately eight days of in-water work.

Project 5: Waterfront Facilities Repair, Magnetic Silencing Facility (MSF)—The MSF at Kings Bay is in a deteriorated condition and Navy plans to replace existing timber fender piles with fiberglass reinforced plastic composite piles. It is anticipated that an average of six piles would be extracted or installed per day for approximately six days of in-water work.

Following completion of Project 4, Project 6 would involve demolition of the existing TPS Pier and north trestle.

Project 6A–B: Demolition of TPS Pier and North Trestle—Both projects would involve vibratory removal of existing concrete piles. For the TPS Pier, it is anticipated that an average of 16 piles would be removed per day for approximately 41 days of in-water work. For the work at the north trestle, it is anticipated that an average of 20 piles would be removed per day for approximately 6 days of in-water work.

Proposed Mitigation

In order to issue an incidental take authorization under section 101(a)(5)(A) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, ''and other means of effecting the least practicable adverse impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for subsistence uses.'' NMFS's implementing regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting such activity or other means

of effecting the least practicable adverse impact upon the affected species or stocks and their habitat (50 CFR 216.104(a)(11)).

The mitigation strategies described below largely follow those required and successfully implemented under previous incidental take authorizations issued in association with similar construction activities. Measurements from similar pile driving events were coupled with practical spreading loss and other relevant information to estimate zones of influence (ZOI; see ''Estimated Take by Incidental Harassment''); these ZOI values were used to develop mitigation measures for pile driving activities at NSB Kings Bay. Background discussion related to underwater sound concepts and terminology is provided in the section on ''Description of Sound Sources,'' later in this preamble. Practical spreading loss is discussed in further detail in the section on ''Zones of Influence,'' later in this preamble. The ZOIs effectively represent the mitigation zone that would be established around each pile to prevent Level A harassment to dolphins, while providing estimates of the areas within which Level B harassment might occur. In addition to the specific measures described later in this section, the Navy would conduct briefings for construction supervisors and crews, marine mammal monitoring team, and Navy staff prior to the start of all pile driving activity, and when new personnel join the work, in order to explain responsibilities, communication procedures, marine mammal monitoring protocol, and operational procedures. All relevant personnel would watch applicable sections of the Navy's Marine Species Awareness Training video. Relevant personnel would also follow NMFS's ''Southeast Region Marine Mammal and Sea Turtle Viewing Guidelines,'' which are described in Attachment 1 of Navy's Monitoring Plan.

Monitoring and Shutdown for Pile Driving

The following measures would apply to the Navy's mitigation through shutdown and disturbance zones:

Shutdown Zone—The purpose of a shutdown zone is to define an area within which shutdown of activity would occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area), thus preventing some undesirable outcome, such as auditory injury or behavioral disturbance of sensitive species (serious injury or death are unlikely outcomes even in the absence of mitigation measures). For all pile driving activities, the Navy would establish a minimum shutdown zone with radial distance of 15 meters (m). This minimum zone is intended to prevent the already unlikely possibility of physical interaction with construction equipment and to establish a precautionary minimum zone with regard to acoustic effects.

Using NMFS's user spreadsheet, an optional companion spreadsheet associated with the alternative implementation methodology provided in Appendix D of NMFS's acoustic guidance (NMFS, 2016), we calculated project, pile type, and pile driving methodology-specific zones within which auditory injury (*i.e.,* Level A harassment) could occur. The user spreadsheet is publicly available online at *www.nmfs.noaa.gov/pr/acoustics/guidelines.htm.* In using the spreadsheet, we assumed practical spreading loss and used supplementary information provided by the Navy regarding assumed number of piles driven per day and number of pile strikes necessary to install a pile (for impact pile driving) and daily duration of pile driving (for vibratory pile driving). Assumed source levels are provided in Table 7.

In most cases, this minimum shutdown zone of 15 m is expected to contain the area in which auditory injury could occur. All predicted auditory injury zones are less than the minimum 15 m shutdown zone (radial distance range: 0.5–13.1 m), with the exception of impact driving of 30-inch (in) steel piles associated with Project 3F (radial distance of 38 m) and impact driving of 24-in steel piles associated with Project 4B (radial distance of 16.6 m). In all cases, predicted injury zones are calculated on the basis of cumulative sound exposure, as peak pressure source levels are below the injury threshold for mid-frequency cetaceans. For these two scenarios we propose shutdown zones of 40 m and 20 m radial distance, respectively.

Injury zone predictions generated using the optional user spreadsheet are precautionary due to a number of simplifying assumptions. For example, the spreadsheet tool assumes that marine mammals remain stationary during the activity and does not account for potential recovery between intermittent sounds. In addition, the tool incorporates the acoustic guidance's weighting functions through use of a single-frequency weighting factor adjustment intended to represent the signal's 95 percent frequency contour percentile (*i.e.,* upper frequency below which 95 percent of total cumulative energy is contained; Charif *et al.,* 2010). This will typically result in higher predicted exposures for broadband sounds, since only one frequency is being considered, compared to exposures associated with the ability to fully incorporate the guidance's weighting functions.

Disturbance Zone—Disturbance zones are the areas in which sound pressure levels (SPLs) equal or exceed 160 and 120 dB root mean square (rms) (for impulsive and non-impulsive, continuous sound, respectively). Disturbance zones provide utility for monitoring conducted for mitigation purposes (*i.e.,* shutdown zone monitoring) by establishing monitoring protocols for areas adjacent to the shutdown zones. Monitoring of disturbance zones enables observers to be aware of and communicate the presence of marine mammals in the project area but outside the shutdown zone, and thus prepare for potential shutdowns of activity. However, the primary purpose of disturbance zone monitoring is for documenting incidents of Level B harassment; disturbance zone monitoring is discussed in greater detail later (see ''Proposed Monitoring and Reporting''). Nominal radial distances for disturbance zones are shown in Table 8.

In order to document observed incidents of harassment, monitors record all marine mammal observations, regardless of location. The observer's location and the location of the pile being driven are known, and the location of the animal may be estimated as a distance from the observer and then compared to the location from the pile. It may then be estimated whether the animal was exposed to sound levels constituting incidental harassment on the basis of predicted distances to relevant thresholds in post-processing of observational data, and a precise accounting of observed incidents of harassment created. This information may then be used to extrapolate observed takes to reach an approximate understanding of actual total takes, in cases where the entire zone was not monitored and/or all days of activity were not monitored.

Monitoring Protocols—Monitoring would be conducted before, during, and after pile driving activities. In addition, observers will record all incidents of marine mammal occurrence, regardless of distance from activity, and monitors will document any behavioral reactions in concert with distance from piles being driven. Observations made outside the shutdown zone will not result in shutdown; that pile segment will be completed without cessation, unless the animal approaches or enters the shutdown zone, at which point all

pile driving activities would be halted. Monitoring will take place from 15 minutes prior to initiation through 30 minutes post-completion of pile driving activities. Pile driving activities include the time to install or remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than thirty minutes. Observation of shutdown zones will always occur, but observation of the larger disturbance zones will occur on a subset of days associated with each specific project (see project-specific details provided in ''Proposed Monitoring and Reporting,'' later in this document). Please see the Monitoring Plan, developed by the Navy in agreement with NMFS, for full details of the monitoring protocols.

The following additional measures apply to visual monitoring:

(1) Monitoring will be conducted by designated observers, who will be placed at the best vantage point(s) practicable (as defined in the Monitoring Plan) to monitor for marine mammals and implement shutdown/delay procedures when applicable by calling for the shutdown to the hammer operator. Observers would have no other construction-related tasks while conducting monitoring. Observers should have the following minimum qualifications:

- Visual acuity in both eyes (correction is permissible) sufficient for discernment of moving targets at the water's surface with ability to estimate target size and distance; use of binoculars may be necessary to correctly identify the target;
- Ability to conduct field observations and collect data according to assigned protocols;
- Experience or training in the field identification of bottlenose dolphins, including the identification of behaviors;
- Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;
- Writing skills sufficient to document observations including, but not limited to: The number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates and times when in-water construction activities were suspended to avoid potential incidental injury of marine mammals from construction noise within a defined shutdown zone; and marine mammal behavior; and
- Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

(2) Prior to the start of pile driving activity, the shutdown zone will be monitored for 15 minutes to ensure that it is clear of marine mammals. Pile driving will only commence once observers have declared the shutdown zone clear of marine mammals; animals will be allowed to remain in the shutdown zone (*i.e.,* must leave of their own volition), and their behavior will be monitored and documented. The shutdown zone may only be declared clear, and pile driving started, when the entire shutdown zone is visible (*i.e.,* when not obscured by dark, rain, fog, etc.). In addition, if such conditions should arise during impact pile driving that is already underway, the activity would be halted.

(3) If a marine mammal approaches or enters the shutdown zone during the course of pile driving operations, activity will be halted and delayed until either the animal has voluntarily left and been visually confirmed beyond the shutdown zone or fifteen minutes have passed without re-detection of the animal. Monitoring will be conducted throughout the time required to drive a pile and for thirty minutes following the conclusion of pile driving.

Soft Start

The use of a soft start procedure is believed to provide additional protection to marine mammals by warning marine mammals or providing them with a chance to leave the area prior to the hammer operating at full capacity, and typically involves a requirement to initiate sound from the hammer at reduced energy followed by a waiting period. This procedure is repeated two additional times. It is difficult to specify the reduction in energy for any given hammer because of variation across drivers and, for impact hammers, the actual number of strikes at reduced energy will vary because operating the hammer at less than full power results in ''bouncing'' of the hammer as it strikes the pile, resulting in multiple ''strikes.'' The Navy will utilize soft start techniques for impact pile driving. We require an initial set of three strikes from the impact hammer at reduced energy, followed by a 30-second waiting period, then 2 subsequent 3-strike sets. Soft start will be required at the beginning of each day's impact pile driving work and at any time following a cessation of impact pile driving of thirty minutes or longer; the requirement to implement soft start for impact driving is independent of whether vibratory driving has occurred within the prior 30 minutes.

We have carefully evaluated the Navy's proposed mitigation measures and considered a range of other measures in the context of ensuring that we prescribed the means of effecting the least practicable adverse impact on the affected marine mammal species and stocks and their habitat. Our evaluation of potential measures included consideration of the following factors in relation to one another: (1) The manner in which, and the degree to which, the successful implementation of the measure is expected to minimize adverse impacts to marine mammals, (2) the proven or likely efficacy of the specific measure to minimize adverse impacts as planned; and (3) the practicability of the measure for applicant implementation.

Any mitigation measure(s) we prescribe should be able to accomplish, have a reasonable likelihood of accomplishing (based on current science), or contribute to the accomplishment of one or more of the general goals listed below:

(1) Avoidance or minimization of injury or death of marine mammals wherever possible (goals 2, 3, and 4 may contribute to this goal).

(2) A reduction in the number (total number or number at biologically important time or location) of individual marine mammals exposed to stimuli expected to result in incidental take (this goal may contribute to 1, above, or to reducing takes by behavioral harassment only).

(3) A reduction in the number (total number or number at a biologically important time or location) of times any individual marine mammal would be exposed to stimuli expected to result in incidental take (this goal may contribute to 1, above, or to reducing takes by behavioral harassment only).

(4) A reduction in the intensity of exposure to stimuli expected to result in incidental take (this goal may contribute to 1, above, or to reducing the severity of behavioral harassment only).

(5) Avoidance or minimization of adverse effects to marine mammal habitat, paying particular attention to the prey base, blockage or limitation of passage to or from biologically important areas, permanent destruction of habitat, or temporary disturbance of habitat during a biologically important time.

(6) For monitoring directly related to mitigation, an increase in the probability of detecting marine mammals, thus allowing for more effective implementation of the mitigation.

Based on our evaluation of the Navy's proposed measures, we have

preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Description of Marine Mammals in the Area of the Specified Activity

We have reviewed the Navy's species descriptions—which summarize available information regarding status and trends, distribution and habitat preferences, behavior and life history, and auditory capabilities of the potentially affected species and stocks—for accuracy and completeness, and refer the reader to Sections 3 and 4 of Navy's application, as well as to NMFS's Stock Assessment Reports (SARs; *www.nmfs.noaa.gov/pr/sars/*), instead of reprinting the information here. Additional general information (*e.g.,* physical and behavioral descriptions) and information on the U.S. regulatory status of species under the MMPA and ESA may be found on NMFS's Web site (*www.nmfs.noaa.gov/pr/species/mammals/*). Table 4 lists all species and stocks with expected potential for occurrence in the specified geographical region where Navy proposes to conduct the specified activity, and summarizes information related to the population or stock, including potential biological removal (PBR). PBR, defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population, is considered in concert with known sources of ongoing anthropogenic mortality (as described in NMFS's SARs).

Only one species under NMFS's jurisdiction is considered to have the potential to co-occur with Navy activities: The bottlenose dolphin. However, multiple stocks of bottlenose dolphin have the potential to be present. The offshore stock of bottlenose dolphins are generally found in deeper waters farther from the coast; biopsy tissue sampling and genetic analysis demonstrated that bottlenose dolphins concentrated close to shore were of the coastal morphotype, while those in waters greater than 40 m depth were from the offshore morphotype (Garrison *et al.,* 2003). However, south of Cape Hatteras, North Carolina, the ranges of the coastal and offshore morphotypes overlap to some degree. Based on genetic analysis of tissue samples collected in nearshore and offshore waters from New York to central Florida, Torres *et al.* (2003) found the offshore morphotype exclusively seaward of 34 kilometers (km) and in waters deeper than 34 m. Within 7.5 km of shore, all animals were of the coastal morphotype. Garrison *et al.* (2003) found offshore morphotype animals as close as 7.3 km from shore in water depths of 13 m. Therefore, the offshore stock of bottlenose dolphins is considered extralimital to the project area and is not discussed further in this document. In addition, the West Indian manatee (*Trichechus manatus latirostris*) may be found in coastal waters of the Atlantic. However, manatees are managed by the U.S. Fish and Wildlife Service and are not considered further in this document. All stocks are assessed in NMFS's U.S. Atlantic SARs (*e.g.,* Waring *et al.,* 2016).

TABLE 4—MARINE MAMMALS POTENTIALLY PRESENT IN THE VICINITY OF NSB KINGS BAY

Species	Stock	ESA/MMPA status; Strategic (Y/N) [1]	Stock abundance (CV, N_{min}, most recent abundance survey) [2]	PBR [3]	Annual M/SI [4]	Relative occurrence in Kings Bay; season of occurrence [5]
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)						
Family Delphinidae						
Bottlenose dolphin	Western North Atlantic Coastal, South Carolina/Georgia.	D; Y	4,377 (0.43; 3,097; 2009).	31	1.2–1.6	Likely; year-round.
	WNA Coastal, Northern Florida.	D; Y	1,219 (0.67; 730; 2009).	7	0.4	Rare; year-round.
	WNA Coastal, Southern Migratory.	D; Y	9,173 (0.46; 6,326; 2009).	63	0–12	Rare; January-March.
	Southern Georgia Estuarine System.	—; Y	194 (0.05; 185; 2009).	1.9	Unk	Likely; year-round.
	Jacksonville Estuarine System.	—; Y	Unknown	Undetermined	1.2	Rare; year-round.

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

[2] CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance. The most recent abundance survey that is reflected in the abundance estimate is presented; there may be more recent surveys that have not yet been incorporated into the estimate.

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

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

[5] The Navy considers ''rare'' to mean that there may be a few confirmed sightings or that the distribution of the stock is near enough to the area of interest that the species could occur there, and that overall the stock may occur but only infrequently or in small numbers. ''Likely'' is considered to mean that confirmed and regular sightings of the species occur year-round. Extralimital stocks are those that are considered unlikely to co-occur with the activity because the action area is outside the range of normal occurrence, but for which there may be some sighting or stranding records.

Bottlenose dolphins range widely in temperate and tropical waters and are found from deep, offshore to coastal areas, including bays, estuaries and river mouths. In the western North Atlantic, there are two morphologically and genetically distinct bottlenose dolphin morphotypes described as the coastal and offshore forms (Duffield *et al.,* 1983; Hersh and Duffield, 1990; Mead and Potter, 1995; Curry and Smith, 1997; Rosel *et al.,* 2009). These forms are genetically distinct based upon both mitochondrial and nuclear markers (Hoelzel *et al.,* 1998; Rosel *et al.,* 2009). As described above, the offshore form—which is distributed primarily along the outer continental shelf and continental slope—is considered extralimital to the project area and is not discussed here. The coastal morphotype is continuously distributed in nearshore coastal and estuarine waters along the U.S. Atlantic coast south of Long Island, New York, around the Florida peninsula and into the Gulf of Mexico. Primary habitat for coastal dolphins generally includes waters less than 20 m deep (*e.g.,* Garrison *et al.,* 2003).

Initially, a single stock of coastal bottlenose dolphins was thought to migrate seasonally between New Jersey (summer months) and central Florida based on seasonal patterns in strandings during a large scale mortality event occurring during 1987–1988 (Scott *et al.,* 1988). However, re-analysis of stranding data and extensive analysis of genetic, photo-identification, and satellite telemetry data demonstrate a complex mosaic of coastal bottlenose dolphin stocks (Zolman, 2002; McLellan *et al.,* 2002; Rosel *et al.,* 2009; Waring *et al.,* 2016). Integrated analysis of these multiple lines of evidence suggests that there are five coastal stocks of bottlenose dolphins, including the South Carolina/Georgia and northern Florida stocks that may be present in the action area.

The coastal morphotype inhabits inshore estuarine waters in addition to coastal nearshore and continental shelf waters, with multiple lines of evidence supporting demographic separation between bottlenose dolphins residing within different estuaries along the Atlantic coast (Wells *et al.,* 1987; Scott *et al.,* 1990; Wells *et al.,* 1996; Zolman, 2002; Speakman *et al.,* 2006; Stolen *et al.,* 2007; Balmer *et al.,* 2008; Mazzoil *et al.,* 2008). In some cases, studies have identified communities of resident dolphins that are seen within relatively restricted home ranges year-round, as well as year-round resident dolphins repeatedly observed across multiple years (Zolman, 2002; Speakman *et al.,* 2006; Stolen *et al.,* 2007; Mazzoil *et al.,* 2008). A few published studies demonstrate that these resident animals are genetically distinct from animals in nearby coastal waters and/or from animals residing in nearby estuarine areas (Caldwell, 2001; Rosel *et al.,* 2009; Litz *et al.,* 2012). However, the degree of spatial overlap between estuarine and coastal populations remains unclear, and the degree of movement of resident estuarine animals into coastal waters on seasonal or shorter time scales is poorly understood (Waring *et al.,* 2016). Bottlenose dolphins inhabiting primarily estuarine habitats are considered distinct stocks from those inhabiting coastal habitats.

The spatial extent of the coastal stocks, their potential seasonal movements, and their relationships with estuarine stocks are poorly understood (Waring *et al.,* 2016). Photo-identification studies documented dolphins in coastal waters off Charleston, South Carolina, that are not known resident members of the estuarine stock (Speakman *et al.,* 2006). Genetic analyses of samples from northern Florida and Georgia and central South Carolina, using both mitochondrial DNA and nuclear microsatellite markers, indicate significant genetic differences between these areas (NMFS, 2001; Rosel *et al.,* 2009). Therefore, NMFS defines separate stocks occurring in coastal Atlantic waters from the North Carolina/South Carolina border south to the Georgia/Florida border, and from the Georgia/Florida border south to 29.4°N. There is likely to be some overlap between actual stock ranges at these borders, which are defined for management purposes, and the action area is located adjacent to the Georgia/Florida border. Therefore, although we would expect that most coastal dolphins encountered would be from the Georgia/South Carolina stock, it is possible that animals from the northern Florida stock could be present.

These five stocks also include migratory stocks that move south seasonally from mid-Atlantic coastal waters. In particular, the southern migratory stock, defined on the basis of satellite tag telemetry studies and stable isotope analysis, is thought to migrate south from waters of southern Virginia and north central North Carolina in the summer to waters south of Cape Fear and as far south as coastal Florida during winter months, where it could overlap with the South Carolina/Georgia coastal stock (and potentially occur in the action area) (Knoff, 2004; Waring *et al.,* 2016). Also based on tagging studies, the northern migratory stock is not thought to move south of Cape Lookout, North Carolina, during cold water months (Waring *et al.,* 2016). Telemetry data suggest this stock occupies waters of southern North Carolina (south of Cape Lookout) during October-December, before moving south during January-March (as far south as northern Florida). During April-June, the stock moves north back to North Carolina, and is presumed to remain in coastal waters north of Cape Lookout, North Carolina, from July-August (Waring et al., 2016). However, during its winter movements the southern migratory stock is thought to occur in waters from 10–30 m depth (*i.e.,* remain further offshore than it does in northern waters, where it is more likely to overlap with estuarine system stocks) (Waring et al., 2016). Therefore, we assume that rare occurrence of migratory stock dolphins during January to March may be possible.

There are two resident estuarine stocks of bottlenose dolphin that may occur in the action area: Those present in southern Georgia and Jacksonville estuarine systems (SGES and JES). Balmer *et al.* (2011) conducted photo-identification studies between 2004 and 2009 in two field sites in south-central Georgia, one in the Turtle/Brunswick River estuary and the second north of the Altamaha River/Sound including the Sapelo Island National Estuarine Research Reserve and extending north to Sapelo Sound. The data revealed strong site fidelity to the two regions and supported Altamaha Sound as an appropriate boundary between the two sites (Balmer *et al.,* 2013). Genetic analysis of mitochondrial DNA control region sequences and microsatellite markers of dolphins biopsied in southern Georgia showed significant genetic differentiation from animals biopsied in northern Georgia and southern South Carolina estuaries as well as from animals biopsied in coastal waters greater than 1 km from shore at the same latitude (Waring *et al.,* 2016). Caldwell (2001) investigated the social structure of bottlenose dolphins inhabiting the estuarine waters between the St. Mary's River (at the Georgia/Florida border) and Jacksonville Beach, Florida, using photo-identification and behavioral data. Multiple behaviorally-different communities were identified during the study, including those inhabiting estuarine waters to the north and south of the St. Johns River, which differed in density, habitat fidelity and social affiliation patterns. Dolphins to the north of the St. Johns River were isolated, with 96 percent of the groups observed containing dolphins that had been photographically identified only in

this area, demonstrating strong year-round site fidelity (Caldwell, 2001). Cluster analyses suggested that dolphins using the northern area did not socialize with those using the area to the south of the St. Johns River (Caldwell, 2001).

The SGES stock is bounded in the south by the Georgia/Florida border at the Cumberland River out through Cumberland Sound and in the north by the Altamaha River out through Altamaha Sound, and encompasses all estuarine waters in between as well as coastal waters out to 1 km from shore. The southern boundary abuts the northern boundary of the JES stock, which is currently considered to extend south to Jacksonville Beach, Florida. Although both stocks may occur in the action area (the proposed construction site is just north of the shared SGES/JES stock boundary), we assume that animals from the JES stock would occur only rarely if at all due to the strong site fidelity exhibited within areas to the south of the St. Mary's River and Cumberland Sound.

The best available abundance estimate for the SGES stock is 194 animals (Table 4). However, seasonal mark-recapture, photo-identification surveys informing this estimate cover less than half of the assumed range of the stock and, therefore, the abundance estimate is negatively biased (Waring *et al.,* 2016). The portion of range surveyed did not include the proposed action area. There is no official abundance estimate for the JES stock because existing data are greater than eight years old. However, photo-identification data from 1994–1997 yielded 334 individually identified dolphins, including an unknown number of seasonal residents and transients (Gubbins *et al.,* 2003). Mark-recapture analyses including all individually identifiable dolphins yielded a population abundance estimate of 412 animals (CV = 0.06; Gubbins *et al.,* 2003). This is considered to be an overestimate because it included non-resident and seasonally resident dolphins (Waring *et al.,* 2016).

In summary, the SGES stock and the South Carolina/Georgia coastal stock are expected to be the two stocks most likely to be affected by the specified activity. Individual animals from the northern Florida and southern migratory (January to March only) coastal stocks and the JES stock may also occur rarely.

Biologically Important Areas—LaBrecque *et al.* (2015) recognize multiple biologically important areas (BIA) for small and resident populations of bottlenose dolphins in the mid- and south Atlantic. Small and resident population BIAs are areas and times within which small and resident populations occupy a limited geographic extent, and are therefore necessarily important areas for those populations. Here, these include areas defined for the SGES and JES populations and correspond with the stock boundaries described above.

Unusual Mortality Events (UME)—A UME is defined under the MMPA as ''a stranding that is unexpected, involves a significant die-off of any marine mammal population, and demands immediate response.'' Beginning in July 2013, elevated strandings of bottlenose dolphins were observed along the Atlantic coast from New York to Florida. The investigation was closed in 2015, with the UME ultimately being attributed to cetacean morbillivirus (though additional contributory factors are under investigation; *www.nmfs.noaa.gov/pr/health/mmume/midatldolphins2013.html;* accessed November 25, 2016). Dolphin strandings during 2013–2015 were greater than 6 times higher than the average from 2007–2012, with the most strandings reported from Virginia, North Carolina, and Florida. A total of approximately 1,650 bottlenose dolphins stranded from June 2013 to March 2015 and, additionally, a small number of individuals of several other cetacean species stranded during the UME and tested positive for morbillivirus (humpback whale, fin whale, minke whale, pygmy sperm whale, and striped dolphin). Approximately one hundred of the stranded dolphins were recovered along the Georgia coast, with at least 31 found on nearby Cumberland Island. Only one offshore ecotype dolphin has been identified, meaning that over 99 percent of affected dolphins were of the coastal ecotype (D. Fauquier; pers. comm.). Research, to include analyses of stranding samples and post-UME monitoring and modeling of surviving populations, will continue in order to better understand the impacts of the UME on the affected stocks. Notably, an earlier major UME in 1987–1988 was also caused by morbillivirus. Over 740 stranded dolphins were recovered during that event.

A second UME, declared in 2010, affected bottlenose dolphins in the St. Johns River (FL). Affected animals likely belonged to the JES stock; the cause of this UME is undetermined. For more information on UMEs, please visit: *www.nmfs.noaa.gov/pr/health/mmume/.*

Take Reduction Planning—Take reduction plans are designed to help recover and prevent the depletion of strategic marine mammal stocks that interact with certain U.S. commercial fisheries, as required by Section 118 of the MMPA. The immediate goal of a take reduction plan is to reduce, within six months of its implementation, the annual human-cause mortality and serious injury (M/SI) of marine mammals incidental to commercial fishing to less than the PBR level. The long-term goal is to reduce, within five years of its implementation, the M/SI of marine mammals incidental to commercial fishing to insignificant levels, approaching a zero serious injury and mortality rate, taking into account the economics of the fishery, the availability of existing technology, and existing state or regional fishery management plans. Take reduction teams are convened to develop these plans.

One take reduction plan has been developed to reduce deaths of Atlantic coastal bottlenose dolphins incidental to commercial fishing. The bottlenose dolphin take reduction plan contains both regulatory and non-regulatory conservation measures, including seasonal gillnet restrictions, gear proximity requirements, and gear length restrictions, as well as continued research and monitoring, enforcement, outreach, and partnership efforts. Gillnet restrictions are in place in Georgia waters. More information is available online at: *www.nmfs.noaa.gov/pr/interactions/trt/bdtrp.html.*

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

This section includes a summary and discussion of the ways that components of the specified activity may impact marine mammals and their habitat. The ''Estimated Take by Incidental Harassment'' section later in this preamble will include a quantitative analysis of the number of incidents of take expected to occur incidental to this activity. The ''Negligible Impact Analysis'' section will include an analysis of how this specific activity will impact marine mammals, and will consider the content of this section, the ''Estimated Take by Incidental Harassment'' section, and the ''Proposed Mitigation'' section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals, and from that on the affected marine mammal populations or stocks. In the following discussion, we provide general background information on sound and marine mammal hearing before considering potential effects to marine mammals from sound produced by pile driving.

Description of Sound Sources

This section contains a brief technical background on sound, on the characteristics of certain sound types, and on metrics used in this proposal inasmuch as the information is relevant to the specified activity and to a discussion of the potential effects of the specified activity on marine mammals found later in this document.

Sound travels in waves, the basic components of which are frequency, wavelength, velocity, and amplitude. Frequency is the number of pressure waves that pass by a reference point per unit of time and is measured in hertz (Hz) or cycles per second. Wavelength is the distance between two peaks or corresponding points of a sound wave (length of one cycle). Higher frequency sounds have shorter wavelengths than lower frequency sounds, and typically attenuate (decrease) more rapidly, except in certain cases in shallower water. Amplitude is the height of the sound pressure wave or the ''loudness'' of a sound and is typically described using the relative unit of the decibel (dB). A sound pressure level (SPL) in dB is described as the ratio between a measured pressure and a reference pressure (for underwater sound, this is 1 microPascal (μPa)), and is a logarithmic unit that accounts for large variations in amplitude; therefore, a relatively small change in dB corresponds to large changes in sound pressure. The source level (SL) represents the SPL referenced at a distance of 1 m from the source (referenced to 1 μPa), while the received level is the SPL at the listener's position (referenced to 1 μPa).

Root mean square (rms) is the quadratic mean sound pressure over the duration of an impulse. Rms is calculated by squaring all of the sound amplitudes, averaging the squares, and then taking the square root of the average (Urick, 1983). Rms accounts for both positive and negative values; squaring the pressures makes all values positive so that they may be accounted for in the summation of pressure levels (Hastings and Popper, 2005). This measurement is often used in the context of discussing behavioral effects, in part because behavioral effects, which often result from auditory cues, may be better expressed through averaged units than by peak pressures.

Sound exposure level (SEL; represented as dB re 1 μPa^2-s) represents the total energy contained within a pulse, and considers both intensity and duration of exposure. Peak sound pressure (also referred to as zero-to-peak sound pressure or 0-p) is the maximum instantaneous sound pressure measurable in the water at a specified distance from the source, and is represented in the same units as the rms sound pressure.

When underwater objects vibrate or activity occurs, sound-pressure waves are created. These waves alternately compress and decompress the water as the sound wave travels. Underwater sound waves radiate in a manner similar to ripples on the surface of a pond and may be either directed in a beam or beams or may radiate in all directions (omnidirectional sources), as is the case for sound produced by the pile driving activity considered here. The compressions and decompressions associated with sound waves are detected as changes in pressure by aquatic life and man-made sound receptors such as hydrophones.

Even in the absence of sound from the specified activity, the underwater environment is typically loud due to ambient sound. Ambient sound is defined as environmental background sound levels lacking a single source or point (Richardson *et al.,* 1995), and the sound level of a region is defined by the total acoustical energy being generated by known and unknown sources. These sources may include physical (*e.g.,* wind and waves, earthquakes, ice, atmospheric sound), biological (*e.g.,* sounds produced by marine mammals, fish, and invertebrates), and anthropogenic (*e.g.,* vessels, dredging, construction) sound. A number of sources contribute to ambient sound, including the following (Richardson *et al.,* 1995):

- *Wind and waves:* The complex interactions between wind and water surface, including processes such as breaking waves and wave-induced bubble oscillations and cavitation, are a main source of naturally occurring ambient sound for frequencies between 200 Hz and 50 kHz (Mitson, 1995). In general, ambient sound levels tend to increase with increasing wind speed and wave height. Surf sound becomes important near shore, with measurements collected at a distance of 8.5 km from shore showing an increase of 10 dB in the 100 to 700 Hz band during heavy surf conditions.
- *Precipitation:* Sound from rain and hail impacting the water surface can become an important component of total sound at frequencies above 500 Hz, and possibly down to 100 Hz during quiet times.
- *Biological:* Marine mammals can contribute significantly to ambient sound levels, as can some fish and snapping shrimp. The frequency band for biological contributions is from approximately 12 Hz to over 100 kHz.
- *Anthropogenic:* Sources of ambient sound related to human activity include transportation (surface vessels), dredging and construction, oil and gas drilling and production, seismic surveys, sonar, explosions, and ocean acoustic studies. Vessel noise typically dominates the total ambient sound for frequencies between 20 and 300 Hz. In general, the frequencies of anthropogenic sounds are below 1 kHz and, if higher frequency sound levels are created, they attenuate rapidly. Sound from identifiable anthropogenic sources other than the activity of interest (*e.g.,* a passing vessel) is sometimes termed background sound, as opposed to ambient sound.

The sum of the various natural and anthropogenic sound sources at any given location and time—which comprise ''ambient'' or ''background'' sound—depends not only on the source levels (as determined by current weather conditions and levels of biological and human activity) but also on the ability of sound to propagate through the environment. In turn, sound propagation is dependent on the spatially and temporally varying properties of the water column and sea floor, and is frequency-dependent. As a result of the dependence on a large number of varying factors, ambient sound levels can be expected to vary widely over both coarse and fine spatial and temporal scales. Sound levels at a given frequency and location can vary by 10–20 dB from day to day (Richardson *et al.,* 1995). The result is that depending on the source type, its intensity, and the receivers' generalized hearing range, sound from a given activity may be a negligible addition to the local environment or could form a distinctive signal that may affect marine mammals.

The underwater acoustic environment at NSB Kings Bay is dominated by noise from day-to-day port and vessel activities. The base is sheltered from most wave noise, but is a high-use area for naval ships, tugs, submarines, and security vessels. When underway, these sources can create noise between 20 Hz and 16 kHz (Lesage *et al.,* 1999), with broadband noise levels up to 180 dB rms. Normal port operations, including transits, docking, and maintenance by multiple vessels would continue throughout the period proposed for the specified activity. As a result of measurements conducted in February 2015, the Navy found that background sound levels averaged around 135 dB rms (Acentech, 2015). Due to the existing loud environment and

similarity to noise produced by existing activity, it is unlikely that noise produced by vibratory pile driving in particular would have any significant impact on marine mammals occurring in the vicinity of NSB Kings Bay. Details of source types are described in the following text.

Sounds are often considered to fall into one of two general types: pulsed and non-pulsed (defined in the following). The distinction between these two sound types is important because they have differing potential to cause physical effects, particularly with regard to hearing (*e.g.,* Ward, 1997 in Southall *et al.,* 2007). Please see Southall *et al.* (2007) for an in-depth discussion of these concepts.

Pulsed sound sources (*e.g.,* airguns, explosions, gunshots, sonic booms, impact pile driving) produce signals that are brief (typically considered to be less than one second), broadband, atonal transients (ANSI, 1986, 2005; Harris, 1998; NIOSH, 1998; ISO, 2003) and occur either as isolated events or repeated in some succession. Pulsed sounds are all characterized by a relatively rapid rise from ambient pressure to a maximal pressure value followed by a rapid decay period that may include a period of diminishing, oscillating maximal and minimal pressures, and generally have an increased capacity to induce physical injury as compared with sounds that lack these features.

Non-pulsed sounds can be tonal, narrowband, or broadband, brief or prolonged, and may be either continuous or non-continuous (ANSI, 1995; NIOSH, 1998). Some of these non-pulsed sounds can be transient signals of short duration but without the essential properties of pulses (*e.g.,* rapid rise time). Examples of non-pulsed sounds include those produced by vessels, aircraft, machinery operations such as drilling or dredging, vibratory pile driving, and active sonar systems (such as those used by the U.S. Navy). The duration of such sounds, as received at a distance, can be greatly extended in a highly reverberant environment.

Impact hammers operate by using a piston or weight to drive the pile into the substrate. The impulsive sound generated by impact hammers is characterized by rapid rise times and high peak levels, a potentially injurious combination (Hastings and Popper, 2005). Vibratory hammers install piles by vibrating them, which liquefies surrounding substrate, and allowing the weight of the hammer to push the pile into the sediment. Vibratory hammers produce non-impulsive, continuous noise at levels significantly lower than those produced by impact hammers. Peak SPLs may be 180 dB or greater, but are generally 10 to 20 dB lower than SPLs generated during impact pile driving of the same-sized pile (Oestman *et al.,* 2009). Rise time is slower, reducing the probability and severity of injury, and sound energy is distributed over a greater amount of time (Nedwell and Edwards, 2002; Carlson *et al.,* 2005).

Acoustic Effects

Here, we first provide background information on marine mammal hearing before discussing the potential effects of the use of active acoustic sources on marine mammals.

Marine Mammal Hearing—Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Current data indicate that not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson *et al.,* 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007) recommended that marine mammals be divided into functional hearing groups based on directly measured or estimated hearing ranges on the basis of available behavioral response data, audiograms derived using auditory evoked potential techniques, anatomical modeling, and other data. Subsequently, NMFS (2016) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 dB threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. Functional groups for cetaceans and the associated frequencies are indicated below (note that these frequency ranges correspond to the range for the composite group, with the entire range not necessarily reflecting the capabilities of every species within that group):

- Low-frequency cetaceans (mysticetes): Generalized hearing is estimated to occur between approximately 7 Hz and 35 kHz, with best hearing estimated to be from 100 Hz to 8 kHz;
- Mid-frequency cetaceans (larger toothed whales, beaked whales, and most delphinids): generalized hearing is estimated to occur between approximately 150 Hz and 160 kHz, with best hearing from 10 to less than 100 kHz;
- High-frequency cetaceans (porpoises, river dolphins, and members of the genera *Kogia* and *Cephalorhynchus;* including two members of the genus *Lagenorhynchus,* on the basis of recent echolocation data and genetic data): generalized hearing is estimated to occur between approximately 275 Hz and 160 kHz.

For more detail concerning these groups and associated frequency ranges, please see NMFS (2016) for a review of available information. The bottlenose dolphin is classified as a mid-frequency cetacean.

Potential Effects of Underwater Sound—Please refer to the information given previously (''Description of Active Acoustic Sources'') regarding sound, characteristics of sound types, and metrics used in this document. Note that, in the following discussion, we refer in many cases to a recent review article concerning studies of noise-induced hearing loss conducted from 1996–2015 (*i.e.,* Finneran, 2015). For study-specific citations, please see that work. Anthropogenic sounds cover a broad range of frequencies and sound levels and can have a range of highly variable impacts on marine life, from none or minor to potentially severe responses, depending on received levels, duration of exposure, behavioral context, and various other factors. The potential effects of underwater sound can result in one or more of the following: temporary or permanent hearing impairment, non-auditory physical or physiological effects, behavioral disturbance, stress, and masking (Richardson *et al.,* 1995; Gordon *et al.,* 2004; Nowacek *et al.,* 2007; Southall *et al.,* 2007; Götz *et al.,* 2009). The degree of effect is intrinsically related to the signal characteristics, received level, distance from the source, and duration of the sound exposure. In general, sudden, high level sounds can cause hearing loss, as can longer exposures to lower level sounds. Temporary or permanent loss of hearing will occur almost exclusively for noise within an animal's hearing range. We first describe specific manifestations of acoustic effects before providing discussion specific to Navy's pile driving.

Richardson *et al.* (1995) described zones of increasing intensity of effect that might be expected to occur, in relation to distance from a source and assuming that the signal is within an animal's hearing range. First is the area

within which the acoustic signal would be audible (potentially perceived) to the animal but not strong enough to elicit any overt behavioral or physiological response. The next zone corresponds with the area where the signal is audible to the animal and of sufficient intensity to elicit behavioral or physiological responsiveness. Third is a zone within which, for signals of high intensity, the received level is sufficient to potentially cause discomfort or tissue damage to auditory or other systems. Overlaying these zones to a certain extent is the area within which masking (*i.e.,* when a sound interferes with or masks the ability of an animal to detect a signal of interest that is above the absolute hearing threshold) may occur; the masking zone may be highly variable in size.

We describe the more severe effects (*i.e.,* certain non-auditory physical or physiological effects) only briefly as we do not expect that there is a reasonable likelihood that Navy pile driving may result in such effects. Non-auditory physiological effects or injuries that theoretically might occur in marine mammals exposed to high level underwater sound or as a secondary effect of extreme behavioral reactions (*e.g.,* change in dive profile as a result of an avoidance reaction) caused by exposure to sound include neurological effects, bubble formation, resonance effects, and other types of organ or tissue damage (Cox *et al.,* 2006; Southall *et al.,* 2007; Zimmer and Tyack, 2007). Marine mammals that show behavioral avoidance of pile driving, including some odontocetes, are especially unlikely to incur auditory impairment or non-auditory physical effects, and Navy construction activities do not involve the use of devices such as explosives or mid-frequency active sonar that are associated with these types of effects.

1. *Permanent Threshold Shift*—Marine mammals exposed to high-intensity sound, or to lower-intensity sound for prolonged periods, can experience hearing threshold shift (TS), which is the loss of hearing sensitivity at certain frequency ranges (Finneran, 2015). TS can be permanent (PTS), in which case the loss of hearing sensitivity is not fully recoverable, or temporary (TTS), in which case the animal's hearing threshold would recover over time (Southall *et al.,* 2007). Repeated sound exposure that leads to TTS could cause PTS. In severe cases of PTS, there can be total or partial deafness, while in most cases the animal has an impaired ability to hear sounds in specific frequency ranges (Kryter, 1985).

When PTS occurs, there is physical damage to the sound receptors in the ear (*i.e.,* tissue damage), whereas TTS represents primarily tissue fatigue and is reversible (Southall *et al.,* 2007). In addition, other investigators have suggested that TTS is within the normal bounds of physiological variability and tolerance and does not represent physical injury (*e.g.,* Ward, 1997). Therefore, NMFS does not consider TTS to constitute auditory injury.

Relationships between TTS and PTS thresholds have not been studied in marine mammals, and there is no PTS data for cetaceans, but such relationships are assumed to be similar to those in humans and other terrestrial mammals. PTS typically occurs (a 40-dB threshold shift approximates PTS onset; *e.g.,* Kryter *et al.,* 1966; Miller, 1974) at exposure levels at least several decibels above that inducing mild TTS (a 6-dB threshold shift approximates TTS onset; *e.g.,* Southall *et al.* 2007). Based on data from terrestrial mammals, a precautionary assumption is that the PTS thresholds for impulse sounds (such as impact pile driving pulses as received close to the source) are at least 6 dB higher than the TTS threshold on a peak-pressure basis, and PTS cumulative sound exposure level thresholds are 15 to 20 dB higher than TTS cumulative sound exposure level thresholds (Southall *et al.,* 2007). Given the higher level of sound or longer exposure duration necessary to cause PTS as compared with TTS, it is considerably less likely that PTS could occur.

2. *Temporary Threshold Shift*—TTS is the mildest form of hearing impairment that can occur during exposure to sound (Kryter, 1985). While experiencing TTS, the hearing threshold rises, and a sound must be at a higher level in order to be heard. In terrestrial and marine mammals, TTS can last from minutes or hours to days (in cases of strong TTS). In many cases, hearing sensitivity recovers rapidly after exposure to the sound ends. Few data on sound levels and durations necessary to elicit mild TTS have been obtained for marine mammals.

Marine mammal hearing plays a critical role in communication with conspecifics, and interpretation of environmental cues for purposes such as predator avoidance and prey capture. Depending on the degree (elevation of threshold in dB), duration (*i.e.,* recovery time), and frequency range of TTS, and the context in which it is experienced, TTS can have effects on marine mammals ranging from discountable to serious. For example, a marine mammal may be able to readily compensate for a brief, relatively small amount of TTS in a non-critical frequency range that occurs during a time where ambient noise is lower and there are not as many competing sounds present. Alternatively, a larger amount and longer duration of TTS sustained during time when communication is critical for successful mother/calf interactions could have more serious impacts.

Currently, TTS data only exist for four species of cetaceans (bottlenose dolphin, beluga whale, harbor porpoise, and Yangtze finless porpoise [*Neophocoena asiaeorientalis*]) exposed to a limited number of sound sources (*i.e.,* mostly tones and octave-band noise) in laboratory settings (Finneran, 2015). In general, harbor porpoises have a lower TTS onset than other measured cetacean species (Finneran, 2015). Additionally, the existing marine mammal TTS data come from a limited number of individuals within these species. There are no data available on noise-induced hearing loss for mysticetes. For summaries of data on TTS in marine mammals or for further discussion of TTS onset thresholds, please see Southall *et al.* (2007), Finneran and Jenkins (2012), and Finneran (2015).

3. *Behavioral effects*—Behavioral disturbance may include a variety of effects, including subtle changes in behavior (*e.g.,* minor or brief avoidance of an area or changes in vocalizations), more conspicuous changes in similar behavioral activities, and more sustained and/or potentially severe reactions, such as displacement from or abandonment of high-quality habitat. Behavioral responses to sound are highly variable and context-specific and any reactions depend on numerous intrinsic and extrinsic factors (*e.g.,* species, state of maturity, experience, current activity, reproductive state, auditory sensitivity, time of day), as well as the interplay between factors (*e.g.,* Richardson *et al.,* 1995; Wartzok *et al.,* 2003; Southall *et al.,* 2007; Weilgart, 2007; Archer *et al.,* 2010). Behavioral reactions can vary not only among individuals but also within an individual, depending on previous experience with a sound source, context, and numerous other factors (Ellison *et al.,* 2012), and can vary depending on characteristics associated with the sound source (*e.g.,* whether it is moving or stationary, number of sources, distance from the source). Please see Appendices B–C of Southall *et al.* (2007) for a review of studies involving marine mammal behavioral responses to sound.

Habituation can occur when an animal's response to a stimulus wanes

with repeated exposure, usually in the absence of unpleasant associated events (Wartzok *et al.,* 2003). Animals are most likely to habituate to sounds that are predictable and unvarying. It is important to note that habituation is appropriately considered as a ''progressive reduction in response to stimuli that are perceived as neither aversive nor beneficial,'' rather than as, more generally, moderation in response to human disturbance (Bejder *et al.,* 2009). The opposite process is sensitization, when an unpleasant experience leads to subsequent responses, often in the form of avoidance, at a lower level of exposure. As noted, behavioral state may affect the type of response. For example, animals that are resting may show greater behavioral change in response to disturbing sound levels than animals that are highly motivated to remain in an area for feeding (Richardson *et al.,* 1995; NRC, 2003; Wartzok *et al.,* 2003). Controlled experiments with captive marine mammals have shown pronounced behavioral reactions, including avoidance of loud sound sources (Ridgway *et al.,* 1997). Observed responses of wild marine mammals to loud pulsed sound sources (typically seismic airguns or acoustic harassment devices) have been varied but often consist of avoidance behavior or other behavioral changes suggesting discomfort (Morton and Symonds, 2002; see also Richardson *et al.,* 1995; Nowacek *et al.,* 2007).

Available studies show wide variation in response to underwater sound; therefore, it is difficult to predict specifically how any given sound in a particular instance might affect marine mammals perceiving the signal. If a marine mammal does react briefly to an underwater sound by changing its behavior or moving a small distance, the impacts of the change are unlikely to be significant to the individual, let alone the stock or population. However, if a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on individuals and populations could be significant (*e.g.,* Lusseau and Bejder, 2007; Weilgart, 2007; NRC, 2005). There are broad categories of potential response, which we describe in greater detail here, and that include alteration of dive behavior, alteration of foraging behavior, effects on breathing, interference with or alteration of vocalization, avoidance, and flight responses.

Changes in dive behavior can vary widely, and may consist of increased or decreased dive times and surface intervals as well as changes in the rates of ascent and descent during a dive (*e.g.,* Frankel and Clark, 2000; Ng and Leung, 2003; Nowacek *et al.;* 2004; Goldbogen *et al.,* 2013a, b). Variations in dive behavior may reflect interruptions in biologically significant activities (*e.g.,* foraging), or they may be of little biological significance. The impact of an alteration to dive behavior resulting from an acoustic exposure depends on what the animal is doing at the time of the exposure and the type and magnitude of the response.

Disruption of feeding behavior can be difficult to correlate with anthropogenic sound exposure, so it is usually inferred by observed displacement from known foraging areas, the appearance of secondary indicators (*e.g.,* bubble nets or sediment plumes), or changes in dive behavior. As for other types of behavioral response, the frequency, duration, and temporal pattern of signal presentation, as well as differences in species sensitivity, are likely contributing factors to differences in response in any given circumstance (*e.g.,* Croll *et al.,* 2001; Nowacek *et al.;* 2004; Madsen *et al.,* 2006; Yazvenko *et al.,* 2007). A determination of whether foraging disruptions incur fitness consequences would require information on or estimates of the energetic requirements of the affected individuals and the relationship between prey availability, foraging effort and success, and the life history stage of the animal.

Variations in respiration naturally vary with different behaviors, and alterations to breathing rate as a function of acoustic exposure can be expected to co-occur with other behavioral reactions, such as a flight response or an alteration in diving. However, respiration rates in and of themselves may be representative of annoyance or an acute stress response. Various studies have shown that respiration rates may either be unaffected or could increase, depending on the species and signal characteristics, again highlighting the importance in understanding species differences in the tolerance of underwater noise when determining the potential for impacts resulting from anthropogenic sound exposure (*e.g.,* Kastelein *et al.,* 2001, 2005, 2006; Gailey *et al.,* 2007).

Marine mammals vocalize for different purposes and across multiple modes, such as whistling, echolocation click production, calling, and singing. Changes in vocalization behavior in response to anthropogenic noise can occur for any of these modes and may result from a need to compete with an increase in background noise or may reflect increased vigilance or a startle response. For example, in the presence of potentially masking signals, humpback whales and killer whales have been observed to increase the length of their songs (Miller *et al.,* 2000; Fristrup *et al.,* 2003; Foote *et al.,* 2004), while right whales have been observed to shift the frequency content of their calls upward while reducing the rate of calling in areas of increased anthropogenic noise (Parks *et al.,* 2007). In some cases, animals may cease sound production during production of aversive signals (Bowles *et al.,* 1994).

Avoidance is the displacement of an individual from an area or migration path as a result of the presence of a sound or other stressors, and is one of the most obvious manifestations of disturbance in marine mammals (Richardson *et al.,* 1995). For example, gray whales are known to change direction—deflecting from customary migratory paths—in order to avoid noise from seismic surveys (Malme *et al.,* 1984). Avoidance may be short-term, with animals returning to the area once the noise has ceased (*e.g.,* Bowles *et al.,* 1994; Goold, 1996; Stone *et al.,* 2000; Morton and Symonds, 2002; Gailey *et al.,* 2007). Longer-term displacement is possible, however, which may lead to changes in abundance or distribution patterns of the affected species in the affected region if habituation to the presence of the sound does not occur (*e.g.,* Bejder *et al.,* 2006; Teilmann *et al.,* 2006).

A flight response is a dramatic change in normal movement to a directed and rapid movement away from the perceived location of a sound source. The flight response differs from other avoidance responses in the intensity of the response (*e.g.,* directed movement, rate of travel). Relatively little information on flight responses of marine mammals to anthropogenic signals exist, although observations of flight responses to the presence of predators have occurred (Connor and Heithaus, 1996). The result of a flight response could range from brief, temporary exertion and displacement from the area where the signal provokes flight to, in extreme cases, marine mammal strandings (Evans and England, 2001). However, it should be noted that response to a perceived predator does not necessarily invoke flight (Ford and Reeves, 2008), and whether individuals are solitary or in groups may influence the response.

Behavioral disturbance can also impact marine mammals in more subtle ways. Increased vigilance may result in costs related to diversion of focus and attention (*i.e.,* when a response consists of increased vigilance, it may come at

the cost of decreased attention to other critical behaviors such as foraging or resting). These effects have generally not been demonstrated for marine mammals, but studies involving fish and terrestrial animals have shown that increased vigilance may substantially reduce feeding rates (*e.g.,* Beauchamp and Livoreil, 1997; Fritz *et al.,* 2002; Purser and Radford, 2011). In addition, chronic disturbance can cause population declines through reduction of fitness (*e.g.,* decline in body condition) and subsequent reduction in reproductive success, survival, or both (*e.g.,* Harrington and Veitch, 1992; Daan *et al.,* 1996; Bradshaw *et al.,* 1998). However, Ridgway *et al.* (2006) reported that increased vigilance in bottlenose dolphins exposed to sound over a five-day period did not cause any sleep deprivation or stress effects.

Many animals perform vital functions, such as feeding, resting, traveling, and socializing, on a diel cycle (24-hour cycle). Disruption of such functions resulting from reactions to stressors such as sound exposure are more likely to be significant if they last more than one diel cycle or recur on subsequent days (Southall *et al.,* 2007). Consequently, a behavioral response lasting less than one day and not recurring on subsequent days is not considered particularly severe unless it could directly affect reproduction or survival (Southall *et al.,* 2007). Note that there is a difference between multi-day substantive behavioral reactions and multi-day anthropogenic activities. For example, just because an activity lasts for multiple days does not necessarily mean that individual animals are either exposed to activity-related stressors for multiple days or, further, exposed in a manner resulting in sustained multi-day substantive behavioral responses.

4. *Stress responses*—An animal's perception of a threat may be sufficient to trigger stress responses consisting of some combination of behavioral responses, autonomic nervous system responses, neuroendocrine responses, or immune responses (*e.g.,* Seyle, 1950; Moberg, 2000). In many cases, an animal's first and sometimes most economical (in terms of energetic costs) response is behavioral avoidance of the potential stressor. Autonomic nervous system responses to stress typically involve changes in heart rate, blood pressure, and gastrointestinal activity. These responses have a relatively short duration and may or may not have a significant long-term effect on an animal's fitness.

Neuroendocrine stress responses often involve the hypothalamus-pituitary-adrenal system. Virtually all neuroendocrine functions that are affected by stress—including immune competence, reproduction, metabolism, and behavior—are regulated by pituitary hormones. Stress-induced changes in the secretion of pituitary hormones have been implicated in failed reproduction, altered metabolism, reduced immune competence, and behavioral disturbance (*e.g.,* Moberg, 1987; Blecha, 2000). Increases in the circulation of glucocorticoids are also equated with stress (Romano *et al.,* 2004).

The primary distinction between stress (which is adaptive and does not normally place an animal at risk) and ''distress'' is the cost of the response. During a stress response, an animal uses glycogen stores that can be quickly replenished once the stress is alleviated. In such circumstances, the cost of the stress response would not pose serious fitness consequences. However, when an animal does not have sufficient energy reserves to satisfy the energetic costs of a stress response, energy resources must be diverted from other functions. This state of distress will last until the animal replenishes its energetic reserves sufficient to restore normal function.

Relationships between these physiological mechanisms, animal behavior, and the costs of stress responses are well-studied through controlled experiments and for both laboratory and free-ranging animals (*e.g.,* Holberton *et al.,* 1996; Hood *et al.,* 1998; Jessop *et al.,* 2003; Krausman *et al.,* 2004; Lankford *et al.,* 2005). Stress responses due to exposure to anthropogenic sounds or other stressors and their effects on marine mammals have also been reviewed (Fair and Becker, 2000; Romano *et al.,* 2002b) and, more rarely, studied in wild populations (*e.g.,* Romano *et al.,* 2002a). For example, Rolland *et al.* (2012) found that noise reduction from reduced ship traffic in the Bay of Fundy was associated with decreased stress in North Atlantic right whales. These and other studies lead to a reasonable expectation that some marine mammals will experience physiological stress responses upon exposure to acoustic stressors and that it is possible that some of these would be classified as ''distress.'' In addition, any animal experiencing TTS would likely also experience stress responses (NRC, 2003).

5. *Auditory masking*—Sound can disrupt behavior through masking, or interfering with, an animal's ability to detect, recognize, or discriminate between acoustic signals of interest (*e.g.,* those used for intraspecific communication and social interactions, prey detection, predator avoidance, navigation) (Richardson *et al.,* 1995; Erbe *et al.,* 2016). Masking occurs when the receipt of a sound is interfered with by another coincident sound at similar frequencies and at similar or higher intensity, and may occur whether the sound is natural (*e.g.,* snapping shrimp, wind, waves, precipitation) or anthropogenic (*e.g.,* shipping, sonar, seismic exploration) in origin. The ability of a noise source to mask biologically important sounds depends on the characteristics of both the noise source and the signal of interest (*e.g.,* signal-to-noise ratio, temporal variability, direction), in relation to each other and to an animal's hearing abilities (*e.g.,* sensitivity, frequency range, critical ratios, frequency discrimination, directional discrimination, age or TTS hearing loss), and existing ambient noise and propagation conditions.

Under certain circumstances, marine mammals experiencing significant masking could also be impaired from maximizing their performance fitness in survival and reproduction. Therefore, when the coincident (masking) sound is man-made, it may be considered harassment when disrupting or altering critical behaviors. It is important to distinguish TTS and PTS, which persist after the sound exposure, from masking, which occurs during the sound exposure. Because masking (without resulting in TS) is not associated with abnormal physiological function, it is not considered a physiological effect, but rather a potential behavioral effect.

The frequency range of the potentially masking sound is important in determining any potential behavioral impacts. For example, low-frequency signals may have less effect on high-frequency echolocation sounds produced by odontocetes but are more likely to affect detection of mysticete communication calls and other potentially important natural sounds such as those produced by surf and some prey species. The masking of communication signals by anthropogenic noise may be considered as a reduction in the communication space of animals (*e.g.,* Clark *et al.,* 2009) and may result in energetic or other costs as animals change their vocalization behavior (*e.g.,* Miller *et al.,* 2000; Foote *et al.,* 2004; Parks *et al.,* 2007; Di Iorio and Clark, 2009; Holt *et al.,* 2009). Masking can be reduced in situations where the signal and noise come from different directions (Richardson *et al.,* 1995), through amplitude modulation of the signal, or through other compensatory behaviors (Houser and Moore, 2014). Masking can

be tested directly in captive species (*e.g.,* Erbe, 2008), but in wild populations it must be either modeled or inferred from evidence of masking compensation. There are few studies addressing real-world masking sounds likely to be experienced by marine mammals in the wild (*e.g.,* Branstetter *et al.,* 2013).

Masking affects both senders and receivers of acoustic signals and can potentially have long-term chronic effects on marine mammals at the population level as well as at the individual level. Low-frequency ambient sound levels have increased by as much as 20 dB (more than three times in terms of SPL) in the world's ocean from pre-industrial periods, with most of the increase from distant commercial shipping (Hildebrand, 2009). All anthropogenic sound sources, but especially chronic and lower-frequency signals (*e.g.,* from vessel traffic), contribute to elevated ambient sound levels, thus intensifying masking.

Potential Effects of Navy Activity—As described previously (see ''Description of Active Acoustic Sound Sources''), the Navy proposes to conduct pile driving, including impact and vibratory driving. The effects of pile driving on marine mammals are dependent on several factors, including the size, type, and depth of the animal; the depth, intensity, and duration of the pile driving sound; the depth of the water column; the substrate of the habitat; the standoff distance between the pile and the animal; and the sound propagation properties of the environment. With both types of pile driving, it is likely that the onset of pile driving could result in temporary, short term changes in an animal's typical behavior and/or avoidance of the affected area. These behavioral changes may include (Richardson *et al.,* 1995): changing durations of surfacing and dives, number of blows per surfacing, or moving direction and/or speed; reduced/increased vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); visible startle response or aggressive behavior (such as tail/fluke slapping or jaw clapping); avoidance of areas where sound sources are located; and/or flight responses.

The biological significance of many of these behavioral disturbances is difficult to predict, especially if the detected disturbances appear minor. However, the consequences of behavioral modification could be expected to be biologically significant if the change affects growth, survival, or reproduction. Significant behavioral modifications that could lead to effects on growth, survival, or reproduction, such as drastic changes in diving/surfacing patterns or significant habitat abandonment are extremely unlikely in this area (*i.e.,* shallow waters in a heavily altered industrial area).

The onset of behavioral disturbance from anthropogenic sound depends on both external factors (characteristics of sound sources and their paths) and the specific characteristics of the receiving animals (hearing, motivation, experience, demography) and is difficult to predict (Southall *et al.,* 2007).

Whether impact or vibratory driving, sound sources would be active for relatively short durations, with relation to potential for masking. The frequencies output by pile driving activity are lower than those used by bottlenose dolphins for communication or foraging. We expect insignificant impacts from masking, and any masking event that could possibly rise to Level B harassment under the MMPA would occur concurrently within the zones of behavioral harassment already estimated for vibratory and impact pile driving, and which have already been taken into account in the exposure analysis.

Anticipated Effects on Marine Mammal Habitat

The proposed activities would not result in permanent impacts to habitats used directly by marine mammals, but may have potential short-term impacts to food sources such as forage fish. The proposed activities could also affect acoustic habitat (see masking discussion above), but meaningful impacts are unlikely. There are no known foraging hotspots, or other ocean bottom structures of significant biological importance to marine mammals present in the marine waters in the vicinity of the project area. Therefore, the main impact issue associated with the proposed activity would be temporarily elevated sound levels and the associated direct effects on marine mammals, as discussed previously in this preamble. The most likely impact to marine mammal habitat occurs from pile driving effects on likely marine mammal prey (*i.e.,* fish) near NSB Kings Bay and minor impacts to the immediate substrate during installation and removal of piles.

Effects to Prey—Impact pile driving would produce pulsed sounds, and fish react to sounds which are especially strong and/or intermittent low-frequency sounds. Short duration, sharp sounds can cause overt or subtle changes in fish behavior and local distribution. Hastings and Popper (2005) identified several studies that suggest fish may relocate to avoid certain areas of sound energy. Additional studies have documented effects of pile driving on fish, although several are based on studies in support of large, multiyear bridge construction projects (*e.g.,* Scholik and Yan, 2001, 2002; Popper and Hastings, 2009). Sound pulses at various received levels may cause subtle to noticeable changes in fish behavior (Pearson *et al.,* 1992; Skalski *et al.,* 1992). SPLs of sufficient strength have been known to cause injury to fish and fish mortality. The most likely impact to fish from pile driving activities at the project area would be temporary behavioral avoidance of the area. The duration of fish avoidance of this area after pile driving stops is unknown, but a rapid return to normal recruitment, distribution and behavior is anticipated. In general, impacts to marine mammal prey species are expected to be minor and temporary due to the expected short daily duration of individual pile driving events and the relatively small areas being affected. It is also not expected that the industrial environment of NSB Kings Bay provides important fish habitat or harbors significant amounts of forage fish.

The area likely impacted by the project is relatively small compared to the available habitat in inland waters in the region. Any behavioral avoidance by fish of the disturbed area would still leave significantly large areas of fish and marine mammal foraging habitat in the nearby vicinity. As described in the preceding, the potential for Navy construction to affect the availability of prey to marine mammals or to meaningfully impact the quality of physical or acoustic habitat is considered to be insignificant. Effects to habitat will not be discussed further in this document.

Estimated Take by Incidental Harassment

Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines ''harassment'' as: ''. . . any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).''

Anticipated takes would be by Level B harassment, as pile driving activity has the potential to result in disruption of behavioral patterns for individual

marine mammals. Level A harassment by auditory injury is unlikely to occur as a result of this activity for bottlenose dolphins (*i.e.,* mid-frequency hearing specialists) and, although it is unlikely that take by Level A harassment would occur even in the absence of the proposed mitigation and monitoring measures, the proposed measures are expected to further minimize such potential. The Navy has requested authorization for the incidental taking by Level B harassment of bottlenose dolphins in the vicinity of NSB Kings Bay that may result from pile driving during waterfront construction activities described previously in this document.

Sound Thresholds

We have historically used generic sound exposure thresholds (see Table 5) to determine when an activity that produces sound might result in impacts to a marine mammal such that a take by harassment might occur. These thresholds should be considered guidelines for estimating when harassment may occur (*i.e.,* when an animal is exposed to levels equal to or exceeding the relevant criterion) in specific contexts; however, useful contextual information that may inform our assessment of effects is typically lacking and we consider these thresholds as step functions. For Level B harassment, the 160 dB and 120 dB rms criteria are used to estimate incidents of take resulting from impact and vibratory pile driving, respectively.

TABLE 5—HISTORICAL ACOUSTIC EXPOSURE CRITERIA

Criterion	Definition	Threshold
Level A harassment	Injury (onset PTS—any level above that which is known to cause TTS).	180 dB rms (cetaceans).
Level B harassment	Behavioral disruption	160 dB rms (impulse sources); 120 dB rms (non-impulsive, continuous sources).

In August 2016, NMFS released its ''Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing,'' which established new thresholds for predicting auditory injury (NMFS, 2016), and which equates to Level A harassment under the MMPA. For more information, please visit *www.nmfs.noaa.gov/pr/acoustics/guidelines.htm.* In the August 4, 2016, **Federal Register** notice announcing the guidance (81 FR 51694), NMFS explained the approach it would take during a transition period, wherein we balance the need to consider this new best available science with the fact that some applicants have already committed time and resources to the development of acoustic analyses based on our previous thresholds and have constraints that preclude the recalculation of take estimates, as well as with a consideration of where the agency is in the decision-making pipeline. In that notice, we included a non-exhaustive list of factors that would inform the most appropriate approach for considering the new guidance, including: how far in the MMPA process the applicant has progressed; the scope of the effects; when the authorization is needed; the cost and complexity of the analysis; and the degree to which the guidance is expected to affect our analysis.

The new guidance identifies the received levels, or thresholds, above which individual marine mammals are predicted to experience changes in their hearing sensitivity (either temporary or permanent) for all underwater anthropogenic sound sources, reflects the best available science, and is intended to better predict the potential for auditory injury than does NMFS's historical criteria. The guidance reflects the best available science on the potential for noise to affect auditory sensitivity by:

- Dividing sound sources into two groups (*i.e.,* impulsive and non-impulsive) based on their potential to affect hearing sensitivity;
- Choosing metrics that better address the impacts of noise on hearing sensitivity, *i.e.,* peak SPL (better reflects the physical properties of impulsive sound sources, to affect hearing sensitivity) and cumulative sound exposure level (cSEL) (accounts for not only level of exposure but also durations of exposure);
- Dividing marine mammals into functional hearing groups and developing auditory weighting functions based on the science supporting that not all marine mammals hear and use sound in the same manner.

NMFS's new guidance (NMFS, 2016) recommends specific thresholds under the dual metric approach (*i.e.,* peak SPL and cSEL) and recommends that marine mammals be divided into functional hearing groups based on measured or estimated functional hearing ranges. The premise of the dual criteria approach is that, while there is no definitive answer to the question of which acoustic metric is most appropriate for assessing the potential for injury, both the intensity and duration of received signals are important to an understanding of the potential for injury. Therefore, peak SPL is used to define a pressure criterion above which tissue injury is predicted to occur, regardless of exposure duration (*i.e.,* any single exposure at or above this level is considered to cause tissue injury), and cSEL is used to account for the total energy received over the duration of sound exposure (*i.e.,* both received level and duration of exposure) (Southall *et al.,* 2007; NMFS, 2016). As a general principle, whichever criterion is exceeded first would be used as the effective injury criterion (*i.e.,* the more precautionary of the criteria). Note that cSEL acoustic threshold levels incorporate marine mammal auditory weighting functions, while peak pressure thresholds do not. NMFS (2016) recommends 24 hours as a maximum accumulation period relative to cSEL thresholds. For further discussion of auditory weighting functions and their application, please see NMFS (2016). Table 6 displays relevant thresholds provided by NMFS (2016).

TABLE 6—EXPOSURE CRITERIA FOR AUDITORY INJURY [1]

Hearing group	Peak pressure [2]	Cumulative sound exposure level [3]
Mid-frequency cetaceans	230 dB	185 dB

[1] Onset PTS—any level above that which is known to cause TTS.
[2] Referenced to 1 μPa; unweighted within generalized hearing range.
[3] Referenced to 1 $\mu Pa^2 s$; weighted according to appropriate auditory weighting function.

NMFS considers these updated thresholds and associated weighting functions to be the best available information for assessing whether exposure to sound from specific activities is likely to result in changes in marine mammal hearing sensitivity. In this case, Navy submitted a timely

request for authorization that was determined to be adequate and complete prior to availability of the guidance. The Navy's analysis considered the potential for auditory injury to marine mammals, but ultimately concluded that injury would be unlikely to occur due to their proposed mitigation measures; *i.e.,* Level A harassment mitigation zones calculated on the basis of NMFS's then-current thresholds for onset of permanent threshold shift (*i.e.,* 180 dB rms). Following release of the new guidance, we have considered the likely implications for potential auditory injury of marine mammals. Based on consideration of the guidance, potential injury zones are much smaller than previously expected, and are fully encompassed by Navy's revised proposed shutdown zones. In consideration of the small injury zones and the Navy's proposed mitigation, we believe that injury will be avoided. In summary, we have considered the new guidance and believe that the likelihood of injury is adequately addressed in this analysis, and appropriate protective measures are in place in the proposed regulations.

Zones of Influence

Sound Propagation—Pile driving generates underwater noise that can potentially result in disturbance to marine mammals in the project area. Transmission loss (TL) is the decrease in acoustic intensity as an acoustic pressure wave propagates out from a source. TL parameters vary with frequency, temperature, sea conditions, current, source and receiver depth, water depth, water chemistry, and bottom composition and topography. The general formula for underwater TL is:

$$TL = B * \log_{10}(R_1/R_2),$$

Where:

R_1 = the distance of the modeled SPL from the driven pile, and

R_2 = the distance from the driven pile of the initial measurement.

This formula neglects loss due to scattering and absorption, which is assumed to be zero here. The degree to which underwater sound propagates away from a sound source is dependent on a variety of factors, most notably the water bathymetry and presence or absence of reflective or absorptive conditions including in-water structures and sediments. Spherical spreading occurs in a perfectly unobstructed (free-field) environment not limited by depth or water surface, resulting in a 6 dB reduction in sound level for each doubling of distance from the source (20*log(range)). Cylindrical spreading occurs in an environment in which sound propagation is bounded by the water surface and sea bottom, resulting in a reduction of 3 dB in sound level for each doubling of distance from the source (10*log(range)). As is common practice in coastal waters, here we assume practical spreading loss (4.5 dB reduction in sound level for each doubling of distance) here. Practical spreading is a compromise that is often used under conditions where water increases with depth as the receiver moves away from the shoreline, resulting in an expected propagation environment that would lie between spherical and cylindrical spreading loss conditions.

Sound Source Levels and Behavioral Zones—The intensity of pile driving sounds is greatly influenced by factors such as the type of piles, hammers, and the physical environment in which the activity takes place. However, there are no measurements available from the specific environment of NSB Kings Bay. Numerous studies have examined sound pressure levels (SPLs) recorded from underwater pile driving projects in California and Washington, and the Navy has conducted a few studies on the east coast. In addition, the majority of studies are focused on steel pipe piles, with less data available for other pile types. In order to determine reasonable SPLs and their associated effects on marine mammals that are likely to result from pile driving at NSB Kings Bay, studies with similar properties to the specified activity were evaluated, and are displayed in Table 7. Where available, data from the east coast were prioritized due to the differences in bathymetry and sediment at west coast sites. For pile types for which data from the east coast were not available, averages of west coast data were used to approximate source levels. For fiberglass reinforced plastic composite piles, no measured data are available. The source level estimates for this type of pile were based on data from timber piles driven on the east coast of the U.S, assuming that this is the most similar pile material. In all cases, where data from the same pile size/type were not available, a more conservative proxy was used. Where appropriate, weighted project averages were considered. Values measured at distances greater than 10 m were normalized to 10 m before calculating averages. For full details of data considered, please see Appendix C of the Navy's application.

TABLE 7—SUMMARY OF PROXY MEASURED UNDERWATER SOUND PRESSURE LEVELS (SPLS)

Method	Pile size and material	Proxy	Proxy source levels (dB at 10 m)		
			rms	pk	SEL
Vibratory	16″ timber; 16–18″ composite	12–16″ timber [1]	161	n/a	n/a
Vibratory	18–24″ concrete	24″ steel pipe [2–5]	166	n/a	n/a
Vibratory	14″ steel H	14″ steel H [6]	163	n/a	n/a
Vibratory	24″ steel pipe	24″ steel pipe [2–5]	166	n/a	n/a
Vibratory	30″ steel pipe	30″ steel pipe [7–9]	166	n/a	n/a
Impact	18″ concrete	18″ concrete [4]	170	184	159
Impact	24″ concrete	24″ concrete [1 6]	174	184	165
Impact	14″ steel H	14″ steel H [4]	178	196	168
Impact	24″ steel pipe	24″ steel pipe [4 10–11]	190	206	179
Impact	30″ steel pipe	30″ steel pipe [4 8 10 12]	193	209	188

Sources: [1] Illingworth & Rodkin, 2015; [2] Illingworth & Rodkin, 2010; [3] Illingworth & Rodkin, 2012; [4] Caltrans, 2012; [5] Illingworth & Rodkin, 2013b; [6] Illingworth & Rodkin, 2013a; [7] Laughlin, 2010a; [8] Laughlin, 2010b; [9] Laughlin, 2011; [10] Laughlin, 2005a; [11] Laughlin, 2005b; [12] MacGillivray and Racca, 2005.

We consider the values presented in Table 7 to be representative of SPLs that may be produced by the specified activity. All calculated distances to and the total area encompassed by the marine mammal sound thresholds are provided in Table 8. Calculated radial distances to the 160 dB threshold assume a field free of obstruction.

However, the waters surrounding NSB Kings Bay do not represent open water conditions and the calculated zone-specific areas take landforms into consideration. Actual zones are depicted in Figures 6–1 through 6–26 of the Navy's application. Although calculated radial distances to threshold do not change, the actual zone sizes may vary depending on the specific project location.

TABLE 8—DISTANCES TO RELEVANT SOUND THRESHOLDS AND AREAS OF ENSONIFICATION

Project	Pile type	Distance to threshold (m) and associated area of emsonification (km²)			
		160 dB		120 dB	
1A	16″ timber	n/a	n/a	5,412	3.69
1A	18″ concrete	46.4	0.01	n/a	n/a
1A	24″ concrete	85.8	0.02	n/a	n/a
1B	16″ timber/composite	n/a	n/a	5,412	3.12
2	14″ steel H	159	0.06	n/a	n/a
3A (FY17)	24″ steel pipe	1,000	0.88	11,659	3.63
3A (FY22)	24″ concrete	85.8	0.02	11,659	3.63
3A (FY22)	24″ steel pipe	1,000	0.88	11,659	3.63
3B	14″ steel H	159	0.04	7,356	2.40
3C	24–30″ steel pipe	1,000	0.75	11,659	3.32
3D	24–30″ steel pipe	1,000	0.90	11,659	3.17
3E	24–30″ steel pipe	1,000	0.88	11,659	3.72
3F	30″ steel pipe	1,585	1.35	11,659	3.49
3G	14″ steel H	159	0.07	7,356	4.00
4A	18″ concrete	46.4	0.02	11,659	7.51
4A	24″ concrete	85.8	0.01	11,659	7.51
4B	24″ steel pipe	1,000	1.63	11,659	6.39
5	16″ timber/18″ composite	n/a	n/a	5,412	10.75
6A/6B	24″ concrete	n/a	n/a	11,659	9.34

Areas presented take into account attenuation and/or shadowing by land. Please see Figures 6–1 to 6–26 in the Navy's application.

Marine Mammal Density

The Navy conducted marine mammal surveys at NSB Kings Bay during 2006–2007 (McKee and Latusek, 2009). Transect lines were run in the waters around NSB Kings Bay during summer and fall 2006 and during winter and spring 2007. The survey area included estuarine waters extending from the mouth of the St. Marys River north through the Cumberland Sound to approximately eight nautical miles (nmi) inland along the Satilla River. The Crooked River and the Brickhill River, which flow into Cumberland Sound, were also part of the study area, though line transects were not possible in these locations, and census counts were substituted here. The geographic limits ranged from 30°40′ N. to 31°00′ N. and inland limits to 81°40′ W. Nearshore Atlantic waters were not included in the surveys.

Observations were made with 7x50 power binoculars and with the naked eye, scanning from 0–90° relative to the vessel's line of travel. Sightings, radial distance and angle to animal, and number of individuals were recorded. For census count areas, the vessel was driven along the center line of the river and distance and angle to sightings were noted. Commercially available software (Distance 5.0) was used to analyze the collected data, including area surveyed, and calculate a seasonal density. Seasonal densities were combined to calculate an average annual density of 1.12 dolphins per km².

Incidental Take Calculation

The species density described above (1.12 animals/km²) was multiplied by the activity-specific ZOIs shown in Table 8 to determine the estimated daily exposures. The Navy then rounded these daily exposure estimates to the nearest whole number before multiplying by activity-specific pile driving days, shown in Table 2, to yield the exposure estimates shown in Table 9. The Navy has requested authorization for a total of 881 incidents of Level B harassment of bottlenose dolphins over the five-year period of validity of these proposed regulations. Table 9 displays the total take estimate broken out by project and year. However, note that year assignments reflect only the projected project start years. Projects may continue into succeeding years, but neither exact start dates nor whether a project would in fact continue into the succeeding year are known at this time.

TABLE 9—INCIDENTAL TAKE TOTALS

Year	Project	Impact	Vibratory
FY17	1A	0	124
	1B	n/a	6
	2	0	n/a
	3A	1	4
	3D	1	4
	5	n/a	72
FY17 Totals	n/a	2	210
		212	
FY18	3C	1	4
	3E	1	4

TABLE 9—INCIDENTAL TAKE TOTALS—Continued

Year	Project	Impact	Vibratory
FY18 Totals	n/a	2	8
		10	
FY19	n/a		
FY20	4A	0	64
	4B	8	32
FY20 Totals	n/a	8	96
		104	
FY21	3B	0	21
	3F	4	8
FY21 Totals	n/a	4	29
		33	
FY22	3A	4	16
	3G	0	32
	6A	n/a	410
	6B	n/a	60
FY22 Totals	n/a	4	518
		522	
FY17–22 Totals	n/a	20	861
		881	

Analyses and Preliminary Determinations

Negligible Impact Analysis

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''. . . an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.'' A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be taken by mortality, serious injury, and Level A or Level B harassment, we consider other factors, such as the likely nature of any behavioral responses (*e.g.,* intensity, duration), the context of any such responses (*e.g.,* critical reproductive time or location, migration), as well as the number and nature of estimated Level A harassment takes (if any), and effects on habitat. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status (*i.e.,* the environmental baseline).

Consistent with the 1989 preamble for NMFS's implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into these analyses via their impacts on the environmental baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, sources of human-caused mortality).

Pile driving activities associated with the wharf construction projects, as described previously, have the potential to disturb or displace marine mammals. Specifically, the specified activities may result in take, in the form of Level B harassment (behavioral disturbance) only, from underwater sounds generated from pile driving. Potential takes could occur if individual bottlenose dolphins are present in the ensonified zone when pile driving is happening.

No serious injury or mortality would be expected even in the absence of the proposed mitigation measures. No Level A harassment is anticipated given the nature of the activities and measures designed to minimize the possibility of injury. The potential for injury is small, and is expected to be essentially eliminated through implementation of the planned mitigation measures—soft start (for impact driving) and shutdown zones. Impact driving, as compared with vibratory driving, has source characteristics (short, sharp pulses with higher peak levels and much sharper rise time to reach those peaks) that are potentially injurious or more likely to produce severe behavioral reactions. Given sufficient notice through use of soft start, marine mammals are expected to move away from a sound source that is annoying prior to its becoming potentially injurious or resulting in more severe behavioral reactions. Environmental conditions in waters surrounding NSB Kings Bay are expected to generally be good, with calm sea states, albeit with high turbidity. Nevertheless, we expect conditions would allow a high marine mammal detection capability, enabling a high rate of success in implementation of shutdowns to avoid injury.

Effects on individuals that are taken by Level B harassment, on the basis of reports in the literature as well as monitoring from other similar activities, will likely be limited to reactions such as increased swimming speeds, increased surfacing time, or decreased foraging (if such activity were occurring) (*e.g.,* Thorson and Reyff, 2006; HDR, Inc., 2012; Lerma, 2014). Most likely, individuals will simply move away from the sound source and be temporarily displaced from the areas of pile driving, although even this reaction has been observed primarily only in association with impact pile driving. The pile driving activities analyzed here are similar to, or less impactful than, numerous other construction activities

conducted in San Francisco Bay and in the Puget Sound region, which have taken place with no known long-term adverse consequences from behavioral harassment.

The Navy has conducted similar multi-year activities potentially affecting bottlenose dolphins in San Diego Bay and in the same general region at Mayport Florida, that have similarly reported no apparently consequential behavioral reactions or long-term effects on bottlenose dolphin populations (Lerma, 2014; Navy, 2015). Repeated exposures of individuals to relatively low levels of sound outside of preferred habitat areas are unlikely to significantly disrupt critical behaviors. Thus, even repeated Level B harassment of some small subset of the overall stock is unlikely to result in any significant realized decrease in viability for the affected individuals, and thus would not result in any adverse impact to the stock as a whole. Level B harassment will be reduced to the level of least practicable adverse impact through use of mitigation measures described herein and, if sound produced by project activities is sufficiently disturbing, animals are likely to simply avoid the area while the activity is occurring. While vibratory driving associated with some project components may produce sound at distances of multiple kilometers from the pile driving site, thus intruding on higher-quality habitat, the project sites themselves and the majority of sound fields produced by the specified activities are within a heavily impacted, industrialized area. Therefore, we expect that animals annoyed by project sound would simply avoid the area and use more-preferred habitats.

In summary, this negligible impact analysis is founded on the following factors: (1) The possibility of injury, serious injury, or mortality may reasonably be considered discountable; (2) the anticipated incidents of Level B harassment consist of, at worst, temporary modifications in behavior; (3) the absence of any significant habitat within the project area, including known areas or features of special significance for foraging or reproduction; and (4) the presumed efficacy of the proposed mitigation measures in reducing the effects of the specified activity to the level of least practicable adverse impact. In addition, while some of the potentially affected stocks are considered depleted under the MMPA, it is unlikely that minor noise effects in a small, localized area would have any effect on the stocks' ability to recover. In combination, we believe that these factors, as well as the available body of evidence from other similar activities, demonstrate that the potential effects of the specified activities will have only minor, short-term effects on individuals. The specified activities are not expected to impact rates of recruitment or survival and will therefore not result in population-level impacts.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed monitoring and mitigation measures, we preliminarily find that the total marine mammal take from the Navy's waterfront construction activities will have a negligible impact on the affected marine mammal species or stocks.

Small Numbers Analysis

Please see Table 9 for information relating to this small numbers analysis; as described previously, although we provide exposure estimates broken out by year and project component, we do not have specific information about when each project would be concluded or therefore how many takes may actually accrue in any given year during the five-year period of validity of these propose regulations. The annual average over the course of the five year period is 176 takes. Of these annual average 176 incidents of behavioral harassment predicted to occur for bottlenose dolphin, we have no information allowing us to parse the predicted incidents amongst the stocks of bottlenose dolphin that may occur in the project area. However, because they would be expected to occur only rarely and/or seasonally, we assume that only small numbers of individuals of the northern Florida coastal, southern migratory coastal, and Jacksonville estuarine system stocks would be potentially present and available to be taken.

The South Carolina/Georgia coastal and southern Georgia estuarine system stocks are expected to potentially be present more regularly. For the South Carolina/Georgia coastal stock, the annual average predicted number of incidents of take proposed for authorization would be considered small—approximately four percent—even if each estimated taking occurred to a new individual. This is an extremely unlikely scenario as, for bottlenose dolphins in estuarine and nearshore waters, there is likely to be some overlap in individuals present day-to-day.

The total number of authorized takes for bottlenose dolphins, if assumed to accrue solely to new individuals of the SGES stock, is higher relative to the total stock abundance, which is currently estimated at 194 individuals. As described previously, this estimate is the result of surveys covering only a portion of the stock range and is assumed to underestimate the stock abundance. Regardless, these numbers represent the estimated incidents of take, not the number of individuals taken. That is, it is highly likely that a relatively small subset of SGES bottlenose dolphins would be harassed by project activities. SGES bottlenose dolphins range from Cumberland Sound at the Georgia-Florida border north to the Altamaha Sound, Georgia, an area spanning approximately 70 linear km of coastline and including habitat consisting of complex inshore and estuarine waterways. SGES dolphins show strong site fidelity (Balmer *et al.,* 2013), and it is likely that the majority of SGES dolphins would not occur within waters ensonified by project activities. In summary, SGES dolphins are known to exhibit strong site fidelity (*i.e.,* individuals do not generally range throughout the recognized overall SGES stock range), and the specified activity will be stationary within a relatively enclosed industrial area not recognized as an area of any special significance that would serve to attract or aggregate dolphins. We therefore believe that the estimated numbers of take, were they to occur, likely represent repeated exposures of a much smaller number of bottlenose dolphins, and that these estimated incidents of take represent small numbers of bottlenose dolphins.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, we preliminarily find that small numbers of marine mammals will be taken relative to the populations of the affected species or stocks.

Proposed Monitoring and Reporting

In order to issue an incidental take authorization for an activity, section 101(a)(5)(A) of the MMPA states that NMFS must set forth ''requirements pertaining to the monitoring and reporting of such taking.'' The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for incidental take authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area.

Any monitoring requirement we prescribe should improve our understanding of one or more of the following:

• Occurrence of marine mammal species in action area (*e.g.,* presence, abundance, distribution, density).

• Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) Action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) affected species (*e.g.,* life history, dive patterns); (3) co-occurrence of marine mammal species with the action; or (4) biological or behavioral context of exposure (*e.g.,* age, calving, or feeding areas).

• Individual responses to acute stressors, or impacts of chronic exposures (behavioral or physiological).

• How anticipated responses to stressors impact either: (1) long-term fitness and survival of an individual; or (2) population, species, or stock.

• Effects on marine mammal habitat and resultant impacts to marine mammals.

• Mitigation and monitoring effectiveness.

The Navy provided a separate Marine Mammal Monitoring Plan, which is available online at *www.nmfs.noaa.gov/pr/permits/incidental/construction.htm.*

Visual Marine Mammal Observations

The Navy will collect sighting data and behavioral responses to construction for marine mammal species observed in the region of activity during the period of activity. All observers will be trained in marine mammal identification and behaviors and are required to have no other construction-related tasks while conducting monitoring. The Navy would monitor all shutdown zones at all times, and would monitor disturbance zones during a varying subset of total project days. Approximately half of disturbance zone monitoring effort is proposed for allocation during the first two years of project activities in order to provide verification during the early stages of the project regarding assumed numbers of bottlenose dolphins present in the area. If compliance monitoring results suggest that the actual number of incidental take events may differ significantly from the number originally authorized, the Navy would consult with NMFS. The Navy would conduct monitoring before, during, and after pile driving, with observers located at the best practicable vantage points. Based on our requirements, the Navy would implement the following procedures for pile driving:

• Marine mammal observers would be located at the best vantage point(s) in order to properly see the entire shutdown zone and as much of the disturbance zone as possible.

• During all observation periods, observers will use binoculars and the naked eye to search continuously for marine mammals.

• If the shutdown zones are obscured by fog or poor lighting conditions, pile driving at that location will not be initiated until that zone is visible. Should such conditions arise while impact driving is underway, the activity would be halted.

• The shutdown zone around the pile would be monitored for the presence of marine mammals before, during, and after all pile driving activity, while disturbance zone monitoring would be implemented according to the schedule proposed here.

Notional marine mammal observation locations are depicted in Figures 3–14 of the Navy's monitoring plan. Total days planned for each project are provided above in Table 2. Project-specific disturbance zone monitoring proposals are described in the following list.

• Project 1A—A minimum of three observers would be deployed to monitor the disturbance zone on a minimum of ten days of vibratory pile driving.

• Project 1B—Only two total days of work are proposed as part of Project 1B, and no disturbance zone monitoring is proposed.

• Project 2—Only impact pile driving is proposed in association with Project 2; therefore, the disturbance zone would be visible during shutdown zone monitoring.

• Project 3A—This project is expected to occur in two phases, beginning in FY2017 and FY2022. During phase one, only two total days of work are proposed and no disturbance zone monitoring is proposed. During phase two, a minimum of three observers would be deployed to monitor the disturbance zone on a minimum of three days of vibratory pile driving.

• Project 3B—A minimum of three observers would be deployed to monitor the disturbance zone on a minimum of five days of vibratory pile driving.

• Projects 3C, 3D, and 3E—A minimum of two observers would be deployed to monitor the disturbance zone during all vibratory driving associated with these projects.

• Project 3F—A minimum of three observers would be deployed to monitor the disturbance zone on a minimum of two days of vibratory pile driving.

• Project 3G—A minimum of three observers would be deployed to monitor the disturbance zone on a minimum of four days of vibratory pile driving.

• Project 4A—A minimum of four observers would be deployed to monitor the disturbance zone on a minimum of eight days of vibratory pile driving.

• Project 4B—A minimum of four observers would be deployed to monitor the disturbance zone on a minimum of three days of vibratory pile driving.

• Project 5—A minimum of four observers would be deployed to monitor the disturbance zone on a minimum of three days of vibratory pile driving.

• Projects 6A and 6B—A minimum of five observers would be deployed to monitor the disturbance zone on a minimum of twelve days of vibratory pile driving.

Individuals implementing the monitoring protocol will assess its effectiveness using an adaptive approach. Monitoring biologists will use their best professional judgment throughout implementation and seek improvements to these methods when deemed appropriate. Any modifications to the protocol will be coordinated between NMFS and the Navy.

Data Collection

We require that observers use standardized data forms. Among other pieces of information, the Navy will record detailed information about any implementation of shutdowns, including the distance of animals to the pile and description of specific actions that ensued and resulting behavior of the animal, if any. We require that, at a minimum, the following information be collected on the sighting forms:

• Date and time that monitored activity begins or ends;

• Construction activities occurring during each observation period;

• Weather parameters (*e.g.,* wind speed, percent cloud cover, visibility);

• Water conditions (*e.g.,* sea state, tide state);

• Species, numbers, and, if possible, sex and age class of marine mammals;

• Description of any observable marine mammal behavior patterns, including bearing and direction of travel and distance from pile driving activity;

• Distance from pile driving activities to marine mammals and distance from the marine mammals to the observation point;

• Description of implementation of mitigation measures (*e.g.,* shutdown or delay).

• Locations of all marine mammal observations; and

• Other human activity in the area.

Acoustic Monitoring

The Navy would implement a sound source level verification study during activities associated with specific project components of interest. Because data is relatively lacking for these pile types, data collection would be targeted towards impact and vibratory driving of concrete, timber and composite piles. A sample scope of work for acoustic monitoring is provided as Attachment 3 of the Navy's monitoring plan. The exact specifications of the acoustic monitoring work would be finalized in consultation with Navy personnel, subject to constraints related to logistics and security requirements. Reporting of measured sound level signals will include the average, minimum, and maximum rms value and frequency spectra for each pile monitored. Peak and single-strike SEL values would also be reported for impact pile driving. Acoustic monitoring would be conducted in association with Project 1A (impact driving of 18–24'' concrete piles and vibratory removal of 16'' timber piles); Project 2 (impact driving of 14'' steel H piles); Project 4A (impact driving of 18–24'' concrete piles and vibratory removal of 24'' concrete piles); and Projects 6A and 6B (vibratory removal of 24'' concrete piles).

Marine Mammal Surveys

Subject to funding availability, additional work would be performed to describe the spatial and temporal distributions of bottlenose dolphins and their densities in areas that may be affected by the specified activities. Surveys would be performed as soon as practicable.

Reporting

A draft report would be submitted to NMFS within 90 days of the completion of the monitoring period for each project. The report will include marine mammal observations pre-activity, during-activity, and post-activity during pile driving days, and will also provide descriptions of any behavioral responses to construction activities by marine mammals and a complete description of all mitigation shutdowns and the results of those actions and an extrapolated total take estimate based on the number of marine mammals observed during the course of construction. A final report must be submitted within thirty days following resolution of comments on the draft report. The Navy would also submit a comprehensive summary report following conclusion of the specified activities.

Adaptive Management

The regulations governing the take of marine mammals incidental to Navy waterfront construction activities would contain an adaptive management component.

The reporting requirements associated with this proposed rule are designed to provide NMFS with monitoring data from the previous year to allow consideration of whether any changes are appropriate. The use of adaptive management allows NMFS to consider new information from different sources to determine (with input from the Navy regarding practicability) on an annual or biennial basis if mitigation or monitoring measures should be modified (including additions or deletions). Mitigation measures could be modified if new data suggests that such modifications would have a reasonable likelihood of reducing adverse effects to marine mammals and if the measures are practicable.

The following are some of the possible sources of applicable data to be considered through the adaptive management process: (1) Results from monitoring reports, as required by MMPA authorizations; (2) results from general marine mammal and sound research; and (3) any information which reveals that marine mammals may have been taken in a manner, extent, or number not authorized by these regulations or subsequent LOAs.

Impact on Availability of Affected Species for Taking for Subsistence Uses

There are no relevant subsistence uses of marine mammals implicated by these actions. Therefore, we have determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act (ESA)

No marine mammal species listed under the ESA are expected to be affected by these activities. Therefore, we have determined that section 7 consultation under the ESA is not required.

National Environmental Policy Act (NEPA)

The Navy has prepared a draft EA in accordance with NEPA and the regulations published by the Council on Environmental Quality. We have posted it on the NMFS Web site concurrently with the publication of these proposed regulations. NMFS will independently evaluate the EA and determine whether or not to adopt it. We may prepare a separate NEPA analysis and incorporate relevant portions of the Navy's EA by reference. Information in the Navy's application, EA, and this notice collectively provide the environmental information related to proposed issuance of the regulations for public review and comment. We will review all comments submitted in response to this notice as we complete the NEPA process, including a decision of whether to sign a FONSI, prior to a final decision on the request for incidental take authorization.

Request for Information

NMFS requests interested persons to submit comments, information, and suggestions concerning the Navy's request and the proposed regulations (see **ADDRESSES**). All comments will be reviewed and evaluated as we prepare the final rule and make final determinations on whether to issue the requested authorizations. This notice and referenced documents provide all environmental information relating to our proposed action for public review.

Classification

Pursuant to the procedures established to implement Executive Order 12866, the Office of Management and Budget has determined that this proposed rule is not significant.

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), the Chief Counsel for Regulation of the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. Navy is the sole entity that would be subject to the requirements in these proposed regulations, and the U.S. Navy is not a small governmental jurisdiction, small organization, or small business, as defined by the RFA. Because of this certification, a regulatory flexibility analysis is not required and none has been prepared.

This proposed rule does not contain a collection-of-information requirement subject to the provisions of the Paperwork Reduction Act (PRA) because the applicant is a Federal agency. Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the PRA unless that collection of information displays a currently valid OMB control number. These requirements have been approved by OMB under control number 0648–0151 and include applications for

regulations, subsequent LOAs, and reports.

List of Subjects in 50 CFR Part 217

Exports, Fish, Imports, Indians, Labeling, Marine mammals, Penalties, Reporting and recordkeeping requirements, Seafood, Transportation.

Dated: December 22, 2016.

Samuel D. Rauch III,

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

For reasons set forth in the preamble, 50 CFR part 217 is proposed to be amended as follows:

PART 217—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

■ 1. The authority citation for part 217 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*

Subpart X [Reserved]

■ 2. Add and reserve subpart X.

Subpart Y [Reserved]

■ 3. Add and reserve subpart Y.

■ 4. Add subpart Z to part 217 to read as follows:

Subpart Z—Taking Marine Mammals Incidental to Navy Waterfront Construction Activities at Naval Submarine Base Kings Bay

Sec.

217.250 Specified activity and specified geographical region.
217.251 Effective dates.
217.252 Permissible methods of taking.
217.253 Prohibitions.
217.254 Mitigation requirements.
217.255 Requirements for monitoring and reporting.
217.256 Letters of Authorization.
217.257 Renewals and modifications of Letters of Authorization.
217.258 [Reserved]
217.259 [Reserved]

§ 217.250 Specified activity and specified geographical region.

(a) Regulations in this subpart apply only to the U.S. Navy (Navy) and those persons it authorizes or funds to conduct activities on its behalf for the taking of marine mammals that occurs in the area outlined in paragraph (b) of this section and that occurs incidental to waterfront construction activities.

(b) The taking of marine mammals by Navy may be authorized in a Letter of Authorization (LOA) only if it occurs within waters adjacent to Naval Submarine Base Kings Bay and Crab Island.

§ 217.251 Effective dates.

Regulations in this subpart are effective from [EFFECTIVE DATE OF FINAL RULE] through [DATE 5 YEARS AFTER EFFECTIVE DATE OF FINAL RULE].

§ 217.252 Permissible methods of taking.

(a) Under LOAs issued pursuant to §§ 216.106 and 217.256 of this chapter, the Holder of the LOA (hereinafter ''Navy'') may incidentally, but not intentionally, take marine mammals within the area described in § 217.250(b) of this chapter by Level B harassment associated with waterfront construction activities, provided the activity is in compliance with all terms, conditions, and requirements of the regulations in this subpart and the appropriate LOA.

§ 217.253 Prohibitions.

Notwithstanding takings contemplated in § 217.250 and authorized by a LOA issued under §§ 216.106 and 217.256 of this chapter, no person in connection with the activities described in § 217.250 of this chapter may:

(a) Violate, or fail to comply with, the terms, conditions, and requirements of this subpart or a LOA issued under §§ 216.106 and 217.256 of this chapter;

(b) Take any marine mammal not specified in such LOAs;

(c) Take any marine mammal specified in such LOAs in any manner other than as specified;

(d) Take a marine mammal specified in such LOAs if NMFS determines such taking results in more than a negligible impact on the species or stocks of such marine mammal; or

(e) Take a marine mammal specified in such LOAs if NMFS determines such taking results in an unmitigable adverse impact on the species or stock of such marine mammal for taking for subsistence uses.

§ 217.254 Mitigation requirements.

When conducting the activities identified in § 217.250 of this chapter, the mitigation measures contained in any LOA issued under §§ 216.106 and 217.256 of this chapter must be implemented. These mitigation measures shall include but are not limited to:

(a) General conditions: (1) A copy of any issued LOA must be in the possession of the Navy, its designees, and work crew personnel operating under the authority of the issued LOA.

(2) The Navy shall conduct briefings for construction supervisors and crews, marine mammal monitoring team, acoustic monitoring team, and Navy staff prior to the start of all pile driving activity, and when new personnel join the work, in order to explain responsibilities, communication procedures, marine mammal monitoring protocol, and operational procedures.

(b) Except for pile driving covered under subsections (c) and (d), for all pile driving activity, the Navy shall implement a minimum shutdown zone of 15 m radius around the pile. If a marine mammal comes within or approaches the shutdown zone, such operations shall cease.

(c) For impact pile driving associated with Project 3F (Warping Wharf with Capstan), the Navy shall implement a minimum shutdown zone of 40 m radius around the pile. If a marine mammal comes within or approaches the shutdown zone, such operations shall cease.

(d) For impact pile driving associated with Project 4B (Small Craft Berth Site VI), the Navy shall implement a minimum shutdown zone of 20 m radius around the pile. If a marine mammal comes within or approaches the shutdown zone, such operations shall cease.

(e) The Navy shall deploy marine mammal observers as indicated in the final Marine Mammal Monitoring Plan and as described in § 217.255 of this chapter.

(1) For all pile driving activities, a minimum of one observer shall be stationed at the active pile driving rig or reasonable proximity in order to monitor the shutdown zone.

(2) Monitoring shall take place from 15 minutes prior to initiation of pile driving activity through 30 minutes post-completion of pile driving activity. Pre-activity monitoring shall be conducted for 15 minutes to ensure that the shutdown zone is clear of marine mammals, and pile driving may commence when observers have declared the shutdown zone clear of marine mammals. In the event of a delay or shutdown of activity resulting from marine mammals in the shutdown zone, animals shall be allowed to remain in the shutdown zone (*i.e.,* must leave of their own volition) and their behavior shall be monitored and documented. Monitoring shall occur throughout the time required to drive a pile. The shutdown zone must be determined to be clear during periods of good visibility (*i.e.,* the entire shutdown zone and surrounding waters must be visible to the naked eye).

(3) If a marine mammal approaches or enters the shutdown zone, all pile driving activities at that location shall be halted. If pile driving is halted or delayed due to the presence of a marine

mammal, the activity may not commence or resume until either the animal has voluntarily left and been visually confirmed beyond the shutdown zone or fifteen minutes have passed without re-detection of the animal.

(4) Monitoring shall be conducted by trained observers, who shall have no other assigned tasks during monitoring periods. Trained observers shall be placed from the best vantage point(s) practicable to monitor for marine mammals and implement shutdown or delay procedures when applicable through communication with the equipment operator.

(f) The Navy shall use soft start techniques for impact pile driving. Soft start for impact drivers requires contractors to provide an initial set of strikes at reduced energy, followed by a thirty-second waiting period, then two subsequent reduced energy strike sets. Soft start shall be implemented at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of thirty minutes or longer.

(g) Pile driving shall only be conducted during daylight hours.

§ 217.255 Requirements for monitoring and reporting.

(a) Trained observers shall complete applicable portions of the Navy's Marine Species Awareness Training, as well as a general environmental awareness briefing conducted by Navy staff. At minimum, training shall include identification of bottlenose dolphins and relevant mitigation and monitoring requirements. All observers shall have no other construction-related tasks while conducting monitoring.

(b) For shutdown zone monitoring, the Navy shall report on implementation of shutdown or delay procedures, including whether the procedures were not implemented and why (when relevant).

(c) The Navy shall deploy additional observers to monitor disturbance zones according to the minimum requirements defined in this chapter. These observers shall collect sighting data and behavioral responses to pile driving for marine mammal species observed in the region of activity during the period of activity, and shall communicate with the shutdown zone observer as appropriate with regard to the presence of marine mammals. All observers shall be trained in identification and reporting of marine mammal behaviors.

(1) During Project 1A (Tug Pier), Navy shall deploy a minimum of three additional marine mammal monitoring observers on a minimum of ten days of vibratory pile driving activity.

(2) During the fiscal year 2022 phase of Project 3A (Explosives Handling Wharf #2), Navy shall deploy a minimum of three additional marine mammal monitoring observers on a minimum of three days of vibratory pile driving activity.

(3) During Project 3B ((Dry Dock) Interface Wharf), Navy shall deploy a minimum of three additional marine mammal monitoring observers on a minimum of five days of vibratory pile driving activity.

(4) During Projects 3C, 3D, and 3E (Refit Wharves #1–3), Navy shall deploy a minimum of two additional marine mammal monitoring observers on all days of vibratory pile driving activity.

(5) During Project 3F (Warping Wharf with Capstan), Navy shall deploy a minimum of three additional marine mammal monitoring observers on a minimum of two days of vibratory pile driving activity.

(6) During Project 3G (Tug Pier), Navy shall deploy a minimum of three additional marine mammal monitoring observers on a minimum of four days of vibratory pile driving activity.

(7) During Project 4A (Transit Protection System (TPS) Pier), Navy shall deploy a minimum of four additional marine mammal monitoring observers on a minimum of eight days of vibratory pile driving activity.

(8) During Project 4B (Small Craft Berth Site VI), Navy shall deploy a minimum of four additional marine mammal monitoring observers on a minimum of three days of vibratory pile driving activity.

(9) During Project 5 (Magnetic Silencing Facility Repairs), Navy shall deploy a minimum of four additional marine mammal monitoring observers on a minimum of three days of vibratory pile driving activity.

(10) During Projects 6A (Demolition of TPS Pier) and 6B (Demolition of North Trestle), Navy shall deploy a minimum of five additional marine mammal monitoring observers on a minimum of twelve days of vibratory pile driving activity.

(d) The Navy shall conduct acoustic data collection (sound source verification), in accordance with NMFS's guidelines, in conjunction with Project 1A (Tug Pier), Project 2 (Unspecified Minor Construction Layberth Fender Pile Modification), and Projects 4A and 6A (TPS Pier).

(e) Reporting: (1) Annual reporting: (i) Navy shall submit an annual summary report to NMFS not later than ninety days following the end of in-water work for each project. Navy shall provide a final report within thirty days following resolution of comments on the draft report.

(ii) These reports shall contain, at minimum, the following:

(A) Date and time that monitored activity begins or ends;

(B) Construction activities occurring during each observation period;

(C) Weather parameters (*e.g.,* wind speed, percent cloud cover, visibility);

(D) Water conditions (*e.g.,* sea state, tide state);

(E) Species, numbers, and, if possible, sex and age class of marine mammals;

(F) Description of any observable marine mammal behavior patterns, including bearing and direction of travel and distance from pile driving activity;

(G) Distance from pile driving activities to marine mammals and distance from the marine mammals to the observation point;

(H) Description of implementation of mitigation measures (*e.g.,* shutdown or delay);

(I) Locations of all marine mammal observations; and

(J) Other human activity in the area.

(2) Navy shall submit a comprehensive summary report to NMFS not later than ninety days following the conclusion of marine mammal monitoring efforts described in this chapter.

(3) Navy shall submit acoustic monitoring reports as necessary pursuant to § 217.255(d) of this chapter.

(f) Reporting of injured or dead marine mammals:

(1) In the unanticipated event that the activity defined in § 217.250 clearly causes the take of a marine mammal in a prohibited manner, Navy shall immediately cease such activity and report the incident to the Office of Protected Resources (OPR), NMFS, and to the Southeast Regional Stranding Coordinator, NMFS. Activities shall not resume until NMFS is able to review the circumstances of the prohibited take. NMFS will work with Navy to determine what measures are necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. Navy may not resume their activities until notified by NMFS. The report must include the following information:

(i) Time, date, and location (latitude/longitude) of the incident;

(ii) Description of the incident;

(iii) Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, visibility);

(iv) Description of all marine mammal observations in the 24 hours preceding the incident;

(v) Species identification or description of the animal(s) involved;

(vi) Fate of the animal(s); and

(vii) Photographs or video footage of the animal(s). Photographs may be taken once the animal has been moved from the waterfront area.

(2) In the event that Navy discovers an injured or dead marine mammal and determines that the cause of the injury or death is unknown and the death is relatively recent (*e.g.,* in less than a moderate state of decomposition), Navy shall immediately report the incident to OPR and the Southeast Regional Stranding Coordinator, NMFS. The report must include the information identified in paragraph (f)(1) of this section. Activities may continue while NMFS reviews the circumstances of the incident. NMFS will work with Navy to determine whether additional mitigation measures or modifications to the activities are appropriate.

(3) In the event that Navy discovers an injured or dead marine mammal and determines that the injury or death is not associated with or related to the activities defined in § 217.250 (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, scavenger damage), Navy shall report the incident to OPR and the Southeast Regional Stranding Coordinator, NMFS, within 24 hours of the discovery. Navy shall provide photographs or video footage or other documentation of the stranded animal sighting to NMFS. Photographs may be taken once the animal has been moved from the waterfront area.

§ 217.256 Letters of Authorization.

(a) To incidentally take marine mammals pursuant to these regulations, Navy must apply for and obtain a LOA.

(b) A LOA, unless suspended or revoked, may be effective for a period of time not to exceed the expiration date of these regulations.

(c) If a LOA expires prior to the expiration date of these regulations, Navy may apply for and obtain a renewal of the LOA.

(d) In the event of projected changes to the activity or to mitigation and monitoring measures required by a LOA, Navy must apply for and obtain a modification of the LOA as described in § 217.257 of this chapter.

(e) The LOA shall set forth:

(1) Permissible methods of incidental taking;

(2) Means of effecting the least practicable adverse impact (*i.e.,* mitigation) on the species, its habitat, and on the availability of the species for subsistence uses; and

(3) Requirements for monitoring and reporting.

(f) Issuance of the LOA shall be based on a determination that the level of taking will be consistent with the findings made for the total taking allowable under these regulations.

(g) Notice of issuance or denial of a LOA shall be published in the **Federal Register** within thirty days of a determination.

§ 217.257 Renewals and modifications of Letters of Authorization.

(a) A LOA issued under §§ 216.106 and 217.256 of this chapter for the activity identified in § 217.250 shall be renewed or modified upon request by the applicant, provided that:

(1) The proposed specified activity and mitigation, monitoring, and reporting measures, as well as the anticipated impacts, are the same as those described and analyzed for these regulations (excluding changes made pursuant to the adaptive management provision in paragraph (c)(1) of this section), and

(2) NMFS determines that the mitigation, monitoring, and reporting measures required by the previous LOA under these regulations were implemented.

(b) For a LOA modification or renewal requests by the applicant that include changes to the activity or the mitigation, monitoring, or reporting (excluding changes made pursuant to the adaptive management provision in paragraph (c)(1) of this section) that do not change the findings made for the regulations or that result in no more than a minor change in the total estimated number of takes (or distribution by species or years), NMFS may publish a notice of proposed LOA in the **Federal Register**, including the associated analysis of the change, and solicit public comment before issuing the LOA.

(c) A LOA issued under §§ 216.106 and 217.256 of this chapter for the activity identified in § 217.250 may be modified by NMFS under the following circumstances:

(1) Adaptive Management—NMFS may modify (including augment) the existing mitigation, monitoring, or reporting measures (after consulting with Navy regarding the practicability of the modifications) if doing so creates a reasonable likelihood of more effectively accomplishing the goals of the mitigation and monitoring set forth in the preamble for these regulations.

(i) Possible sources of data that could contribute to the decision to modify the mitigation, monitoring, or reporting measures in a LOA:

(A) Results from Navy's monitoring from previous years.

(B) Results from other marine mammal and/or sound research or studies.

(C) Any information that reveals marine mammals may have been taken in a manner, extent or number not authorized by these regulations or subsequent LOAs.

(ii) If, through adaptive management, the modifications to the mitigation, monitoring, or reporting measures are substantial, NMFS will publish a notice of proposed LOA in the **Federal Register** and solicit public comment.

(2) Emergencies—If NMFS determines that an emergency exists that poses a significant risk to the well-being of the species or stocks of marine mammals specified in a LOA issued pursuant to §§ 216.106 and 217.256 of this chapter, a LOA may be modified without prior notice or opportunity for public comment. Notice would be published in the **Federal Register** within thirty days of the action.

§ 217.258 [Reserved]

§ 217.259 [Reserved]

[FR Doc. 2016–31702 Filed 12–30–16; 8:45 am]

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Federal Register

Vol. 82, No. 1

Tuesday, January 3, 2017

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FEDERAL REGISTER PAGES AND DATE, JANUARY

1–710 3

CFR PARTS AFFECTED DURING JANUARY

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Executive Orders:
13694 (amended by 13757) 1
13757 1

14 CFR

39 .....5, 7, 10, 12
Proposed Rules:
39 .....48, 50, 52, 54

15 CFR

Proposed Rules:
4 56

16 CFR

Proposed Rules:
1015 59

22 CFR

120 15
123 15
126 15

29 CFR

1614 654

31 CFR

Proposed Rules:
40 67

33 CFR

165 20

40 CFR

52 22
Proposed Rules:
721 80

42 CFR

414 24
416 24
419 24
431 .....24, 37
433 .....24, 37
438 .....24, 37
440 .....24, 37
457 .....24, 37
482 24
486 24
488 24
495 .....24, 37
510 180
512 180

44 CFR

204 40
206 40
207 40

45 CFR

1171 44

46 CFR

502 46

48 CFR

504 46

50 CFR

Proposed Rules:
217 684

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Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List December 22, 2016

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When a date falls on a weekend or holiday, the next Federal business day is used. (See 1 CFR 18.17)

A new table will be published in the first issue of each month.

Date of FR publication	15 days after publication	21 days after publication	30 days after publication	35 days after publication	45 days after publication	60 days after publication	90 days after publication
January 3	Jan 18	Jan 24	Feb 2	Feb 7	Feb 17	Mar 6	Apr 3
January 4	Jan 19	Jan 25	Feb 3	Feb 8	Feb 21	Mar 6	Apr 4
January 5	Jan 20	Jan 26	Feb 6	Feb 9	Feb 21	Mar 6	Apr 5
January 6	Jan 23	Jan 27	Feb 6	Feb 10	Feb 21	Mar 7	Apr 6
January 9	Jan 24	Jan 30	Feb 8	Feb 13	Feb 23	Mar 10	Apr 10
January 10	Jan 25	Jan 31	Feb 9	Feb 14	Feb 24	Mar 13	Apr 10
January 11	Jan 26	Feb 1	Feb 10	Feb 15	Feb 27	Mar 13	Apr 11
January 12	Jan 27	Feb 2	Feb 13	Feb 16	Feb 27	Mar 13	Apr 12
January 13	Jan 30	Feb 3	Feb 13	Feb 17	Feb 27	Mar 14	Apr 13
January 17	Feb 1	Feb 7	Feb 16	Feb 21	Mar 3	Mar 20	Apr 17
January 18	Feb 2	Feb 8	Feb 17	Feb 22	Mar 6	Mar 20	Apr 18
January 19	Feb 3	Feb 9	Feb 21	Feb 23	Mar 6	Mar 20	Apr 19
January 23	Feb 7	Feb 13	Feb 22	Feb 27	Mar 9	Mar 24	Apr 24
January 24	Feb 8	Feb 14	Feb 23	Feb 28	Mar 10	Mar 27	Apr 24
January 25	Feb 9	Feb 15	Feb 24	Mar 1	Mar 13	Mar 27	Apr 25
January 26	Feb 10	Feb 16	Feb 27	Mar 2	Mar 13	Mar 27	Apr 26
January 27	Feb 13	Feb 17	Feb 27	Mar 3	Mar 13	Mar 28	Apr 27
January 30	Feb 14	Feb 21	Mar 1	Mar 6	Mar 16	Mar 31	May 1
January 31	Feb 15	Feb 21	Mar 2	Mar 7	Mar 17	Apr 3	May 1