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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 510 and 512

[CMS-5519-P]

RIN 0938-AS90

Medicare Program; Advancing Care Coordination through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR)

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

ACTION: Proposed rule.

SUMMARY: This proposed rule proposes to implement three new Medicare Parts A and B episode payment models under section 1115A of the Social Security Act. Acute care hospitals in certain selected geographic areas will participate in retrospective episode payment models targeting care for Medicare fee-for-service beneficiaries receiving services during acute myocardial infarction, coronary artery bypass graft, and surgical hip/femur fracture treatment episodes. All related care within 90 days of hospital discharge will be included in the episode of care. We believe this model will further our goals of improving the efficiency and quality of care for Medicare beneficiaries receiving care for these common clinical conditions and procedures. This proposed rule also includes several proposed modifications to the Comprehensive Care for Joint Replacement model.

DATES: Comment period: To be assured consideration, comments on this proposed rule must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EDT on **[Insert date 60 days from date of publication by the Office of the Federal Register].**

ADDRESSES: In commenting, please refer to file code CMS-5519-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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Baltimore, MD 21244-1850.

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a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,

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Washington, DC 20201

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b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

7500 Security Boulevard,

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Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

For questions related to the proposed EPMs: NEPMRULE@cms.hhs.gov.

For questions related to the CJR model: CJR@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

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Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

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Alphabetical List of Acronyms

Because of the many terms to which we refer by acronym, abbreviation, or short form in this proposed rule, we are listing the acronyms, abbreviations and short forms used and their corresponding terms in alphabetical order.

ACE	Acute-care episode
ACO	Accountable Care Organization
ALOS	Average length of stay
AMA	American Medical Association
AMI	Acute Myocardial Infarction
APM	Alternative Payment Model
ASC QRP	Ambulatory Surgical Center Quality Reporting Program
ASC	Ambulatory Surgical Center
ASPE	Assistant Secretary for Planning and Evaluation
BPCI	Bundled Payments for Care Improvement
CABG	Coronary Artery Bypass Graft
CAD	Coronary artery disease
CAH	Critical access hospital
CBSA	Core-Based Statistical Area
CC	Complication or comorbidity
CCDA	Consolidated clinical document architecture
CCDE	Core clinical data elements
CCN	CMS Certification Number
CEC	Comprehensive ESRD Care Initiative

CEHRT	Certified Electronic Health Record Technology
CFR	Code of Federal Regulations
CJR	Comprehensive Care for Joint Replacement
CMHC	Community Mental Health Center
CMI	Case Mix Index
CMMI	Center for Medicare and Medicaid Innovation
CMP	Civil monetary penalty
CMS	Centers for Medicare & Medicaid Services
CoP	Condition of Participation
CPC	Comprehensive Primary Care Initiative
CPT	Current Procedural Terminology
CR	Cardiac rehabilitation
CSA	Combined Statistical Area
CVICU	Cardiovascular intensive care units
CY	Calendar year
DME	Durable medical equipment
DMEPOS	Durable medical equipment, prosthetics, orthotics, and supplies
DSH	Disproportionate Share Hospital
ECQM	Electronic Clinical Quality Measures
EFT	Electronic funds transfer
EHR	Electronic health record
E/M	Evaluation and management

EPM	Episode payment model
ESCO	ESRD Seamless Care Organization
ESRD	End-Stage Renal Disease
FFS	Fee-for-service
GAAP	Generally-Accepted Accounting Principles
GEM	General Equivalence Mapping
GPCI	Geographic Practice Cost Index
HAC	Hospital-Acquired Condition
HACRP	Hospital-Acquired Condition Reduction Program
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems
HCC	Hierarchical Condition Category
HCPCS	Healthcare Common Procedure Coding System
HHA	Home health agency
HHPPS	Home Health Prospective Payment System
HHRG	Home Health Resource Group
HHS	U.S. Department of Health and Human Services
HH QRP	Home Health Quality Reporting Program
HICN	Health Insurance Claim Number
HIPPA	Health Insurance Portability and Accountability Act
HIQR	Hospital Inpatient Quality Reporting
Health IT	Health Information Technology
HLMR	HCAHPS Linear Mean Roll Up

HOOS Hip Dysfunction and Osteoarthritis Outcome Score

HOPD Hospital outpatient department

HRRP Hospital Readmissions Reductions Program

HRR Hospital Referral Region

HVBP Hospital Value-Based Purchasing Program

HIV Human Immunodeficiency Virus

ICD-9-CM International Classification of Diseases, 9th Revision, Clinical Modification

IRFQRICD-10-CM International Classification of Diseases, 10th Revision, Clinical Modification

ICR Intensive Cardiac Rehabilitation

IME Indirect medical education

IPPS Inpatient Prospective Payment System

IPF Inpatient psychiatric facility

IRF QRP Inpatient Rehabilitation Facility Quality Reporting Program

IPF QRP Inpatient Psychiatric Facility Quality Reporting Program

IRF Inpatient rehabilitation facility

KOOS Knee Injury and Osteoarthritis Outcome Score

LEJR Lower-extremity joint replacement

LIP Low-income percentage

LOS Length-of-stay

LTCH QRP Long-Term Care Hospital Quality Reporting Program

LTCH Long-term care hospital

LUPA	Low-utilization payment adjustment
MAC	Medicare Administrative Contractor
MACRA	Medicare Access and CHIP Reauthorization Act of 2015
MAPCP	Multi-Payer Advanced Primary Care Practice
MAT	Measure Authoring Tool
MCC	Major complications or comorbidities
MCCM	Medicare Care Choices Model
MDC	Major diagnostic category
MDH	Medicare-Dependent Hospital
MedPAC	Medicare Payment Advisory Commission
MIPS	Merit-based Incentive Payment System
MP	Malpractice
MSA	Metropolitan Statistical Area
MS-DRG	Medical Severity Diagnosis-Related Group
NPI	National Provider Identifier
NPRA	Net Payment Reconciliation Amount
NQF	National Quality Forum
OCM	Oncology Care Model
OIG	Department of Health and Human Services' Office of the Inspector General
OPPS	Outpatient Prospective Payment System
OQR	Outpatient Quality Reporting
PBPM	Per-beneficiary per-month

PCI	Percutaneous Coronary Intervention
PCMH	Primary Care Medical Homes
PE	Practice Expense
PFS	Physician Fee Schedule
PGP	Physician group practice
PQRS	Physician Quality Reporting System
PHA	Partial hip arthroplasty
PPS	Prospective Payment System
PRO	Patient-Reported Outcome
PROMIS	Patient-Reported Outcomes Measurement Information Systems
PRO-PM	Patient-Reported Outcome Performance Measure
PTCA	Percutaneous transluminal coronary angioplasty
PY	Performance year
QIO	Quality Improvement Organization
RAC	Recovery Audit Contractor
RRC	Rural Referral Center
RSCR	Risk-Standardized Complication Rate
RSRR	Risk-Standardized Readmission Rate
RSMR	Risk-Standardized Mortality Rate
RVU	Relative Value Unit
SCH	Sole Community Hospital
SHFFT	Surgical hip/femur fracture treatment

SILS2	Single Item Health Literacy Screening
SNF	QRP Skilled Nursing Facility Quality Reporting Program
SNF	Skilled nursing facility
THA	Total hip arthroplasty
TIN	Taxpayer identification number
TKA	Total knee arthroplasty
TP	Target price
UHDDS	Uniform Hospital Discharge Data Set
VR-12	Veterans Rand 12 Item Health Survey

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I. Executive Summary

A. Purpose

The purpose of this proposed rule - Advancing Care Coordination through Episode Payment Models, is to propose the creation and testing of three new episode payment models (EPMs) and a Cardiac Rehabilitation (CR) incentive payment model under the authority of the Center for Medicare and Medicaid Innovation (CMMI or "the Innovation Center"). Section 1115A of the Social Security Act ("the Act") authorizes the Innovation Center to test innovative payment and service-delivery models to reduce Medicare, Medicaid, and Children's

Health Insurance Program expenditures while preserving or enhancing the quality of care furnished to such programs' beneficiaries. Under the fee-for-service (FFS) program, Medicare makes separate payments to providers and suppliers for the items and services furnished to a beneficiary over the course of treatment (an episode of care). With the amount of payments dependent on the volume of services delivered, providers may not have incentives to invest in quality-improvement and care-coordination activities. As a result, care may be fragmented, unnecessary, or duplicative. The goal for the proposed EPMs is to improve the quality of care provided to beneficiaries in an applicable episode while reducing episode spending through financial accountability.[1] The proposed EPMs would include models for episodes of care surrounding an acute myocardial infarction (AMI), coronary artery bypass graft (CABG), and surgical hip/femur fracture treatment excluding lower extremity joint replacement (SHFFT). Under the proposed rule, the Centers for Medicare & Medicaid Services (CMS) will test whether an EPM for AMI, CABG, and SHFFT episodes of care will reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. We anticipate the proposed models would benefit Medicare beneficiaries by improving the coordination and transition of care, improving the coordination of items and services paid for through FFS Medicare, encouraging more provider investment in infrastructure and redesigned care processes for higher-quality and more efficient service delivery, and incentivizing higher-value care across the inpatient and post-acute care spectrum. We propose to test the proposed EPMs for 5 performance years, beginning July 1, 2017, and ending December 31, 2021.

[1] In this proposed rule, we use the terms "AMI episode," "CABG episode," and "SHFFT episode" to refer to episodes of care as described in section III.C. of this proposed rule.

Within this proposed rule, we propose three distinct EPMs focused on episodes of care for AMI, CABG, and SHFFT episodes. We chose these episodes for the proposed models because, as discussed in depth in section III.A. of this proposed rule, we believe hospitals would have significant opportunity to redesign care and improve quality of care furnished during the applicable episode. In addition, significant variation in spending occurs during these high-expenditure, common episodes. The proposed EPMs would enable hospitals to consider the most appropriate strategies for care redesign, including: (1) increasing post-hospitalization follow-up and medical management for patients; (2) coordinating across the inpatient and post-acute care spectrum; (3) conducting appropriate discharge planning; (4) improving adherence to treatment or drug regimens; (5) reducing readmissions and complications during the post-discharge period; (6) managing chronic diseases and conditions that may be related to the proposed EPMs' episodes; (7) choosing the most appropriate post-acute care setting; and (8) coordinating between providers and suppliers such as hospitals, physicians, and post-acute care providers. The proposed EPMs would offer hospitals the opportunity to examine and better understand their own care processes and patterns with regard to patients in AMI, CABG, and SHFFT episodes, as well as the processes of post-acute care providers and physicians.

We previously have used our statutory authority under section 1115A of the Act to test other episode payment models such as the Bundled Payments for Care Improvement (BPCI) initiative and Comprehensive Care for Joint Replacement (CJR) model. Bundled payments for multiple services in an episode of care hold participating organizations financially accountable for that episode of care. Such models also allow participants to receive payments based in part on the reduction in Medicare expenditures that arise from such participants' care redesign

efforts. This payment can be used for investments in care redesign strategies and infrastructure, as well as to incentivize collaboration with other providers and suppliers furnishing services to beneficiaries included in the models.

We believe the proposed EPMs would further the Innovation Center's mission and the Administration's goal of increasingly paying for value and outcomes, rather than for volume alone,[2] by promoting the alignment of financial and other incentives for all health care providers caring for beneficiaries during SHFFT, CABG, or AMI episodes. The acute care hospital where an eligible beneficiary has an initial hospitalization for one of the procedures or clinical conditions included in these proposed EPMs would be held accountable for spending during the episode of care. EPM participants could earn reconciliation payments by appropriately reducing expenditures and meeting certain quality metrics. EPM participants also would gain access to data and educational resources to better understand care patterns during the inpatient hospitalization and post-acute periods, as well as associated spending. Payment approaches that reward providers for assuming financial and performance accountability for a particular episode of care create incentives for the implementation and coordination of care redesign between participants and other providers and suppliers such as physicians and post-acute care providers.

The proposal for the AMI, CABG, and SHFFT models would require the participation of hospitals in multiple geographic areas that might not otherwise participate in testing episode payment for the proposed episodes of care. CMS is testing other episode payment models with the BPCI initiative and the CJR model. The BPCI initiative is voluntary; providers applied to participate and chose from 48 clinical episodes. BPCI participants entered the at-risk phase between 2013 and 2015 and have the option to continue participating in the initiative through FY

2018. In the CJR model, acute care hospitals in selected geographic areas are required to participate in the CJR model for all eligible lower-extremity joint replacement (LEJR) episodes that initiate at a CJR participant hospital. The CJR model began its first of 5 performance years on April 1, 2016. Realizing the full potential of new EPMs will require the engagement of an even broader set of providers than have participated to date in our episode payment models such as the BPCI initiative and the CJR model. As such, we are interested in testing and evaluating the impact of episode payment for the three proposed EPMs in a variety of circumstances, including those hospitals that may not otherwise participate in such a test.

While we note that testing of the CJR model that began in April 2016 will allow CMS to gain experience with requiring hospitals to participate in an episode payment model, the clinical circumstances of the episodes we are proposing (AMI, CABG, and SHFFT) differ in important ways from the LEJR episodes included in the CJR model. LEJR procedures are common among the Medicare population, and the majority of such procedures are elective. In contrast, under the three proposed EPMs, CMS would test episode payment for certain cardiac conditions and procedures, as well as SHFFT. We expect the patient population included in these episodes would be substantially different from the patient population in CJR episodes, due to the clinical nature of the cardiac and SHFFT episodes. Beneficiaries in these episodes commonly have chronic conditions that contribute to the initiation of the episodes, and need both planned and unplanned care throughout the EPM episode following discharge from the initial hospitalization that begins the episode. Both AMI and CABG model episodes primarily include beneficiaries with cardiovascular disease, a chronic condition which likely contributed to the acute events or procedures that initiate the episodes. About half the average AMI model historical episode

spending was for the initial hospitalization, with the majority of spending following discharge from the initial hospitalization due to hospital readmissions, while there was relatively less spending on SNF services, Part B professional services, and hospital outpatient services. In CABG model historical episodes, about three-quarters of episode spending was for the initial hospitalization, with the remaining episode spending relatively evenly divided between Part B professional services and hospital readmissions, and a lesser percentage on SNF services. Similar to AMI episodes, post-acute care provider use was relatively uncommon in CABG model historical episodes, while hospital readmissions during CABG model historical episodes were relatively common. SHFFT model historical episodes also were accompanied by substantial spending 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 proposed in this rulemaking financially incentivize improved quality of care and reduced cost by aligning the financial incentives of all providers and suppliers caring for model beneficiaries with these goals. This alignment leads to a heightened focus on care coordination and management throughout the

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[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).

episode that prioritizes the provision of those items and services which improve beneficiary outcomes and experience at the lowest cost. A more detailed discussion of the evidence supporting the episode selection for these models can be found in section III.A.1. of the propose rule.

The proposed models would also allow CMS to gain additional experience with episode-payment approaches for hospitals with variance in (1) historic care and utilization patterns; (2) patient populations and care patterns; (3) roles within their local markets; (4) volumes of services; (5) levels of access to financial, community, or other resources; and (6) levels of population and health-care-provider density, including local variations in the availability and use of different categories of post-acute care providers. We believe that participation in the proposed EPMs by a large number of hospitals with diverse characteristics would result in a robust data set for evaluating this payment approach and would stimulate the rapid development of new evidence-based knowledge. Testing the proposed EPMs in this manner would also allow us to learn more about patterns of inefficient utilization of health care services and how to incentivize quality improvement for beneficiaries receiving services in AMI, CABG, and SHFFT episodes. This knowledge potentially could inform future Medicare payment policies.

We propose the CR incentive payment model to test the effects on quality of care and Medicare expenditures of providing financial incentives to hospitals for beneficiaries hospitalized for treatment of AMI or CABG to encourage care coordination and greater utilization of medically necessary CR and intensive cardiac rehabilitation (ICR) services for 90 days post-hospital discharge where the beneficiary's overall care is paid under either an EPM or

the Medicare FFS program. Despite the evidence from multiple studies that CR services improve health outcomes, the literature also indicates that these services are underutilized, estimating that only about 35 percent of AMI patients older than 50 receive this indicated treatment.[4,5,6] Recent analysis confirms a similar pattern of underutilization for Medicare beneficiaries who are eligible for and could benefit from CR.

Considering the evidence demonstrating that CR/ICR services improve long-term patient outcomes, the room for improvement in CR/ICR service utilization for beneficiaries eligible for this benefit, and the need for ongoing, chronic treatment for underlying coronary artery disease (CAD) among beneficiaries that have had an AMI or a CABG, we believe that there is a need for improved long-term care management and care coordination for beneficiaries that have had an AMI or a CABG and that incentivizing the use of CR/ICR services is an important component of meeting this need. We want to reduce barriers to high-value care by testing a financial incentive for hospitals that encourages the management of beneficiaries that have had an AMI or a CABG in ways that may contribute to long-term improvements in quality and reductions in Medicare spending. We seek public comment on the proposals contained in this proposed rule, and also on any alternatives considered.

B. Summary of the Major Provisions

1. Model Overview - EPM Episodes of Care

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[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.

Under the proposed EPMs, as described further in section III.B.2. of this proposed rule, an AMI, CABG, or SHFFT model episode would begin with an inpatient admission to an anchor hospital assigned to one of the following MS-DRGs upon beneficiary discharge. Acute care hospital services furnished to beneficiaries in AMI, CABG, and SHFFT episodes currently are paid under the Inpatient Prospective Payment System (IPPS) through several Medicare Severity-Diagnosis Related Groups (MS-DRGs): for AMI episodes, AMI MS-DRGs (280-282) and those Percutaneous Coronary Intervention (PCI) MS-DRGs (246-251) representing IPPS admissions for AMI that are treated with PCIs; CABG MS-DRGs (231-236); and SHFFT MS-DRGs (480-482). Episodes would end 90 days after the date of discharge from the anchor hospital, as defined under § 512.2. Defining EPMs' episodes of care in such a manner offers operational simplicity for both providers and CMS. The proposed EPMs' episodes would include the inpatient stays and all related care covered under Medicare Parts A and B within the 90 days after discharge, including hospital care, post-acute care, and physician services.

2. Model Scope

Consistent with the CJR model, we propose that acute care hospitals would be the episode initiators and bear financial risk under the proposed AMI, CABG and SHFFT models. In comparison to other health care facilities, hospitals are more likely to have resources that would allow them to appropriately coordinate and manage care throughout an episode, and hospital staff members already are involved in hospital-discharge planning and post-acute care recommendations for recovery, key dimensions of high-quality and efficient care. We propose to require all hospitals that are paid under the IPPS, have a CMS Certification Number (CCN), and have an address located in selected geographic areas to participate in the EPMs, with limited

exceptions. An eligible beneficiary who receives care at such a hospital will automatically be included in the applicable EPM. We propose to select geographic areas through a random sampling methodology.

Under the CR incentive payment model, we propose to provide a CR incentive payment specifically to selected hospitals with financial responsibility for AMI or CABG model episodes (hereinafter EPM-CR participants) because they are already engaged in managing the AMI or CABG model beneficiary's overall care for a period of time following hospital discharge. Similarly, we believe there are opportunities to test the same financial incentives for hospitals where the beneficiary's overall care is paid under the Medicare FFS program. Thus, we also propose to provide a CR incentive payment specifically to selected hospitals that are not AMI or CABG model participants (hereinafter FFS-CR participants).

Our proposed geographic-area selection process is detailed further in section III.B.4. of this proposed rule.

3. Payment

We propose to test the AMI, CABG, and SHFFT EPMs for 5 performance years. The first performance year will begin July 1, 2017. During these performance years we propose to continue paying hospitals and other providers and suppliers according to the usual Medicare FFS payment systems. However, after the completion of a performance year, the Medicare claims payments for services furnished to the beneficiary during the episode, based on claims data, would be combined to calculate an actual episode payment. The actual episode payment would then be reconciled against an established EPM quality-adjusted target price. The amount of this calculation, if positive, would be paid to the participant. This would be called a reconciliation

payment. If negative, we would require repayment from the participant hospital beginning with episodes ending in the second quarter of performance year 2 of the EPMs. EPM participants' quality performance also would be assessed at reconciliation; each participant would receive a composite quality score and a corresponding quality category. EPM participants that achieve a quality category of "acceptable" or higher would be eligible for a reconciliation payment. We also propose to phase in the requirement that participants whose actual episode payments exceed the quality-adjusted target price pay the difference back to Medicare beginning for performance year 2. Under this proposal, Medicare would not require repayment from hospitals for performance year 1 for actual episode payments that exceed their target price in performance year 1, and an applicable discount factor would be used for calculating repayment amounts for performance years 2 and 3, consistent with our final policies for the CJR model.

In contrast to the CJR model, due to the clinical characteristics and common patterns of care in AMI episodes, we propose payment adjustments in the cases of certain transfers and readmissions of beneficiaries to inpatient hospitals for these episodes. These payment adjustments are discussed in detail in section III.D.4.b.(1). of this proposed rule. We also propose to limit how much a hospital can gain or lose based on its actual episode payments relative to quality-adjusted target prices. Finally, we propose additional policies to further limit the risk of high payment cases for all participants and for special categories of participants as described in section III.D. of this proposed rule.

In addition to the EPMs, we propose to test a CR incentive payment model to encourage the utilization of CR/ICR services for beneficiaries hospitalized for treatment of AMI or CABG. To determine the CR incentive payment, we propose to count the number of CR/ICR services for

the relevant time periods under the Outpatient Prospective Payment System (OPPS) and PFS on the basis of the presence of paid claims of the HCPCS codes that report CR/ICR services and the units of service billed. The initial level of the per-service CR incentive amount would be $25 per CR/ICR service for each of the first 11 CR/ICR services paid for by Medicare during an AMI or CABG model episode or AMI or CABG care period. After 11 CR/ICR services are paid for by Medicare for a beneficiary, the level of the per-service CR incentive amount would increase to $175 per CR/ICR service for each additional CR/ICR service paid for by Medicare during the AMI or CABG model episode or AMI care period or CABG care period. A more detailed discussion of the CR incentive payment is located in section VI.E.1 of this proposed rule. The CR performance years would be the same as the performance years proposed for the EPMs in section III.D.2.a. of this proposed rule. Further details about the payment structure and design of the CR incentive payment model can be found in section VI. of this proposed rule.

4. Similar, Previous, and Concurrent Models

The proposed EPMs are informed by other models and demonstrations currently and previously conducted by CMS, and would explore additional ways to use episode payment to enhance coordination of care and improve the quality of care.

We recently announced practices that will participate in the Oncology Care Model (OCM), an episode payment model for physician practices administering chemotherapy. Under OCM, practices will enter into payment arrangements that include both financial and performance accountability for episodes of care surrounding chemotherapy

administration to cancer patients. We will coordinate with other payers to align with OCM in order to facilitate enhanced services and care at participating practices.[7]

CMMI previously tested innovative episode payment approaches in the Medicare Acute Care Episode (ACE) demonstration,[8] and, as described in this proposed rule, currently is testing additional approaches under the BPCI initiative and the CJR model. The ACE demonstration tested a bundled payment approach for cardiac and orthopedic inpatient surgical services and procedures. All Medicare Part A and Part B services pertaining to the inpatient stay were included in the ACE demonstration episodes of care. Evaluations of the ACE demonstration found that while there was not strong quantitative evidence indicating improvements in quality, there was qualitative evidence that hospitals worked to improve processes and outcomes as a result of their participation in the demonstration.

We currently are testing the BPCI initiative, which is composed of four related payment models that link payments for multiple services that a Medicare beneficiary receives during an episode of care into a bundled payment. Under the initiative, entities enter into payment arrangements with CMS that include financial and performance accountability for episodes of care. Episodes of care under the BPCI initiative begin with either: (1) an inpatient hospital stay or (2) post-acute care services following a qualifying inpatient hospital stay. The BPCI initiative is evaluating the effects of episode-based payment approaches on patient experience of care, outcomes, and cost of care for Medicare FFS beneficiaries. Participating organizations chose from 48 clinical episodes, including hip and femur procedures except major joint, acute

[7] More information on the OCM can be found on the Innovation Center's website at http://innovation.cms.gov/initiatives/Oncology-Care/.
[8] Information on the ACE Demonstration can be found on the Innovation Center's website at http://innovation.cms.gov/initiatives/ACE/.

myocardial infarction, percutaneous coronary intervention, and coronary artery bypass graft surgery. BPCI Model 2 is an episode payment model in which a qualifying acute care hospitalization initiates a 30-, 60-, or 90-day episode of care. The episode includes the inpatient stay in an acute care hospital and all related services covered under Medicare Parts A and B during the episode, including post-acute care services.[9] Our experience testing BPCI Model 2 informed the design of the three proposed EPMs. Although some interim evaluation results from the BPCI models are available, final evaluation results for the models within the BPCI initiative are not yet available. However, we believe that CMS' experiences with BPCI support the design of the proposed EPMs. Stakeholders both directly and indirectly involved in testing BPCI models have conveyed that they perceive the initiative to be an effective mechanism for advancing better, more accountable care and aligning providers along the care continuum. This message has been reinforced through CMS site visits to participating entities, the Bundled Payments summit in Washington, in-person meetings with Awardees at CMS, and Awardee-led Affinity Group discussions. The BPCI initiative incorporates 48 clinical episodes, including cardiac and orthopedic episodes similar to those proposed for the AMI, CABG, and SHFFT models. These clinical episodes are being tested by over 1200 Medicare providers, including acute care hospitals, physician group practices, skilled nursing facilities, and home health agencies. Cardiac and orthopedic clinical episodes are among the most popular episodes in BPCI, indicating that BPCI awardees participating in BPCI believe they can reduce cost and improve quality for beneficiaries in these episodes of care.

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[9] More information on BPCI Model 2 can be found on the Innovation Center's website at http://innovation.cms.gov/initiatives/BPCI-Model-2/.

Our design and implementation of the CJR model, which is an episode payment model for LEJR episodes, also informed the design of the proposed AMI, CABG, and SHFFT EPMs. After releasing a proposed rule in July 2015 and receiving nearly 400 comments from the public, in November 2015 we released final regulations implementing the CJR model. Approximately 800 acute care hospitals (approximately 23 percent of all IPPS hospitals) now participate in the CJR model. The first CJR performance year began on April 1, 2016. The CJR model will continue for 5 performance years, ending on December 31, 2020. The proposed AMI, CABG, and SHFFT models build upon our experience designing and implementing the CJR model, including feedback from providers and other public stakeholders during the CJR model's rulemaking and implementation processes.

Further information of why specific elements of the models and initiatives were incorporated into the EPMs' designs is discussed later in this proposed rule.

5. Overlap with Ongoing CMS Efforts

We propose to exclude from participation in the AMI, CABG, and SHFFT models certain acute care hospitals participating in BPCI Models 2 and 4 for the hip and femur procedures except major joint or for all three of the BPCI cardiac episodes (AMI, PCI, and CABG). We propose to exclude beneficiaries in the proposed EPMs' episodes from being included in certain Innovation Center ACO models, the Next Generation ACO Model and Comprehensive ESRD Care. Other CMS programs, such as the Medicare Shared Savings Program and other accountable care organization (ACO) or total cost of care initiatives will remain eligible for EPM episode initiation. We propose to account for overlap, that is, where EPM beneficiaries also are included in other models and programs to ensure the financial policies of the models are

maintained and results and spending reductions are attributed to one model or program. More detail on our proposed policies for accounting for provider- and beneficiary-level overlap is discussed in section III.D.6. of this proposed rule.

The amendments made by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10, April 16, 2015) created two paths for eligible clinicians to link quality to payments: the Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs). These two paths create a flexible payment system called the Quality Payment Program as proposed by CMS in the Quality Payment Program proposed rule (81 FR 28161 through 28586). The MIPS streamlines and improves on three current programs — the Physician Quality Reporting System (PQRS), the Physician Value-based Payment Modifier (VM), and the Medicare Electronic Health Record (EHR) Incentive Program — and continues the focus on quality and value in one cohesive program. Through participation in Advanced APMs, eligible clinicians can become Qualifying APM Participants (QPs) for a year beginning with CY 2019 and receive an APM Incentive Payment (or, in later years, a more favorable payment update under the PFS) for the year.

So that the EPMs may be able to meet the criteria to be Advanced APMs based on the requirements proposed in the Quality Payment Program proposed rule, we propose to require EPM participants to use Certified Electronic Health Record Technology (CEHRT) (as defined in section 1848(o)(4) of the Act) in Track 1 of each EPM. We propose that EPM participants in these tracks must use certified health information technology (IT) functions, in accordance with the definition of CEHRT under our regulation at 42 CFR 414.1305, to document and communicate clinical care with patients and other health care professionals as described in the

Quality Payment Program proposed rule (81 FR 28161 and 28299). We also make similar proposals with respect to CJR.

We propose to implement two different tracks within the EPMs whereby EPM participants that meet proposed requirements for use of CEHRT and financial risk would be in Track 1 (an Advanced APM track) and EPM participants that do not meet these requirements would be in Track 2 (a non-Advanced APM track). The different tracks would not change how EPM participants operate within the EPM itself, beyond the requirements associated with selecting to meet CEHRT use requirements. The only distinction between the two tracks is that only Track 1 EPMs could be considered an Advanced APM for purposes of the Quality Payment Program based on the proposed criteria in the Quality Payment Program proposed rule. We make similar proposals with respect to CJR. We would consider modifying requirements proposed in this rule as necessary to reconcile them with policies adopted in the Quality Payment Program final rule. A more detailed discussion of the proposals for how EPMs and CJR could qualify as Advanced APMs, and how eligible clinicians participating in the EPMs and CJR would be identified and affected, can be found in sections III.A.2 and V.O. of this proposed rule.

6. Quality Measures and Reporting Requirements

Similar to the quality measures selected for the CJR model, we propose to use established measures used in other CMS quality-reporting programs for the proposed EPMs' episodes. We propose to use these measures to test EPMs' success in achieving its goals under section 1115A of the Act and to monitor for beneficiary safety. For the SHFFT model, we propose applying the same quality measures selected for the CJR model.

The following proposed quality measures for SHFFT episodes are:

- THA/TKA Complications: Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (National Quality Forum [NQF] #1550)
- Hospital Consumer Assessment of Healthcare Providers and Systems (HCAPHS) Survey (NQF #0166)
- Successful Voluntary Reporting of Patient-Reported Outcomes

We propose the following measures for the AMI model:

- MORT-30-AMI: Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0230).
- AMI Excess Days: Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction (acute care days include emergency department, observation, and inpatient readmission days)
- HCAPHS Survey (NQF #0166), linear mean roll-up (HLMR) scores like CJR

We propose the following measures for the CABG model:

- MORT-30-CABG: Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft Surgery (NQF #2558)
- HCAPHS Survey (NQF #0166), HLMR scores like CJR

Finally, we are proposing and requesting public feedback on options for including successful implementation testing of the Hybrid AMI measure as a quality measure for the AMI episode. The Hybrid AMI measure will assess a hospital's 30-day risk-standardized acute myocardial infarction mortality rate and will incorporate a combination of claims data and EHR data submitted by hospitals.

Additionally, similar to the CJR model, we propose to adopt a pay-for-performance methodology for EPMs that relies upon a composite quality score to assign respective EPM participants to four quality categories. These quality categories will determine an EPM participant's eligibility for a reconciliation payment should such EPM participant achieve spending below the quality-adjusted target price, as well as the effective discount percentage at reconciliation. Points for quality performance and improvement (as applicable) will be awarded for each episode measure and then summed to develop a composite quality score that will determine the EPM participant's quality category for the episode. Quality performance will make up the majority of available points in the composite quality score, with improvement points available as "bonus" points for the measure. This approach resembles the CJR model methodology.

7. Beneficiary Protections

As with the CJR model, Medicare beneficiaries in the proposed models will retain the right to obtain health services from any individual or organization qualified to participate in the Medicare program. Eligible beneficiaries who receive services from model participants would not have the option to opt out of inclusion in the applicable model. We propose to require participants to supply beneficiaries with written information regarding the design and implications of these models as well as the beneficiaries' rights under Medicare, including their right to use their providers of choice. We would make a robust effort to reach out to beneficiaries and their advocates to help them understand the models. We also propose to use our existing authority, if necessary, to audit participant hospitals if claims analysis indicates an inappropriate change in delivered services. Beneficiary protections are discussed in greater

depth in section III.G. of this proposed rule.

8. Financial Arrangements

We propose to use the same general framework finalized in the CJR model to hold participants financially responsible for AMI, CABG and SHFFT model episodes as discussed in section III.I. of this proposed rule. Specifically, only the EPM participants would be directly subject to the requirements of this proposed rule for the proposed EPMs. EPM participants would be responsible for ensuring that other providers and suppliers collaborating with the EPM participants on care redesign for the applicable EPM episodes are in compliance with the applicable EPM's terms and conditions.

We propose adding hospitals to the list of providers and suppliers eligible for gainsharing as EPM collaborators due to the expected participation of multiple hospitals in the episode care for some beneficiaries in AMI and CABG episodes. We further propose adding ACOs to be eligible for gainsharing as EPM collaborators due to the interest of ACOs in gainsharing during the CJR model rulemaking and the ongoing challenges of addressing overlap between episode payment models and ACOs. We also propose provisions that allow for certain gainsharing within ACOs, detailed further in section III.I. of this proposed rule.

In contrast, the CR incentive payment model is specifically tied to increased utilization of CR/ICR services within AMI and CABG model episodes and, therefore, is designed to reward increased referral of AMI and CABG model beneficiaries to CR/ICR programs, as well as supporting beneficiary adherence to the referral and participation in CR/ICR services, rather than the quality and efficiency of EPM episodes themselves. Thus, we do not propose to allow CR incentive payments to be included in sharing arrangements, and the CR incentive payments may

be shared with other individual and entities only under circumstances which comply with all existing laws and regulations, including fraud and abuse laws. Financial arrangements are discussed in further detail in section VI.E. of the proposed rule.

9. Data Sharing

Based on our experience with various Medicare programs and models, including the BPCI initiative, the CJR model, the Shared Savings Program, and the Pioneer ACO model, we believe that providing certain beneficiary claims data to model participants will be essential to their success. We propose to share data with participants upon request throughout the performance period of the models to the extent permitted by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule and other applicable law. We propose to share upon request both raw claims-level data and claims summary data with participants. This approach would allow participants without prior experience analyzing claims to use summary data for analysis of care and spending patterns, while allowing those participants who prefer raw claims-level data the opportunity to analyze claims. We propose to provide participants with up to 3 years of retrospective claims data upon request that will be used to develop their quality-adjusted target price. In accordance with the HIPAA Privacy Rule, we would limit the content of this data to the minimum data necessary for the participant to conduct quality assessment and improvement activities and effectively coordinate care.

10. Program Waivers

Section 1115A of the Act authorizes the Secretary to waive Medicare program requirements as necessary to implement provisions for testing models. Under the CJR model, CMS waived certain program rules regarding the direct supervision requirement for certain

post-discharge home visits, telehealth services, and the skilled nursing facility (SNF) 3-day rule. CMS finalized these waivers to offer providers and suppliers more flexibility so that they may increase coordination of care and management of beneficiaries in model episodes. Adopting the CJR waivers for the proposed EPMs required further examination to determine if such adoption would increase financial vulnerability to the Medicare program or would create inappropriate incentives to reduce the quality of beneficiary care. As discussed in section III.J. of this proposed rule, we propose to do the following:

- Adopt waivers of the telehealth originating site and geographic site requirement and to allow in-home telehealth visits for all three proposed EPMs, as well as the general waiver to allow post-discharge nursing visits in the home;
- Provide model-specific limits to the number of post-discharge nursing visits and make model-specific decisions about offering the SNF 3-day stay waiver; and
- Adopt a waiver for furnishing cardiac and intensive cardiac rehabilitation services to allow a Nurse Practitioner, Clinical Nurse Specialist, or Physician Assistant, in addition to a physician, to perform specific physician functions.

C. Summary of Economic Effects

As shown in our impact analysis, we expect the EPMs to result in savings to Medicare of $170 million over the 5 performance years of the model. We note that a composite quality score will be calculated for each hospital in order to determine eligibility for a reconciliation payment and whether the hospital qualifies for quality incentive payments that will reduce the effective discount percentage experience by the hospital at reconciliation for a given performance year.

More specifically, in performance year 1 of the model, we estimate a Medicare cost of approximately $12 million, as hospitals will not be subject to downside risk in the first year and the first quarter of the second performance year of the model. As we introduce downside risk beginning in the second quarter of performance year 2 of the model, we estimate Medicare savings of approximately $13 million. In performance year 3 of the model, we estimate Medicare savings of $30 million. In performance years 4 and 5 of the model, we will move from target episode pricing that is based on a hospital's experience to target pricing based on regional experience, and we estimate Medicare savings of $61 million and $79 million, respectively.

As a result, we estimate the net savings to Medicare to be $170 million over the 5 performance years of the model. We anticipate there will be a broader focus on care coordination and quality improvement for EPMs among hospitals and other providers and suppliers within the Medicare program that will lead to both increased efficiency in the provision of care and improved quality of the care provided to beneficiaries.

Additionally, the CR incentive model estimates that the impact on the Medicare program may range from up to $27 million of additional spending to $32 million of savings between 2017 and 2024, depending on the change in utilization of CR/ICR services based on the proposed incentive structure.

Finally, the change in the estimated net financial impact to the Medicare program from the CJR model modifications in this proposed rule is $22 million in spending, and the updated assumptions regarding the number of hospitals that will report quality data result in an increase of $14 million dollars in spending. The total estimated net financial impact to the Medicare

program from both the modifications in the proposed rule and revised assumptions are $35 million in spending.

We note that under section 1115A(b)(3)(B) of the Act, the Secretary is required to terminate or modify a model unless certain findings can be made with respect to savings and quality after the model has begun. If during the course of testing the model it is determined that termination or modification is necessary, such actions will be undertaken through rulemaking.

II. Background

This proposed rule proposes the implementation of three new EPMs and a CR incentive payment model under the authority of section 1115A of the Act. Under the AMI, CABG, and SHFFT EPMs, acute care hospitals in certain selected geographic areas will be financially accountable for quality performance and spending for applicable episodes of care. We propose to retrospectively apply through a reconciliation process the episode payment methodology; hospitals and other providers and suppliers would continue to submit claims and receive payment via the usual Medicare FFS payment systems throughout the proposed EPMs' performance years. Hospitals participating in the proposed EPMs would receive target prices, which reflect expected spending for care during an episode as well as a discount to reflect savings to Medicare, on a prospective basis, prior to the beginning of a performance year. All related care covered under Medicare Parts A and B and furnished within 90 days after the date of hospital discharge from the anchor hospitalization which initiated the applicable EPM episode would be included in the episode of care. We believe the proposed models will further our goals of improving the efficiency and quality of care for Medicare beneficiaries for these medical conditions and procedures.

III. Provisions of the Proposed Regulations

A. Selection of Episodes, Advanced Alternative Payment Model Considerations, and Future Directions

1. Selection of Episodes for Episode Payment Models in this Rulemaking

a. Overview

CMS has been engaged since 2013 in testing various approaches to episode payment for Medicare FFS beneficiaries for 48 clinical episodes in the BPCI initiative. As of April 1, 2016, the BPCI initiative has 1,522 participants in the risk-bearing phase, comprised of 321 Awardees and 1,201 Episode Initiators. The breakdown of BPCI participants by provider type is as follows: acute care hospitals (385); skilled nursing facilities (681); physician group practices (283); home health agencies (99); inpatient rehabilitation facilities (9); and long-term care hospitals (1).[10] In BPCI Models 2 and 3, there is participation across all 48 clinical episodes, and in Model 4 there is participation in 19 clinical episodes. The 10 clinical episodes with the most participation are: major joint replacement of the lower extremity; simple pneumonia and respiratory infections; congestive heart failure; chronic obstructive pulmonary disease; bronchitis; asthma; hip and femur procedures except major joint; sepsis; urinary tract infection; acute myocardial infarction (medical management only); medical non-infectious orthopedic; and other respiratory.[11]

In November 2015, CMS released the Final Rule for the Comprehensive Care for Joint Replacement (CJR) model (80 FR 73274 through 73554), the first test of episode payment for Medicare FFS beneficiaries in which providers are required to participate. The CJR model,

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[10] https://innovation.cms.gov/initiatives/bundled-payments/.
[11] https://innovation.cms.gov/Files/x/bpcianalyticfile.xlsx.

which began on April 1, 2016, focuses on the episode-of-care for lower-extremity joint replacement (LEJR) procedures. As discussed in the Final Rule (80 FR 73277), LEJR episodes were chosen for the CJR model because they represent one of the most common high-expenditure, high-utilization procedures furnished to Medicare beneficiaries and have significant variation in episode spending. We believe this high volume, coupled with substantial variation in utilization and spending across individual providers and geographic regions, created a significant opportunity to test whether an episode payment model focused on a defined set of procedures could improve the quality and coordination of care, as well as result in savings to Medicare. Notably, both BPCI and the CJR model are focused on care that is related to an inpatient hospitalization, with CJR and BPCI Model 2 episodes beginning with an inpatient hospitalization (anchor hospitalization) and extending up to 90 days post-hospital discharge.

In this rulemaking, we propose three new EPMs that, like the CJR model, would require provider participation in selected geographic areas. Episodes in the new EPMs would begin with admissions for hospitalizations in IPPS hospitals, and would extend 90 days post-hospital discharge. The episodes included in these three EPMs are AMI, CABG, and SHFFT excluding lower extremity joint replacement. The proposed AMI model includes beneficiaries discharged under AMI MS-DRGs (280-282), representing IPPS admissions for AMI that are treated with medical management. The proposed AMI model also includes beneficiaries discharged under PCI MS-DRGs (246-251) with AMI International Classification of Disease, Tenth Edition, Clinical Modification (ICD-10-CM) diagnosis codes for initial AMI diagnoses in the principal or secondary diagnosis code positions, representing IPPS admissions for AMI that are treated with PCIs. The proposed CABG model includes beneficiaries discharged under CABG MS-DRGs (231-236), representing IPPS admissions for this coronary revascularization

procedure irrespective of AMI diagnosis. The proposed SHFFT model includes beneficiaries discharged under hip and femur procedures except major joint replacement MS-DRGs (480-482), representing IPPS admissions for hip-fixation procedures in the setting of hip fractures.

Similar to the selection of LEJR episodes for the CJR model (80 FR 73277), we selected the AMI, CABG, and SHFFT episodes because they represent high-expenditure, high-volume episodes-of-care experienced by Medicare beneficiaries. Based on analysis of historical episodes beginning in CY 2012-2014, the average annual number of historical episodes that began with IPPS hospitalizations and extended 90 days post-hospital discharge, and therefore would have been included in the proposed models, is approximately 168,000 for AMI; 48,000 for CABG; and 109,000 for SHFFT.[12] The total annual Medicare spending for these historical episodes was approximately $4.1 billion, $2.3 billion, and $4.7 billion, respectively.[13] Each of the episodes provides different opportunities in an EPM to improve the coordination and quality of care, as well as efficiency of care during the episode, based on varying current patterns of utilization and Medicare spending.

However, in contrast to LEJR episodes in CJR, which are predominantly elective and during which hospital readmissions are rare and substantial post-acute care provider utilization is common, the proposed AMI, CABG, and SHFFT model episodes have very different current patterns of care. Beneficiaries in these episodes commonly have chronic conditions that contribute to the initiation of the episodes and need both planned and unplanned care throughout

[12] Episodes for AMI, CABG, and SHFFT beneficiaries initiated by all U.S. IPPS hospitals not in Maryland and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that began in CY 2012-2014.

[13] Episodes for AMI, CABG, and SHFFT beneficiaries initiated by all U.S. IPPS hospitals not in Maryland and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that began in CY 2012-2014.

the EPM episode following discharge from the initial hospitalization that begins the episode. Both AMI and CABG model episodes primarily include beneficiaries with cardiovascular disease, a chronic condition which likely contributed to the acute events or procedures that initiate the episodes. About half the average AMI model historical episode spending was for the initial hospitalization, with the majority of spending following discharge from the initial hospitalization due to hospital readmissions, while there was relatively less spending on SNF services, Part B professional services, and hospital outpatient services. In CABG model historical episodes, about three-quarters of episode spending was for the initial hospitalization, with the remaining episode spending relatively evenly divided between Part B professional services and hospital readmissions, and a lesser percentage on SNF services. Similar to AMI episodes, post-acute care provider use was relatively uncommon in CABG model historical episodes, while hospital readmissions during CABG model historical episodes were relatively common. SHFFT model historical episodes also were accompanied by substantial spending for hospital readmissions, and post-acute care provider use in these episodes also was high.[14] The number of affected beneficiaries and potential impact of the models on quality and Medicare spending present an important opportunity to further the Administration's goal of shifting health care payments to support the quality of care over the quantity of services by promoting better coordination among health care providers and suppliers and greater efficiency in the care of beneficiaries in these models, while reducing Medicare expenditures.[15] Pay-for-performance episode payment models such as the three EPMs proposed in this rulemaking financially

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[14] Episodes for AMI, CABG, and SHFFT beneficiaries initiated by all U.S. IPPS hospitals not in Maryland and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that end in CY 2014.

[15] Sylvia Mathews Burwell, HHS Secretary, Progress Towards Achieving Better Care, Smarter Spending, Healthier People, http://www.hhs.gov/blog/2015/01/26/progress-towards-better-care-msarter-spending-healthier-people.html (January 26, 2015).

incentivize improved quality of care and reduced cost by aligning the financial incentives of all providers and suppliers caring for model beneficiaries with these goals. This alignment leads to a heightened focus on care coordination and management throughout the episode that prioritizes the provision of those items and services which improve beneficiary outcomes and experience at the lowest cost.

We selected all of the proposed EPM episodes based on their clinical homogeneity, site-of-service, and MS-DRG assignment considerations. We anticipate these proposed new EPMs, like the CJR model, would benefit Medicare beneficiaries by improving the coordination and transition of care among various care settings to facilitate beneficiaries' return to their communities as their recoveries progress, improving the coordination of items and services paid through Medicare FFS, encouraging more provider investment in infrastructure and redesigned care processes for higher quality and more efficient service delivery, and incentivizing higher value care across the inpatient and post-acute care spectrum spanning the episode-of-care (80 FR 73276). However, improving value in the EPMs through these means requires a cohort of beneficiaries with similar clinical features such that coordination and care redesign efforts can be targeted. Therefore, we propose EPM episodes built on common pathologic and treatment processes; that is, beneficiaries included in both the AMI and CABG models have cardiovascular pathologies that drive their clinical courses during the episodes, and SHFFT model beneficiaries all share similar diagnoses of hip fracture and treatment with hip fixation that drive their clinical courses during their respective episodes.

b. SHFFT Model

The SHFFT model was selected to complement the CJR model. The SHFFT model is being tested in the same hospitals participating in the CJR model as discussed in section III.B.4

of this proposed rule, so that all surgical treatment options for Medicare beneficiaries with hip fracture (hip arthroplasty and fixation) would be included in episode payment models. Hip fracture is a serious and sometimes catastrophic event for Medicare beneficiaries. In 2010, 258,000 people aged 65 and older were admitted to the hospital for hip fracture, with an estimated $20 billion in lifetime cost for all hip fractures in the United States in a single year.[16] In 2013, fracture of the neck of the femur (the most common location for hip fracture) was the eighth most common principal discharge diagnosis for hospitalized Medicare FFS beneficiaries, constituting 2.7 percent of discharges.[17] Mortality associated with hip fracture is 5-10 percent after 1 month and approximately 33 percent at 1 year.[18] Hip arthroplasty and hip fixation, or "hip pinning," represent the two broad surgical options for treating hip fractures.[19] The CJR model episodes begin with admission to acute care hospitals for LEJR procedures assigned to MS-DRG 469 (Major joint replacement or reattachment of lower extremity with major complications or comorbidities) or MS-DRG 470 (Major joint replacement or reattachment of lower extremity without major complications or comorbidities) upon beneficiary discharge and paid under the IPPS, including total and partial hip replacement in the setting of hip fracture (80 FR 73280). Therefore, the SHFFT model, which would additionally test an episode payment for hip fixation, provides an opportunity to complete the transition to episode payment for the surgical treatment and recovery of the significant clinical condition of hip fracture.

c. AMI and CABG Models

The AMI and CABG models, which we propose to be tested at a single set of hospitals as

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[16] Smith et al. Increase in Disability Prevalence Before Hip Fracture. J Am Geriatr Soc. 2015 Oct;63(10):2029-35.
[17] Krumholz HM, Nuti SV, Downing NS, Normand ST, Wang Y. Mortality, Hospitalizations, and Expenditures for the Medicare Population Aged 65 Years or Older, 1999-2013. JAMA. 2015; 314(4):355-365.
[18] Parker et al. Hip Fracture. BMJ. 2006 Jul 1;333(7557):27-30.
[19] American Academy of Orthopaedic Surgeons, OrthoInfo: Hip Fractures, http://orthoinfo.aaos.org (April 12, 2016).

discussed in section III.B.5 of this proposed rule, were selected to include all beneficiaries who have an AMI treated medically or with revascularization with PCI, as well as all beneficiaries who undergo CABG (whether performed during the care of an AMI or performed electively for stable ischemic heart disease or other indication). Both cardiac models represent clinical conditions that result in a significant burden of morbidity and expenditures in the Medicare population. CABG typically is the preferred revascularization modality for patients with ST elevation AMI where the coronary anatomy is not amenable to PCI or there is a mechanical complication (for example, ventricular septal defect, rupture of the free wall of the ventricle, or papillary-muscle rupture with severe mitral regurgitation); for patients with CAD other than ST elevation AMI where there is left main coronary artery disease or multi-vessel disease with complex lesions; and for patients with clinically significant CAD in at least one vessel and refractory symptoms despite medical therapy and PCI.[20] Despite the greater acute morbidity related to major cardiothoracic surgery, CABG is associated with lower longer-term rates of major adverse cardiac and cerebrovascular events in comparison to PCI for certain groups of patients.[21] Moreover, a recent study found that in a group of patients with ischemic cardiomyopathy, the rates of death from any cause, death from cardiovascular causes, and death from any cause or hospitalization for cardiovascular causes were significantly lower over 10 years among patients who underwent CABG in addition to receiving medical therapy than among those who received medical therapy alone.[22] While about 30 percent of CABGs are performed during the care of AMIs, we propose to include these particular AMI beneficiaries

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[20] Alexander JH, Smith PK. Coronary-Artery Bypass Grafting. N Engl J Med. 2016 May 19;374(2):1954-1964.
[21] Sepehripour et al. Developments in surgical revascularization to achieve improved morbidity and mortality. Expert Rev Cardiovasc Ther. 2016 Mar;14(3):367-79. doi: 10.1586/14779072.2016.1123619. Epub 2015 Dec 17.
[22] Velazquez et al. Coronary Artery Bypass Surgery in Patients with Ischemic Cardiomyopathy. N Engl J Med. 2016 Apr 3.

generally in the same episode as CABG for other indications, rather than in the AMI episode, since we anticipate hospitals will seek to improve the quality and efficiency of care for that surgical intervention, regardless of indication.[23]

We propose AMI as the episode for an EPM because we recognize it as a significant clinical condition for which evidence-based clinical guidelines are available for the most common AMI scenarios that begin with a beneficiary's presentation for urgent care, most commonly to a hospital emergency department. The hospital phase involves medical management for all patients, as well as potential revascularization, most commonly with PCI. Secondary prevention and plans for long-term management begin early during the hospitalization and extend following hospital discharge and are addressed in clinical guidelines.[24,25] The AMI model is the first Innovation Center episode payment model that includes substantially different clinical care pathways (medical management and PCI) for a single clinical condition in one episode in a model and, as such, represents an important next step in testing episode payment models for clinical conditions which involve a variety of different approaches to treatment and management.

The American Heart Association estimates that every 42 seconds, someone in the United

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[23] Episodes for CABG beneficiaries initiated by all U.S. IPPS hospitals not in Maryland and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule ,that end in CY 2014.

[24] Amsterdam EA, Wenger NK, Brindis RG, Casey DE Jr, Ganiats TG, Holmes DR Jr, Jaffe AS, Jneid H, Kelly RF, Kontos MC, Levine GN, Liebson PR, Mukherjee D, Peterson ED, Sabatine MS, Smalling RW, Zieman SJ. 2014 ACC/AHA guideline for the management of patients with non–ST-elevation acute coronary syndromes: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation. 2014;130:e344–e426.

[25] O'Gara PT, Kushner FG, Ascheim DD, Casey DE Jr, Chung MK, de Lemos JA, Ettinger SM, Fang JC, Fesmire FM, Franklin BA, Granger CB, Krumholz HM, Linderbaum JA, Morrow DA, Newby LK, Ornato JP,Ou N, Radford MJ, Tamis-Holland JE, Tommaso CL, Tracy CM, Woo YJ, Zhao DX. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013;127:

States has a myocardial infarction.[26] 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.[27,28] In 2013, AMI was the sixth most common principal discharge diagnosis for hospitalized Medicare FFS beneficiaries, constituting 2.9 percent of discharges.[29] Of the approximately 395,000 Medicare FFS beneficiaries with short-term acute care hospital discharges (excluding Maryland) for AMI in FY 2014, 60 percent were discharged under MS-DRGs proposed to be included in the AMI model, specifically 33 percent under AMI MS-DRGs and 25 percent under PCI MS-DRGs.[30] An additional 3 percent of beneficiaries were in MS-DRGs assigned for death from AMI in the hospital. Although 5 percent of beneficiaries with hospital discharges for AMI were discharged under CABG MS-DRGs, we note that because both PCI and fibrinolysis can restore blood flow in an acutely occluded coronary artery more quickly than CABG, these interventions are currently preferred to CABG in most cases of AMI. Furthermore, over recent years cardiovascular clinical practice patterns have generally shifted away from surgical treatment of coronary artery

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[26] Mozaffarian D, Benjamin EJ, Go AS, Arnett DK, Blaha MJ, Cushman M, Das SR, de Ferranti S, Després J-P, Fullerton HJ, Howard VJ, Huffman MD, Isasi CR, Jiménez MC, Judd SE, Kissela BM, Lichtman JH, Lisabeth LD, Liu S, Mackey RH, Magid DJ, McGuire DK, Mohler ER III, Moy CS, Muntner P, Mussolino ME, Nasir K, Neumar RW, Nichol G, Palaniappan L, Pandey DK, Reeves MJ, Rodriguez CJ, Rosamond W, Sorlie PD, Stein J, Towfighi A, Turan TN, Virani SS, Woo D, Yeh RW, Turner MB; on behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2016 update: a report from the American Heart Association. Circulation. 2016 Jan 26; 133(4):447-54.

[27] Krumholz HM, Nuti SV, Downing NS, Normand ST, Wang Y. Mortality, Hospitalizations, and Expenditures for the Medicare Population Aged 65 Years or Older, 1999-2013. JAMA. 2015; 314(4):355-365.

[28] Dharmarajan K, Hsieh AF, Lin Z, et al. Diagnoses and Timing of 30-Day Readmissions After Hospitalization for Heart Failure, Acute Myocardial Infarction, or Pneumonia. JAMA. 2013; 309(4):355-363.

[29] Krumholz HM, Nuti SV, Downing NS, Normand ST, Wang Y. Mortality, Hospitalizations, and Expenditures for the Medicare Population Aged 65 Years or Older, 1999-2013. JAMA. 2015; 314(4):355-365.

[30] Inpatient claims from all U.S. IPPS hospitals not in Maryland were derived from the October 2013 – September 2014 Inpatient Claims File located in the Chronic Conditions Warehouse.

occlusion toward percutaneous, catheter-based interventions.[31] The remaining 34 percent of beneficiaries with AMI diagnoses were distributed across a heterogeneous group of over 300 other MS-DRGs, such as septicemia, respiratory system diagnosis with ventilator support, and major cardiovascular procedures. For this latter group of beneficiaries, the AMI diagnosis appeared in a secondary position on the hospital claim in more than 90 percent of the cases, therefore most likely representing circumstances where the beneficiary hospitalized for another clinical condition experienced an AMI during the hospital stay. By focusing the AMI model on AMIs treated medically or with revascularization with PCI, we propose to test a condition-specific EPM that is discretely defined and includes a significant majority of beneficiaries with AMI in the AMI model. In CYs 2012-2014, the average Medicare spending for an AMI episode that extends 90 days post-hospital discharge was approximately $24,200.[32] From the AMI model, we expect to better understand the impact such an EPM can have on efficiency and quality of care for beneficiaries across the entire spectrum of AMI care, including diagnosis, treatment, and recovery, as well as short-term secondary prevention.

Beneficiaries in the proposed AMI and CABG models would all have CAD. In 2010 in the U.S, the prevalence of CAD in the population 65 years and older was about 20 percent.[33] Patients with CAD also often experience other conditions with significant health-related implications, including diabetes. To improve care for patients with CAD, most approaches in the private and public sectors focus on improving the efficiency and quality of care around

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[31] Epstein et al. JAMA. 2011 May 4; 305(17): 1769–1776.

[32] Episodes for beneficiaries with AMI diagnosis initiated by all U.S. IPPS hospitals not in Maryland and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that began in CYs 2012-2014.

[33] National Center for Chronic Disease Prevention and Health Promotion, Division for Heart Disease and Stroke Prevention, August 10, 2015.

procedures such as PCI and CABG. The BPCI models are an example of such an approach. As discussed previously in this section, our proposal for the AMI model extends beyond a procedure-based EPM to include beneficiaries hospitalized for medical management or PCI for AMI in a single EPM, and we propose to test the CABG model, which also would include beneficiaries with AMI, at the same participant hospitals. We believe that hospitalization for AMI, whether accompanied solely by medical management or including revascularization during the initial hospitalization or in a planned CABG readmission, is a sentinel event indicating the need for an increased focus on condition-specific management, as well as on care coordination and active management to prevent future acute events, both during the AMI and CABG model episodes and beyond. We also believe that improving the quality and efficiency of CAD care over a long period of time is important given the chronic nature of this condition that has serious implications for beneficiary health.

The AMI and CABG models provide an opportunity for us to incentivize CAD-specific care management and care coordination for AMI and CABG model beneficiaries that lay the groundwork for longer-term improvements in quality and efficiency of care for beneficiaries with CAD. We note that the quality measures proposed for use in the pay-for-performance methodologies of the AMI and CABG models do not currently include longer-term outcomes or patient experience outside of the AMI or CABG model episode itself, as discussed in sections III.E.2.b. and c. of this proposed rule, although we are interested in comments about potential future measures that could incorporate longer-term outcomes. Moreover, as discussed in section VI. of this proposed rule, we also propose to test a cardiac rehabilitation (CR)/intensive cardiac rehabilitation (ICR) incentive payment, hereinafter CR incentive payment, in AMI and CABG model participants located in some of the MSAs selected for AMI and CABG model

participation, as well as in hospitals located in some of the MSAs that are not selected for AMI or CABG model participation. We would evaluate the effects of the CR incentive payment in the context of an episode payment model and Medicare FFS on utilization of CR/ICR, as well as short-term (within the period of time extending 90 days following hospital discharge from an AMI or CABG hospitalization) and longer-term outcomes. We believe this test may result in valuable findings about effective strategies to increase utilization of CR/ICR services that have a strong evidence-base for their effectiveness but a long history of underutilization.

2. Advanced Alternative Payment Model Considerations

a. Overview for the EPMs

The MACRA created two paths for eligible clinicians to link quality to payments: the MIPS and Advanced APMs. These two paths create a flexible payment system called the Quality Payment Program as proposed by CMS in the Quality Payment Program proposed rule (81 FR 28161 through 28586).

As proposed in the Quality Payment Program proposed rule, an APM must meet three criteria to be considered an Advanced APM (81 FR 28298). First, the APM must provide for payment for covered professional services based on quality measures comparable to measures described under the performance category described in section 1848(q)(2)(B)(i) of the Act, which is the MIPS quality performance category. Under the Quality Payment Program proposed rule, we proposed that the quality measures on which the Advanced APM bases payment for covered professional services (as that term is defined in section 1848(k)(3)(A) of the Act) must include at least one of the following types of measures, provided that they have an evidence-based focus and are reliable and valid (81 FR 28302):

- Any of the quality measures included on the proposed annual list of MIPS quality

measures.

- Quality measures that are endorsed by a consensus-based entity.
- Quality measures developed under section 1848(s) of the Act.
- Quality measures submitted in response to the MIPS Call for Quality Measures under section 1848(q)(2)(D)(ii) of the Act.
- Any other quality measures that CMS determines to have an evidence-based focus and be reliable and valid.

As we discussed in the Quality Payment Program proposed rule, because the statute identifies outcome measures as a priority measure type and we wanted to encourage the use of outcome measures for quality performance assessment in APMs, we further proposed in that rule that, in addition to the general quality measure requirements, an Advanced APM must include at least one outcome measure if an appropriate measure is available on the MIPS list of measures for that specific QP Performance Period, determined at the time when the APM is first established (81 FR 28302 through 28303).

Second, the APM must either require that participating APM Entities bear risk for monetary losses of a more than nominal amount under the APM or be a Medical Home Model expanded under section 1115A(c) of the Act. Except for Medical Home Models, we proposed in the Quality Payment Program proposed rule that, for an APM to meet the nominal amount standard, the specific level of marginal risk must be at least 30 percent of losses in excess of expected expenditures; a minimum loss rate, to the extent applicable, must be no greater than 4 percent of expected expenditures; and total potential risk must be at least 4 percent of expected expenditures (81 FR 28306).

Third, the APM must require participants to use CEHRT (as defined in section 1848(o)(4) of the Act), as specified in section 1833(z)(3)(D)(i)(I) of the Act, to document and communicate clinical care with patients and other health care professionals. Specifically, where the APM participants are hospitals, the APM must require each hospital to use CEHRT (81 FR 28298 through 28299).

In this proposed rule, we propose to adopt two different tracks for the EPMs—Track 1 in which EPMs and EPM participants would meet the criteria for Advanced APMs as proposed in the Quality Payment Program proposed rule, and Track 2 in which the EPMs and EPM participants would not meet those proposed criteria. For the proposed AMI, CABG, and SHFFT models, we propose pay-for-performance methodologies that use quality measures that we believe would meet the proposed Advanced APM quality measure requirements in the Quality Payment Program proposed rule. As discussed in sections III.E.2. and 3. of this proposed rule, all but one of the AMI, CABG, and SHFFT model measures used in the EPM pay-for-performance methodologies are NQF-endorsed and have an evidence-based focus and are reliable and valid. Therefore, we believe they would meet the proposed Advanced APM general quality measure requirements. The Excess Days in Acute Care after Hospitalization for AMI (AMI Excess Days) measure, which is proposed for the AMI model, is not currently NQF-endorsed, but we believe it meets the measure requirements by having an evidence-based focus and being reliable and valid because this measure has been proposed and adopted through rulemaking for use in the Hospital Inpatient Quality Reporting (HIQR) Program.

Each of the proposed EPM pay-for-performance methodologies includes one outcome measure that is NQF-endorsed, has an evidence-based focus, and is reliable and valid. The EPM quality measures are discussed in detail in section III.E. of this proposed rule, where we assign

the quality measures to quality domains. For the AMI model, we propose to use the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (NQF #0230) (MORT-30-AMI) outcome measure. For the CABG model, we propose to use the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF# 2558) (MORT-30-CABG) outcome measure. Finally, for the SHFFT model, we propose to use the Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550) (Hip/Knee Complications) outcome measure. Thus, based on the proposed use of these three outcomes measures in the EPMs, we believe the proposed AMI, CABG, and SHFFT models would meet the requirement proposed for Advanced APMs in the Quality Payment Program proposed rule for use of an outcome measure that also meets the general quality measure requirements.

In terms of the proposed nominal risk criteria for Advanced APMs, beginning in performance year 2 for episodes ending between April 1, 2018 and December 31, 2018, EPM participants would begin to bear downside risk for excess actual EPM-episode spending above the quality-adjusted target price as discussed in section III.D.2.c. of this proposed rule. The marginal risk for excess actual EPM-episode spending above the quality-adjusted target price would be 100 percent over the range of spending up to the stop-loss limit, which would exceed 30 percent marginal risk, and there would be no minimum loss rate. As a result, we believe the EPMs would meet the marginal risk and minimum loss rate elements of the nominal risk criteria for Advanced APMs proposed in the Quality Payment Program proposed rule. Total potential risk for most EPM participants would be 5 percent of expected expenditures beginning in the second quarter of performance year 2, and increasing in subsequent performance years as discussed in section III.D.7.b. of this proposed rule. Therefore, we believe the total potential risk

applicable to most EPM participants, with the lowest total potential risk being 5 percent for EPM episodes ending on or after April 1, 2018 in performance year 2, would meet the total potential risk element of the nominal risk amount standard for Advanced APMs proposed in the Quality Payment Program proposed rule because it is greater than the value of at least 4 percent of expected expenditures.

We note that we propose that EPM participants that are rural hospitals, sole community hospitals (SCHs), Medicare Dependent Hospitals (MDHs) and Rural Referral Centers (RRCs) would have a stop-loss limit of 3 percent beginning in the second quarter of performance year 2 as discussed in section III.D.7.c. of this proposed rule. Because 3 percent is less than the proposed threshold of at least 4 percent of expected expenditures for total potential risk proposed for Advanced APMs in the Quality Payment Program proposed rule, those rural hospitals, SCHs, MDHs, and RRCs that are EPM participants subject to special protections would be in Track 2 EPMs that would not meet the proposed nominal risk standard for Advanced APMs for performance year 2. We recognize that this proposal might initially limit the ability of rural hospitals, SCHs, MDHs, and RRCs to be in Track 1 EPMs that are Advanced APMs. We believe this potential limitation on rural hospitals, SCHs, MDHs, and RRCs is appropriate for the following reasons: (1) greater risk protections for these hospitals proposed for the EPMs beginning in the second quarter of performance year 2 and subsequent performance years compared to other EPM participants are necessary, regardless of their implications regarding Advanced APMs based on the nominal risk standard proposed in the Quality Payment Program proposed rule, because these hospitals have unique challenges that do not exist for most other hospitals, such as being the only source of health care services for beneficiaries or certain beneficiaries living in rural areas or being located in areas with fewer providers, including fewer

physicians and post-acute care facilities; and (2) under the risk arrangements proposed for the EPMs, these hospitals would not bear an amount of risk in performance year 2 that we determined to be more than nominal in the Quality Payment Program proposed rule. However, we seek comment on whether we should allow EPM participants that are rural hospitals, SCHs, MDHs, or RRCs to elect a higher stop-loss limit for the part of performance year 2 where downside risk applies in order to permit these hospitals to be in Track 1 EPMs for that part of performance year 2. We note that by performance year 3, the stop-loss limit for these hospitals with special protections under the EPMs would increase to 5 percent under our proposal, so these hospitals could be in Track 1 EPMs based on the nominal risk standard proposed in the Quality Payment Program proposed rule.

As addressed in the Quality Payment Program proposed rule, it is necessary for an APM to require the use of CEHRT in order to meet the criteria to be considered to be an Advanced APM. Therefore, according to the requirements proposed in the Quality Payment Program proposed rule, so that the EPMs may meet the proposed criteria to be Advanced APMs, we propose to require EPM participants to use CEHRT (as defined in section 1848(o)(4) of the Act) to participate in Track 1 of the EPMs. We propose that Track 1 EPM participants must use certified health IT functions, in accordance with the definition of CEHRT under our regulation at 42 CFR 414.1305, to document and communicate clinical care with patients and other health care professionals as proposed in the Quality Payment Program proposed rule (81 FR 28299). We believe this proposal would allow Track 1 EPMs to be able to meet the proposed criteria to be Advanced APMs.

Without the collection of identifying information on eligible clinicians (physicians, nonphysician practitioners, physical and occupational therapists, and qualified speech-language

pathologists) who would be considered Affiliated Practitioners as proposed in the Quality Payment program proposed rule under the EPMs, CMS would not be able to consider participation in the EPMs in making determinations as to whom could be considered a QP (81 FR 28320). As detailed in the Quality Payment Proposed rule, these determinations are based on whether the eligible clinician meets the QP threshold under either the Medicare Option starting in payment year 2019 or the All-Payer Combination Option, which is available starting in payment year 2021 (81 FR 28165). Thus, we make proposals in the following sections to specifically address these issues that might otherwise preclude the EPMs from being considered Advanced APMs, or prevent us from operationalizing them as Advanced APMs. Based on the proposals for Advanced APM criteria in the Quality Payment Program proposed rule, we seek to align the design of the proposed EPMs with the proposed Advanced APM criteria and enable CMS to have the necessary information on eligible clinicians to make the requisite QP determinations.

b. EPM Participant Tracks

To be considered an Advanced APM, the APM must require participants to use CEHRT (as defined in section 1848(o)(4) of the Act), as specified in section 1833(z)(3)(D)(i)(I) of the Act. We propose that all EPM participants must choose whether to meet the CEHRT use requirement. EPM participants that do not choose to meet and attest to the CEHRT use requirement would be in Track 2 of the EPMs. EPM participants selecting to meet the CEHRT use requirement would be in Track 1 of the EPMs and would be required to attest in a form and manner specified by CMS to their use of CEHRT that meets the definition in our regulation at § 414.1305 to document and communicate clinical care with patients and other health professionals, consistent with the proposal in the Quality Payment Program proposed rule for the

CEHRT requirement for Advanced APMs (81 FR 28299). EPM participants choosing not to meet and attest to the CEHRT use requirement would not be required to submit an attestation.

We believe that the selection by EPM participants to meet and attest to the CEHRT use requirement would create no significant additional administrative burden on EPM participants. Moreover, the choice of whether to meet and attest to the CEHRT use requirement would not otherwise change any EPM participant's requirements or opportunity under the EPM. However, to the extent that eligible clinicians who enter into financial arrangements related to Track 1 EPM participants are considered to furnish services through an Advanced APM, those services could be considered for purposes of determining whether the eligible clinicians are QPs.

The proposals for CEHRT use and attestation for EPM participants are included in § 512.120(a). We seek comment on our proposals for EPM participant CEHRT use requirements.

c. Clinician Financial Arrangements Lists under the EPMs

In order for CMS to make determinations as to eligible clinicians who could be considered QPs based on services furnished under the EPMs (to the extent the models are determined to be Advanced APMs), we require accurate information about eligible clinicians who enter into financial arrangements under the Track 1 EPMs under which the Affiliated Practitioners support the participants' cost or quality goals as discussed in section III.I. of this proposed rule. We note that eligible clinicians could be EPM collaborators engaged in sharing arrangements with an EPM participant; PGP members who are collaboration agents engaged in distribution arrangements with a PGP that is an EPM collaborator; or PGP members who are downstream collaboration agents engaged in downstream distribution arrangements with a PGP that is also an ACO participant in an ACO that is an EPM collaborator. These terms as they

apply to individuals and entities with financial arrangements under the EPMs are discussed in section III.I. of this proposed rule. A list of physicians and nonphysician practitioners in one of these three types of arrangements could be considered an Affiliated Practitioner List of eligible clinicians who are affiliated with and support the Advanced APM Entity in its participation in the Advanced APM as proposed in the Quality Payment Program proposed rule. Therefore, this list could be used to make determinations of who would be considered for a QP determination based on services furnished under the EPMs (81 FR 28320).

Thus, we propose that each EPM participant that chooses to meet and attest to the CEHRT use requirement must submit to CMS a clinician financial arrangements list in a form and manner specified by CMS on a no more than quarterly basis. The list must include the following information for the period of the EPM performance year specified by CMS:

- For each EPM collaborator who is a physician, nonphysician practitioner, or provider of outpatient therapy services during the period of the EPM performance year specified by CMS:

++ The name, tax identification number (TIN), and national provider identifier (NPI) of the EPM collaborator.

++ The start date and, if applicable, end date, for the sharing arrangement between the EPM participant and the EPM collaborator.

- For each collaboration agent who is a physician or nonphysician practitioner of a PGP that is an EPM collaborator during the period of the EPM performance year specified by CMS:

++ The TIN of the PGP that is the EPM collaborator, and the name and NPI of the physician or nonphysician practitioner.

++ The start date and, if applicable, end date, for the distribution arrangement between the EPM collaborator that is a PGP and the physician or nonphysician practitioner who is a PGP

member.

- For each downstream collaboration agent who is a physician or nonphysician practitioner member of a PGP that is also an ACO participant in an ACO that is an EPM collaborator during the period of the EPM performance year specified by CMS:

++ The TIN of the PGP that is the ACO participant, and the name and NPI of the physician or nonphysician practitioner.

++ The start date and, if applicable, end date, for the downstream distribution arrangement between the collaboration agent that is both PGP and an ACO participant and the physician or nonphysician practitioner who is a PGP member.

- If there are no individuals that meet the requirements to be reported as EPM collaborators, collaboration agents, or downstream collaboration agents, the EPM participant must attest in a form and manner required by CMS that there are no individuals to report on the clinician financial arrangements list.

As discussed in the Quality Payment program proposed rule, those physicians or nonphysician practitioners who are included on the Affiliated Practitioner List as of December 31 of a performance period would be assessed to determine whether they qualify for APM Incentive Payments (81 FR 28320).

While the required submission of this information may create some additional administrative requirements for certain EPM participants, we expect that Track 1 EPM participants could modify their contractual relationships with their EPM collaborators and, correspondingly, require those EPM collaborators to include similar requirements in their contracts with collaboration agents and in the contracts of collaboration agents with downstream collaboration agents.

The proposal for the submission of a clinician financial arrangements list by EPM participants that meet and attest to the CEHRT use requirement for the EPMs is included in § 512.120(b). We seek comments on the proposal for submission of this information. We are especially interested in comments about approaches to information submission, including the periodicity and method of submission to CMS that would minimize the reporting burden on EPM participants while providing CMS with sufficient information about eligible clinicians in order to facilitate QP determinations to the extent EPMs are considered Advanced APMs.

d. Documentation Requirements

For each EPM participant that chooses to meet and attest to CEHRT use, we propose that the EPM participant must maintain documentation of their attestation to CEHRT use and clinician financial arrangements lists submitted to CMS. These documents would be necessary to assess the completeness and accuracy of materials submitted by an EPM participant in the Track 1 EPM and to facilitate monitoring and audits. For the same reason, we further propose that the EPM participant must retain and provide access to the required documentation in accordance with § 512.110.

The proposal for documentation of attestation to CEHRT use and clinician financial arrangements lists submitted to CMS is included in § 512.120(c). We seek comment on this proposal for required documentation.

3. Future Directions for Episode Payment Models

a. Refinements to the BPCI Initiative Models

The BPCI initiative Models 2, 3, and 4 would not currently qualify as Advanced APMs based on the two of the Advanced APM criteria in the Quality Payment Program proposed rule, payment based on quality measures and CEHRT use (81 FR 28298). Specifically, BPCI

participants are not currently required to use CEHRT, and although CMS examines the quality of episode care in the BPCI evaluation, BPCI episode payments are not specifically tied to quality performance. Instead, BPCI episode payments are based solely on episode spending performance, although we expect that reductions in spending would generally be linked to improved quality through reductions in hospital readmissions and complications. However, building on the BPCI initiative, the Innovation Center intends to implement a new voluntary bundled payment model for CY 2018 where the model(s) would be designed to meet the criteria to be an Advanced APM.

b. Potential Future Condition-Specific Episode Payment Models

In the context of our proposal for the AMI and CABG models that include beneficiaries with CAD who experience an acute event or a major surgical procedure, we seek comment on model design features for potential future condition-specific episode payment models that could focus on an acute event or procedure or longer-term care management, including other models for beneficiaries with CAD that may differ from the design of the EPMs proposed in this rulemaking. We believe such future models may have the potential to be Advanced APMs that emphasize outpatient care and, like the proposed AMI and CABG models, could incentivize the alignment of physicians and other eligible professionals participating in the Advanced APM through accountability for the costs and quality of care. Such condition-specific episode payment models may provide for a transition from hospital-led EPMs to physician-led accountability for episode quality and costs, especially given the importance of care management over long periods of time for beneficiaries with many chronic conditions.

We request that commenters provide specific information regarding all relevant issues for potential future condition-specific episode payment models, including identifying beneficiaries

for the model; including services in the episode definition; beginning and ending episodes; pricing episodes, including risk-adjustment; designating the accountable entity for the quality and cost of the episode, including the role of physician-led opportunities; sharing of responsibility for quality and spending between primary care providers, specialty physicians, and other health care professionals; incentivizing the engagement of physicians and other providers and suppliers in episode care; measuring quality and including quality performance and improvement in the payment methodology; interfacing with other CMS models and programs responsible for population health and costs, such as ACOs and Primary Care Medical Homes (PCMHs); and other considerations specific to identifying future models as Advanced APMs; and any other issues of importance for the design of such an EPM.

c. Potential Future Event-Based Episode Payment Models for Procedures and Medical Conditions

Given the proposed EPM methodology discussed in section III.C.4.a. of this proposed rule for the three models that would begin the episodes with initial hospitalizations, the proposed AMI, CABG, and SHFFT episodes are similar to the LEJR episodes in the CJR model because they reflect clinical conditions for which care is almost always begun during an inpatient hospitalization, either on an emergency or elective basis. In addition, the clinical conditions represented by these EPM episodes generally result in straightforward assignment to MS-DRGs at discharge that are specific to clinical conditions included in the episodes. This contrasts with procedure-related clinical conditions for which the site-of-service can be inpatient or outpatient (for example, elective PCI for non-AMI beneficiaries) or hospitalization for medical conditions for which the ultimate MS-DRG assigned is less clear at the beginning of an episode (for example, hospitalization for respiratory symptoms which may lead to discharge

from heart failure, pneumonia, or other MS-DRGs based on reporting of ICD-CM diagnosis codes on hospital claims).

To address the issues related to the development of future episode payment models for a broader range of clinical conditions, we seek comment on model design features that would be important for episode payment models targeting procedures that may be performed in both the inpatient and outpatient setting, as well as models focused on hospitalization for acute medical conditions which may overlap or interact (for example, sepsis related to pneumonia or acute kidney injury related to congestive heart failure exacerbation). In particular, episode payment models must clearly define the beginning of the episode as well as set an episode price that is appropriate for beneficiaries included in the episode, which has commonly been based on historical spending for such beneficiaries in both existing CMS models and the three proposed EPMs. These parameters pose specific challenges as the variety of clinical conditions targeted for episode payments expands beyond lower extremity orthopedic procedures and acute cardiac conditions, and we expect that such potential future models would need to be designed differently than the CJR model or the EPMs proposed in this rulemaking.

For example, because procedures such as PCI for non-AMI beneficiaries or cardioverter defibrillator implantations can occur in the inpatient or outpatient setting, an episode payment model would need to include beneficiaries receiving such procedures at all sites-of-service so as to not influence decisions on where procedures are performed based on payment-related rather than clinical considerations. Episode payment models that begin with the same procedure performed in the inpatient or outpatient setting would require methodological development beyond the approaches that have been used thus far in CMS's other EPMs that rely upon the MS-DRG for a hospitalization to begin an episode and identify historical episodes for setting

episode prices. Such models that involve episode payment for procedures furnished in the inpatient or outpatient setting may allow for significant physician-led opportunities that would allow the models to be identified as Advanced APMs. We seek comment on how these types of procedures could be included in future episode payment models, including identifying the accountable entity, and the role of physician-led opportunities; defining the episode beginning and end; setting episode prices; applying risk-adjustment to account for differences in expected episode spending for a heterogeneous population of beneficiaries; and any other issues of importance for the design of such an episode payment model.

We also seek comment on potential future episode payment models that would include care for medical conditions that result in the serious health event of an inpatient hospitalization, which often represents, regardless of the specific reason for the hospitalization, a common pathway that includes failure of outpatient care management and care coordination for beneficiaries with chronic conditions. While we do include in the proposed AMI model beneficiaries who solely receive medical treatment, we note that beneficiaries with AMI are almost always hospitalized and their MS-DRGs at discharge are generally predictable and consistent based on their AMI diagnoses. This is not the case for a number of medical conditions for which grouping by MS-DRGs is more complicated or less consistent. Many non-procedural hospitalizations of Medicare beneficiaries are ultimately categorized based on the principal ICD-CM diagnosis code reported on a claim, which in turn is mapped to a Major Diagnostic Category (MDC) based on the involved organ system, which then leads to the assignment of any of various specific MS-DRGs based on the medical groups in the MDC. For example, the medical groups for the Respiratory System MDC are pulmonary embolism, infections, neoplasms, chest trauma, pleural effusion, pulmonary edema and respiratory failure, chronic

obstructive pulmonary disease, simple pneumonia, RSV pneumonia and whooping cough, interstitial lung disease, pneumothorax, bronchitis and asthma, respiratory symptoms and other respiratory diagnoses.[34] Unlike a beneficiary who undergoes a surgical procedure or who is hospitalized for a specific medical condition such as AMI, the ultimate MS-DRG at discharge assigned to a beneficiary hospitalized for diagnosis and management of respiratory symptoms may not be clear during the hospitalization itself, or even afterward, until the inpatient claim is submitted and paid by Medicare. This makes it challenging for providers to engage in care delivery redesign targeted to a specific patient population identified by MS-DRG. Additionally, it is possible that beneficiaries hospitalized for certain medical conditions also may follow common clinical pathways before and after discharge for which similar care redesign strategies could be developed and used despite those beneficiaries' assignments to different MS-DRGs for their anchor hospitalizations. Thus, we believe that hospitalization for most medical conditions would require special consideration in the development of potential future episode payment models that goes beyond CMS's current approach of relying upon the MS-DRG for the anchor hospitalization to begin an episode and identify historical episodes for setting episode prices. We seek comment on design features needed to address these considerations, including defining the beginning and end of episodes; setting episode prices, including risk-adjustment, that would support the provision of appropriate and coordinated care for beneficiaries following hospital discharge for a period of time during the episode; and any other issues of importance for the design of such an episode payment model.

d. Health Information Technology Readiness for Potential Future Episode Payment Models

We are particularly interested in issues related to readiness of providers and suppliers that

[34] Medical Severity Diagnosis Related Groups (MS-DRGs): Definitions Manual. Version 33.0A. 3M Health Information Systems. (October 1, 2015).

are not hospitals to take on financial responsibility for episode cost and quality in potential future episode payment models. We have some experience in BPCI Models 2 and 3 with non-hospital providers and suppliers, specifically post-acute care providers and physician group practices (PGPs), who assume financial responsibility for the cost of episode care. In BPCI Model 2, PGPs may directly bear financial responsibility for episode cost for up to 48 clinical conditions for the anchor inpatient admission and up to 90 days post-hospital discharge. In BPCI Model 3, PGPs and post-acute care providers, including skilled nursing facilities, home health agencies, inpatient rehabilitation facilities, and long-term care hospitals, may directly bear financial responsibility for episode cost for up to 48 clinical conditions for a duration that extends up to 90 days following initiation of post-acute care following discharge from an inpatient hospitalization.

Under these circumstances, PGPs and post-acute care providers typically need to use health IT to assist them in effectively coordinating the care of BPCI beneficiaries across settings throughout the episodes. The risk-bearing entities participating in BPCI have expressed readiness to take on financial responsibility for episode cost, and they commonly rely upon health IT for assistance in managing the care for BPCI beneficiaries across settings for episodes that extend for a substantial period of time. However, a recent national survey of IT in nursing homes showed common use of IT for administrative activities but less use for clinical care.[35] Anecdotally, stakeholders have told us that accountable non-hospital providers and suppliers, especially those that are not integrated with health systems, may have less well-developed tools for following patients throughout episodes, potentially resulting in greater challenges in reducing the cost and improving the quality of episode care under the BPCI models. Therefore, we understand that limitations in the availability of health IT that can be used in beneficiary

[35] Alexander, Gregory L. "An Analysis of Nursing Home Quality Measures and Staffing." Quality management in health care 17.3 (2008): 242–251. PMC. Web. 16 July 2016.

management across care settings may pose a significant barrier to the readiness of non-hospital providers and suppliers to assume financial responsibility for episodes in potential future episode payment models.

In the CJR model, acute care hospitals are financially responsible for cost and quality during LEJR episodes-of-care. CJR model participant hospitals may form partnerships with post-acute care providers such as skilled nursing facilities and home health agencies, as well as physicians and PGPs, to share financial risk and collaborate on care redesign strategies, as in BPCI. Although hospitals are the financially responsible entities under the CJR model, we recognize that partnerships with post-acute care providers could be a crucial driver of episode spending and quality, given that many beneficiaries in the CJR model receive post-acute care services after discharge from the hospital. We also recognize that tools such as health IT may be critical for certain care management and quality strategies targeted toward the goal of lower cost and higher quality episode care. Limitations in the availability of health IT may pose a barrier to effective post-acute care provider collaboration and sharing of financial risk in episode payment models even when hospitals are the financially responsible entities under such models, such as the CJR model and the three new EPMs proposed in this rulemaking.

We recognize that there is wide variation in the readiness of other providers and suppliers to bear financial responsibility for episodes, either directly or indirectly through sharing arrangements with the directly responsible entities where those arrangements may include upside and downside risk. For instance, adoption of health IT among providers in the post-acute care market, such as skilled nursing facilities, continues to lag behind hospitals and providers of ambulatory care services. In addition to facing significant resource constraints, post-acute care providers were not included as an eligible provider type under the Medicare and Medicaid

Electronic Health Record (EHR) Incentive Programs. The recent extension of Medicaid 90/10 funding offers new opportunities for states to include post-acute care providers in projects focused on infrastructure development, but will not address the cost of health IT adoption among post-acute care providers.[36]

To ensure that post-acute care providers and other types of providers and suppliers can succeed under future episode payment models, either as the directly financially responsible entity or as collaborators with other directly financially responsible entities, we are interested in opportunities to increase provider readiness as part of the design of potential future episode payment models and the potential refinement of current episode payment models. Specifically, we would like to explore: incentives to encourage post-acute care providers, as well as other providers and suppliers that furnish services to episode payment model beneficiaries, to make necessary investments in health IT infrastructure; payment mechanisms that could leverage savings achieved under episode payment models to contribute to these investments; and any other strategies to enhance the adoption, implementation, and upgrading of certified health IT. We seek comment on these ideas, as well as the following questions:

- What are key challenges associated with the inclusion of post-acute care providers as the financially responsible entity or as collaborators with other financially responsible entities in episode payment models today?
- What would be a sufficient financial incentive or bonus to enhance the adoption, implementation, and upgrading of certified health IT in post-acute care settings?
- How else can episode payment models encourage the use of certified health IT and information sharing among providers and suppliers caring for episode payment model

[36] https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16003.pdf.

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?

B. Proposed Definition of the Episode Initiator and Selected Geographic Areas

1. Background

The proposed new EPMs will complement the current CJR model and continue efforts to move Medicare towards paying providers based on quality and value. As discussed during rulemaking for the CJR model, CMS is interested in testing and evaluating the impact of an episode payment approach for a broad range of episodes in a variety of other circumstances. In addition to including hospitals that have not chosen to voluntarily participate in earlier models, we also are interested in expanding the range of episodes included beyond elective surgical procedures such that the impact on a broader range of beneficiaries, hospitals, and circumstances may be tested. We also are interested in evaluating the impact on hospitals when an increasing percentage of care to Medicare beneficiaries is paid for through alternative payment models.

As with CJR, we propose in § 512.105(c) that the hospital be the accountable financial entity and that these episode payment models be implemented in all IPPS hospitals in the geographic areas selected, subject to exclusions as specified in §§ 512.230 and 512.240

of the proposed rule. While these are considered new episode payment models and do not reflect an expansion or extension of any previous models, they do intentionally build significantly upon the work of BPCI and, most significantly, the framework established for CJR under 42 CFR Part 510 published on November 24, 2015. Given the extensive consideration given to many of these issues during the CJR model planning and rulemaking periods, we believe this is important as we seek to build a model that is scalable across all providers and episode types. We also seek to limit the burden for hospitals and other providers that may be participating across multiple episode types. Therefore, to the extent applicable and appropriate, we have sought consistency with rules established for the CJR model. We seek comment on those areas where alternative options are proposed or should be considered that would not add additional operational burden or complexity.

2. Proposed Definition of Episode Initiator

Under the proposed EPMs, we propose, consistent with our definition under the CJR model that episodes would begin with the admission to an IPPS acute-care hospital that triggers an AMI, CABG or SHFFT episode as specified in section III.C.4.a. of this proposed rule. As with the CJR model, we propose that hospitals would be the only episode initiators in these episode payment models. For purposes of these episodes payment models the term "hospital" means a hospital as defined in section 1886(d)(1)(B) of the Act. This statutory definition of hospital includes only acute care hospitals paid under the IPPS. Under this proposal, all acute care hospitals in Maryland would be excluded and payments to Maryland hospitals would be excluded in the regional pricing calculations as described in section III.D.4. of this proposed rule. This is the same policy that is being followed with the CJR model. In addition, we also propose to exclude other all-payer state models which may be implemented in the future. We welcome

comments on this proposal and whether there are potential approaches for including Maryland acute-care hospitals or, potentially, other hospitals in future all-payer state models in these episode payment models.

As implemented with the CJR model, we propose to designate IPPS hospitals as the episode initiators to ensure that all services covered under FFS Medicare and furnished by EPM participant hospitals in selected geographic areas to beneficiaries who do not meet the exclusion criteria specified in section III.C.4. of this proposed rule are included. In addition, the episodes must not be BPCI episodes that we are proposing to exclude as outlined in this section and in section III.C.4. of this proposed rule. We believe that utilizing the hospital as the episode initiator is a straightforward approach for these models because patients covered under these DRGs and diagnoses require hospital admission for these services, whether provided on an emergent or planned basis. Under these new models covering medical admissions and services that are not necessarily elective, we will be able to expand our testing of a more generalized bundled payment model. Finally, as described in section III.B.4., our proposed geographic area selection approach relies upon our definition of hospitals as the entities that initiate episodes.

3. Financial Responsibility for the Episode of Care

As with the CJR model, we continue to believe it is most appropriate to identify a single type of provider to bear financial responsibility for making repayment, if any, to CMS under the model and propose to make hospitals, as the episode initiators, financially responsible for the episode of care for the following several reasons:

- Hospitals play a central role in coordinating episode-related care and ensuring smooth transitions for beneficiaries undergoing services related to SHFFT, AMI and CABG episodes. A

large portion of a beneficiary's recovery trajectory from an AMI, CABG, or SHFFT begins during the hospital stay.

- Most hospitals already have some infrastructure related to health information technology, patient and family education, and care management and discharge planning. This includes post-acute care coordination infrastructure and resources such as case managers, which hospitals can build upon to achieve efficiencies under these EPMs.

- By definition, these episodes always begin with an acute care hospital stay. While often preceded by an emergency room visit and possible transfer from another hospital's emergency room, or followed by post-acute care, these parties are not necessarily always present and would not be appropriate to target as the financially responsible party for this purpose.

EPM episodes may be associated with multiple hospitalizations through transfers. When multiple hospitalizations occur, we propose that the financial responsibility be given to the hospital to which the episode is attributed as described in section III.C.4. We recognize that, particularly where the admission may be preceded by an emergency room visit and subsequent transfer to a tertiary or other regional hospital facility, patients often wish to return home to their local area for post-acute care. Many hospitals have recently heightened their focus on aligning their efforts with those of community providers, both those in the immediate area as well as more outlying areas from which they receive transfers and referrals, to provide an improved continuum of care. In many cases, this is due to the incentives under other CMS models and programs, including ACO initiatives such as the Shared Savings Program, the Hospital Readmissions Reduction Program (HRRP), and the CJR model. By focusing on the hospital as the accountable or financially responsible entity, we hope to continue to encourage

this coordination across providers and seek comment on ways we can best encourage these relationships within the scope of these EPMs.

In support of our proposal that hospitals be the episode initiators under these EPMs, we believe that hospitals are more likely than other providers to have an adequate number of episode cases to justify an investment in episode management for these EPMs. We also believe that hospitals are most likely to have access to resources that would allow them to appropriately manage and coordinate care throughout these episodes. Finally, the hospital staff is already involved in discharge planning and placement recommendations for Medicare beneficiaries, and more efficient post-acute care service delivery provides substantial opportunities for improving quality and reducing costs under EPMs. For those hospitals that are already participating in CJR, we believe the efforts that have been put in place to support patients receiving LEJR will be supportive of the new EPMs proposed under this rule, particularly for SHFFT episodes which we propose to implement in the same geographic areas as the CJR model.

Finally, as noted when planning for the CJR model, although the BPCI initiative includes the possibility of a physician group practice as a type of episode initiating participant, the physician groups electing to participate in BPCI have done so because their practice structure supports care redesign and other infrastructure necessary to bear financial responsibility for episodes. These physician groups are not necessarily representative of the typical group practice. As with the CJR model, the infrastructure necessary to accept financial responsibility for episodes is not present across all physician group practices, and thus we do not believe it would be appropriate to designate physician group practices to bear the financial responsibility for making repayments to CMS under the proposed EPMs. We seek comment

on our proposal to establish financial responsibility and accountability under the AMI, CABG, and SHFFT EPMs consistent with our implementation of the CJR model.

Currently, there are SHFFT, AMI, and CABG episodes being tested in BPCI Models 2, 3 or 4. The last remaining BPCI Model 1 hospital will end December 31, 2016 and will, therefore, not overlap with EPM. In addition, under BPCI, there are episodes for PCI, which, if an AMI were also involved, would fall under the AMI model being proposed here. We are proposing that IPPS hospitals located in an area selected for any one of the episode payment models proposed in this rule that also are episode initiators for episodes in the risk-bearing phase of BPCI Models 2 or 4, be excluded from participating in the AMI, CABG, or SHFFT EPMs if the applicable episode otherwise would qualify to be covered under BPCI. This exclusion would be in effect only during the time that the relevant qualifying episodes are included in one of the BPCI models. Likewise, we are proposing that if the EPM participant is not an episode initiator for overlapping episodes under BPCI Models 2 or 4, but these same episodes are initiated during the anchor hospitalization by a physician group practice (PGP) under BPCI Model 2 (where the services are provided at the episode initiating hospital) then the episode also shall be covered under BPCI and be excluded from the EPMs being proposed under this rule. Otherwise qualifying EPM episodes (that is, those that are not part of an overlapping BPCI AMI, CABG, PCI or SHFFT episode) at the participant hospital would be included in these new EPMs. However, because BPCI participation is voluntary and participating providers may select which episodes to participate in, a BPCI participating provider will participate in any of the proposed AMI, CABG, or SHFFT EPMs for any episodes not otherwise preempted under their BPCI participation. For example, a BPCI Model 2 hospital in an AMI episode model geographic area participating in BPCI only for

CABGs will be an EPM participant in the AMI model. Similarly, an acute care hospital participating in BPCI for LEJR but not SHFFT episodes would be exempt from participation in the CJR model in a CJR model geographic area but would participate in the SHFFT model for SHFFT episodes. In addition, providers participating in BPCI may also collaborate with an EPM participant for episodes not covered under BPCI. It should be noted that due to differences in how the AMI episode is defined under the AMI model versus BPCI and the inclusion of PCI MS-DRGs under the latter, a patient with the same discharge MS-DRG and diagnoses may qualify for a PCI episode under BPCI and an AMI episode under the AMI model. Our intent is to give precedence to BPCI regardless of which episode a patient qualifies for if the patient would be covered under BPCI.

In section III.D.6. we discuss in more detail how we propose to handle situations when a beneficiary receives services that would qualify for inclusion in more than one CMS payment model during the same or overlapping periods of time. We welcome input on how these overlaps should be handled to best encourage ongoing care coordination while minimizing the impact on other models and limiting confusion and operational burden for providers.

While we propose that the EPM participant be financially responsible for the episode of care under these EPMs, we also believe that effective care redesign requires meaningful collaboration among acute care hospitals, post-acute care providers, physicians, and other providers and suppliers within communities to achieve the highest value care for Medicare beneficiaries. We believe it may be essential for key providers to be aligned and engaged, financially and otherwise, with the EPM participants, with the potential to share financial responsibility with those EPM participants. We note that all relationships between and among

providers and suppliers must comply with all relevant laws and regulations, including the fraud and abuse laws and all Medicare payment and coverage requirements unless otherwise specified further in this section and in sections III.I. and III.J. of this proposed rule. Depending on a hospital's current degree of clinical integration, new and different contractual relationships among hospitals and other health care providers may be important, although not necessarily required, for EPM success in a community. We acknowledge that financial incentives for other providers may be important aspects of the model in order for EPM participants to partner with these providers and incentivize certain strategies to improve episode efficiency.

While we acknowledge the important role of conveners in the BPCI model, and AMI, CABG, and SHFFT model participants may wish to enter into relationships with EPM collaborators and other entities in order to manage the episode of care or distribute risk, we propose that the ultimate financial responsibility of the episode remains with the EPM participant. Exceptions to this general rule for beneficiaries covered under certain risk bearing ACO arrangements are outlined in section III.D.6. As with the CJR model, we do not intend to restrict the ability of EPM participants to enter into administrative or risk sharing arrangements related to these EPMs, except to the extent that such arrangements are already restricted or prohibited by existing law. We refer readers to section III.I. of this proposed rule for further discussion of model design elements that may outline financial arrangements between EPM participants and other providers and suppliers.

4. Proposed Geographic Unit of Selection and Exclusion of Selected Hospitals

In order to determine the geographic unit of selection for these episode payment models, we conducted an analysis similar to that used for the CJR model. For the CJR model, we considered using a stratified random sampling methodology to select: (1) certain counties based on their

Core-Based Statistical Area (CBSA) status; (2) certain zip codes based on their Hospital Referral Regions (HRR) status or (3) certain states. We concluded that selection based on MSAs provided the best balance between choosing smaller geographic units while still capturing the impact of market patterns reflecting the mobility of patients and providers and limiting the potential risk for patient shifting and steerage between MSAs. HRRs are based on where patients receive selected tertiary care services which do not include orthopedic services. Therefore, HRRs may not be representative of where patients receive specialty orthopedic care or more routine orthopedic services such as hip and knee arthroplasty. Selection of states rather than MSAs would have greatly reduced the number of independent geographic areas subject to selection and, therefore, the statistical power of the evaluation. For similar reasons and to maintain consistency with the CJR model, we are, similarly, recommending implementation at the MSA level.

We also similarly considered whether these new models should be limited to hospitals where a high volume of these episodes occur, which would result in a more narrow test on the effects of an episode-based payment, or whether to include all hospitals in particular geographic areas, which would result in testing the effects of an episode-based payment approach more broadly across an accountable care community seeking to coordinate care longitudinally across settings. However, as with the CJR model, there would be more potential for behavioral changes that could include patient shifting and steering between hospitals in a given geographic area that could impact the test. Additionally, this approach would provide less information on testing payments for these episodes across a wide variety of hospitals with different characteristics. Selecting geographic areas and including all IPPS hospitals in those areas not otherwise excluded due to BPCI overlap as previously described and in section

III.D.6. of this proposed rule as model participants would help to minimize the risk of participant hospitals shifting higher cost cases out of the EPM.

In determining where to implement these EPMs, we also considered whether implementation of the CJR model in the same geographic area should be a factor. We realize that there is likely to be considerable overlap in the selection criteria between MSAs where the SHFFT EPM might be appropriate and those MSAs where the CJR model is now being implemented. While limiting burden on hospitals is an important consideration, we also believe that the infrastructure being put in place as a result of the CJR model presents significant advantages for implementation of the SHFFT model. For similar reasons, and in order to minimize patient steerage and/or transfer for reasons due solely to the implementation of these new payment models, we believe that it is appropriate to implement the AMI model and CABG model together in the same geographic areas, albeit not necessarily in the same areas as the CJR model.

Therefore, given the authority in section 1115A(a)(5) of the Act, which allows the Secretary to elect to limit testing of a model to certain geographic areas, we propose that the SHFFT model be implemented in those MSAs where the CJR model is being implemented. We also are proposing that the AMI and CABG models be implemented in MSAs selected independently based on the criteria discussed in this proposed rule. This will result in four separate categories of MSAs: (1) MSAs where only the CJR and SHFFT model episodes are being implemented; (2) MSAs where only the CABG model and AMI model episodes are being implemented; (3) MSAs where the CJR as well as the AMI, CABG, and SHFFT models are being implemented; and (4) MSAs where neither CJR nor any of the new episode payment models are being implemented. We believe this will provide an opportunity to test the impact

of implementing EPMs across not only a greater diversity of episodes but also as an increasing percentage of hospital discharges. We seek comment on our proposal to implement the SHFFT model in the same geographic region as the CJR model and to implement both the AMI model and the CABG model in the same MSAs, some of which may overlap with MSAs where the CJR and SHFFT models also are being implemented.

5. Overview and Options for Geographic Area Selection for AMI and CABG Episodes

We propose that the AMI and CABG EPMs be implemented together in the same MSAs. These AMI/CABG-participating MSAs may or may not also be LEJR/SHFFT-participating MSAs. The selection of MSAs for AMI/CABG EPMs would occur through a random selection of eligible MSAs.

We propose to require participation in the AMI and CABG models of all hospitals, with limited exceptions as previously discussed in section III.B.4. of this proposed rule, paid under the IPPS that are physically located in a county in an MSA selected through the methodology outlined in section III.B.5.b. in this proposed rule, to test and evaluate the effects of an episode-based payment approach for the proposed EPMs. We propose to determine that a hospital is located in an area selected if the hospital is physically located within the boundary of any of the counties in that MSA as of the date the selection is made.

Although MSAs are revised periodically, with counties added or removed from certain MSAs, we propose to maintain the same cohort of selected hospitals throughout the 5-year performance periods of the EPMs with limited exceptions as described later in this section. Thus, we propose neither to add hospitals to an EPM if after the start of such EPM new counties are added to one of the selected MSAs nor to remove hospitals from an EPM if counties are removed from one of the selected MSAs. We believe that this approach will best maintain the consistency of the participants in the EPMs, which is crucial for our ability to evaluate their respective results. However, we retain the possibility of adding a hospital that is opened or incorporated within one of the selected counties after the selection is made and during the period of performance. (See section III.D. of this proposed rule for discussion of how target prices will be determined for such hospitals.)

The manner in which CMS tracks and identifies hospitals is through the CMS Certification Number (CCN). In keeping with this approach, these EPMs will administer model related activities at the CCN level including the determination of physical location. The physical location associated with the CCN at the time of an EPM's start will be used to determine whether that CCN is located in a selected MSA. For hospitals that share a CCN across various locations, all hospitals under that CCN would be required to participate in the applicable EPM if the physical address associated with the CCN is in the MSA selected, unless otherwise excluded. Similarly, all hospitals under the same CCN, even if some are physically located in the MSA selected for participation, would not participate in the applicable EPM if the physical address associated with the CCN is not in the MSA.

We considered including hospitals in a given MSA based on whether the hospitals were classified into the MSA for IPPS wage index purposes. However, such a process would be more complicated, and we could not find any compelling reasons favoring such approach. For example, we could assign hospitals to metro divisions of MSAs when those divisions exist. In addition, there is the IPPS process of geographic reclassification by which a hospital's payments can be based on a geographic area other than the one where the hospital is physically located. For the purpose of the EPMs, it is simpler and more straightforward to use a hospital's physical location as the basis of its assignment to a geographic unit. This decision would have no impact on a hospital's payment under the IPPS. We seek comment on our proposal to include a hospital as an EPM participant based on the physical location associated with the CCN of the hospital in one of the counties included in a selected MSA.

a. Exclusion of Certain MSAs

We considered whether certain MSAs should be exempt from the possibility of selection

for the AMI/CABG EPMs' implementation. We considered exclusions based on the anticipated number of AMI episodes and CABG episodes in the MSA. We also considered exclusions based on the degree to which such EPMs' episodes would be impacted by overlaps with other payment initiatives, including BPCI and ACOs.

First, we considered the advisability of MSA exclusions based on the number of episodes in a year. We identified qualifying AMI and CABG episodes that initiated between January 1, 2014, and December 31, 2014. AMI and CABG episodes were attributed to an MSA based on the location of the CCN associated with the initiating hospital using the Provider of Service file. Due to the smaller number of relevant AMI and CABG episodes occurring in MSAs, an exclusion rule that required a large number of episodes in each MSA would result in fewer MSAs eligible for selection than was necessary given the desired number of MSAs and the requirement that to have 50 percent or more of MSAs remain in a pool of possible comparison MSAs. From the perspective of evaluating changes to utilization and spending under EPMs, there is no analytic need to eliminate MSAs with small numbers. In fact, including smaller MSAs has the analytic advantage of giving CMS more experience operating EPMs in the smaller-MSA contexts that will help us generalize our EPM-evaluation findings.

We have a strong interest in being able to observe how well EPMs operate in areas with a lower volume of episodes, and, in particular, the consequences of the model for AMI episodes where CABG is not commonly performed or where standard practice is to refer all CABGs outside of the MSA. Given our desire to assess the operation of the AMI EPM in areas with little or no CABG episodes and the desire to have the two cardiac EPMs be administered together in the same MSAs, we propose that the MSA exclusion rules be based on the number of AMI episodes only. This will allow for the inclusion of MSAs with no CABGs.

There is no analytic requirement for a minimum number of cases and there are advantages to including smaller cities. At the same time, we acknowledge that areas with few AMI cases may believe that they will face challenges under the EPMs. Therefore, we propose an exclusion rule that MSAs with fewer than 75 AMI episodes (determined as discussed in section III.C. of this proposed rule) will be removed from the possibility of selection. Cases in hospitals paid under either the CAH methodology or the Maryland All-Payer Model are not included in the count of eligible episodes. We examined a number of different minimum-episode-number cutoffs. The use of the 75 AMIs in a year was a designed to balance limiting the impact of outlier cases on the MSA average episode spending and the desire to retain a non-negligible representation of MSAs in the under 100,000 population and the 100,000 to 200,000 population ranges in our selection pool. The application of Exclusion Rule 1: "less than 75 qualifying AMI episodes in the reference year" resulted in the removal of 49 MSAs from possible selection.

Second, we assessed exclusion rules based on overlap with BPCI. We propose Exclusion Rule 2 such that MSAs are removed from possible selection if there were fewer than 75 non-BPCI AMI episodes in the MSA in the reference year. For the purposes of this exclusion, the number of non-BPCI episodes was estimated by subtracting BPCI cases from the total number of cases used in Exclusion Rule 1. BPCI cases for this purpose are ones during the reference year associated with a hospital or a PGP BPCI Model 2 or 4 episode initiator participating in an AMI, PCI, or CABG episode as of January 1, 2016. Such criterion removed an additional 26 MSAs from potential selection.

Third, we propose to exclude MSAs from possible selection based on whether the number of non-BPCI AMI episodes calculated under Exclusion Rule 2 is less than 50 percent of the total number of AMI episodes calculated under Exclusion Rule 1. We anticipate that some

degree of overlap in the BPCI and other EPMs will be mutually helpful. However, we acknowledge that some providers may have concerns that a BPCI Model 2 AMI and PCI participation rate of more than 50 percent may impair the ability of participants in either the EPMs or the BPCI models to succeed in the objectives of the initiative. As a result of this third criterion, 13 additional MSAs were removed from possible selection.

We considered whether there should be an exclusion rule based on the anticipated degree of overlap between the AMI and CABG EPMs and patients who are aligned prospectively to ACOs that are taking two-sided risk, such as ACOs participating in the Next Generation ACO model or Track 3 of the Shared Savings Program. We examined numbers associated with ACOs meeting this status as of May 1, 2016, and this examination did not result in any additional MSAs falling below the 75 AMI episodes threshold. Consequently, we are not proposing any MSA exclusion rule based on the presence of ACOs.

Please refer to Table 1 for the status of each MSA based on these exclusion criteria, available at http://innovation.cms.gov/initiatives/epm. After applying these three exclusions, 294 MSAs out of 384 total MSAs are eligible for selection using our proposed selection methodology.

TABLE 1: MSA EXCLUSION RULE STATUS AND ELIGIBILITY FOR SELECTION STATUS FOR INCLUSION IN AMI AND CABG EPMS

CBSA_ OMB	MSA Name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA Eligible for Selection
10180	Abilene, TX	Pass	Pass	Pass	Include
10380	Aguadilla-Isabela, PR	Fail	Fail	Pass	Exclude
10420	Akron, OH	Pass	Pass	Pass	Include
10500	Albany, GA	Pass	Pass	Pass	Include
10540	Albany, OR	Fail	Fail	Pass	Exclude
10580	Albany-Schenectady-Troy, NY	Pass	Pass	Fail	Exclude
10740	Albuquerque, NM	Pass	Pass	Pass	Include
10780	Alexandria, LA	Pass	Pass	Pass	Include
10900	Allentown-Bethlehem-Easton, PA-NJ	Pass	Pass	Pass	Include
11020	Altoona, PA	Pass	Pass	Pass	Include
11100	Amarillo, TX	Pass	Pass	Pass	Include
11180	Ames, IA	Pass	Pass	Pass	Include
11260	Anchorage, AK	Pass	Pass	Pass	Include
11460	Ann Arbor, MI	Pass	Pass	Pass	Include
11500	Anniston-Oxford-Jacksonville, AL	Pass	Pass	Pass	Include
11540	Appleton, WI	Pass	Pass	Pass	Include
11640	Arecibo, PR	Fail	Fail	Pass	Exclude
11700	Asheville, NC	Pass	Pass	Pass	Include
12020	Athens-Clarke County, GA	Pass	Pass	Pass	Include
12060	Atlanta-Sandy Springs-Roswell, GA	Pass	Pass	Pass	Include
12100	Atlantic City-Hammonton, NJ	Pass	Pass	Pass	Include
12220	Auburn-Opelika, AL	Pass	Pass	Pass	Include
12260	Augusta-Richmond County, GA-SC	Pass	Pass	Pass	Include
12420	Austin-Round Rock, TX	Pass	Pass	Pass	Include
12540	Bakersfield, CA	Pass	Pass	Fail	Exclude
12620	Bangor, ME	Pass	Pass	Pass	Include
12700	Barnstable Town, MA	Pass	Pass	Pass	Include
12940	Baton Rouge, LA	Pass	Pass	Pass	Include
12980	Battle Creek, MI	Fail	Fail	Pass	Exclude
13020	Bay City, MI	Pass	Pass	Pass	Include
13140	Beaumont-Port Arthur, TX	Pass	Pass	Pass	Include
13220	Beckley, WV	Pass	Pass	Pass	Include
13380	Bellingham, WA	Pass	Pass	Pass	Include
13460	Bend-Redmond, OR	Pass	Pass	Pass	Include
13740	Billings, MT	Pass	Pass	Pass	Include

CBSA_ OMB	MSA Name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA Eligible for Selection
13780	Binghamton, NY	Pass	Fail	Fail	Exclude
13820	Birmingham-Hoover, AL	Pass	Pass	Pass	Include
13900	Bismarck, ND	Pass	Pass	Pass	Include
13980	Blacksburg-Christiansburg-Radford, VA	Fail	Fail	Pass	Exclude
14010	Bloomington, IL	Pass	Pass	Pass	Include
14020	Bloomington, IN	Pass	Pass	Pass	Include
14100	Bloomsburg-Berwick, PA	Pass	Pass	Pass	Include
14260	Boise City, ID	Pass	Pass	Pass	Include
14460	Boston-Cambridge-Newton, MA-NH	Pass	Pass	Pass	Include
14500	Boulder, CO	Pass	Fail	Pass	Exclude
14540	Bowling Green, KY	Pass	Fail	Fail	Exclude
14740	Bremerton-Silverdale, WA	Pass	Fail	Fail	Exclude
14860	Bridgeport-Stamford-Norwalk, CT	Pass	Pass	Pass	Include
15180	Brownsville-Harlingen, TX	Pass	Pass	Pass	Include
15260	Brunswick, GA	Pass	Pass	Pass	Include
15380	Buffalo-Cheektowaga-Niagara Falls, NY	Pass	Pass	Fail	Exclude
15500	Burlington, NC	Fail	Fail	Pass	Exclude
15540	Burlington-South Burlington, VT	Pass	Pass	Pass	Include
15940	Canton-Massillon, OH	Pass	Pass	Pass	Include
15980	Cape Coral-Fort Myers, FL	Pass	Pass	Pass	Include
16020	Cape Girardeau, MO-IL	Pass	Pass	Pass	Include
16060	Carbondale-Marion, IL	Pass	Pass	Pass	Include
16180	Carson City, NV	Pass	Pass	Pass	Include
16220	Casper, WY	Pass	Fail	Pass	Exclude
16300	Cedar Rapids, IA	Pass	Pass	Pass	Include
16540	Chambersburg-Waynesboro, PA	Pass	Pass	Pass	Include
16580	Champaign-Urbana, IL	Pass	Pass	Pass	Include
16620	Charleston, WV	Pass	Pass	Pass	Include
16700	Charleston-North Charleston, SC	Pass	Pass	Pass	Include
16740	Charlotte-Concord-Gastonia, NC-SC	Pass	Pass	Pass	Include
16820	Charlottesville, VA	Pass	Pass	Pass	Include
16860	Chattanooga, TN-GA	Pass	Pass	Pass	Include
16940	Cheyenne, WY	Pass	Pass	Pass	Include
16980	Chicago-Naperville-Elgin, IL-IN-WI	Pass	Pass	Pass	Include
17020	Chico, CA	Pass	Pass	Pass	Include
17140	Cincinnati, OH-KY-IN	Pass	Pass	Pass	Include
17300	Clarksville, TN-KY	Pass	Pass	Pass	Include
17420	Cleveland, TN	Fail	Fail	Pass	Exclude

CBSA_ OMB	MSA Name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA Eligible for Selection
17460	Cleveland-Elyria, OH	Pass	Pass	Pass	Include
17660	Coeur d'Alene, ID	Pass	Pass	Pass	Include
17780	College Station-Bryan, TX	Pass	Pass	Pass	Include
17820	Colorado Springs, CO	Pass	Pass	Pass	Include
17860	Columbia, MO	Pass	Pass	Pass	Include
17900	Columbia, SC	Pass	Pass	Pass	Include
17980	Columbus, GA-AL	Pass	Pass	Pass	Include
18020	Columbus, IN	Pass	Pass	Pass	Include
18140	Columbus, OH	Pass	Pass	Fail	Exclude
18580	Corpus Christi, TX	Pass	Pass	Pass	Include
18700	Corvallis, OR	Pass	Pass	Pass	Include
18880	Crestview-Fort Walton Beach-Destin, FL	Pass	Pass	Pass	Include
19100	Dallas-Fort Worth-Arlington, TX	Pass	Pass	Pass	Include
19140	Dalton, GA	Pass	Fail	Fail	Exclude
19180	Danville, IL	Fail	Fail	Pass	Exclude
19300	Daphne-Fairhope-Foley, AL	Pass	Pass	Pass	Include
19340	Davenport-Moline-Rock Island, IA-IL	Pass	Pass	Pass	Include
19380	Dayton, OH	Pass	Pass	Pass	Include
19460	Decatur, AL	Fail	Fail	Pass	Exclude
19500	Decatur, IL	Pass	Pass	Pass	Include
19660	Deltona-Daytona Beach-Ormond Beach, FL	Pass	Pass	Pass	Include
19740	Denver-Aurora-Lakewood, CO	Pass	Pass	Pass	Include
19780	Des Moines-West Des Moines, IA	Pass	Pass	Pass	Include
19820	Detroit-Warren-Dearborn, MI	Pass	Pass	Pass	Include
20020	Dothan, AL	Pass	Pass	Pass	Include
20100	Dover, DE	Pass	Pass	Pass	Include
20220	Dubuque, IA	Pass	Fail	Fail	Exclude
20260	Duluth, MN-WI	Pass	Pass	Pass	Include
20500	Durham-Chapel Hill, NC	Pass	Pass	Pass	Include
20700	East Stroudsburg, PA	Pass	Fail	Pass	Exclude
20740	Eau Claire, WI	Pass	Pass	Pass	Include
20940	El Centro, CA	Fail	Fail	Fail	Exclude
21060	Elizabethtown-Fort Knox, KY	Pass	Pass	Pass	Include
21140	Elkhart-Goshen, IN	Pass	Pass	Pass	Include
21300	Elmira, NY	Pass	Pass	Pass	Include
21340	El Paso, TX	Pass	Pass	Pass	Include
21500	Erie, PA	Pass	Pass	Pass	Include
21660	Eugene, OR	Pass	Pass	Pass	Include

CBSA_ OMB	MSA Name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA Eligible for Selection
21780	Evansville, IN-KY	Pass	Pass	Pass	Include
21820	Fairbanks, AK	Fail	Fail	Pass	Exclude
22020	Fargo, ND-MN	Pass	Pass	Pass	Include
22140	Farmington, NM	Pass	Pass	Pass	Include
22180	Fayetteville, NC	Pass	Pass	Pass	Include
22220	Fayetteville-Springdale-Rogers, AR-MO	Pass	Pass	Pass	Include
22380	Flagstaff, AZ	Fail	Fail	Pass	Exclude
22420	Flint, MI	Pass	Pass	Pass	Include
22500	Florence, SC	Pass	Pass	Pass	Include
22520	Florence-Muscle Shoals, AL	Pass	Pass	Pass	Include
22540	Fond du Lac, WI	Fail	Fail	Pass	Exclude
22660	Fort Collins, CO	Pass	Pass	Pass	Include
22900	Fort Smith, AR-OK	Pass	Pass	Fail	Exclude
23060	Fort Wayne, IN	Pass	Pass	Pass	Include
23420	Fresno, CA	Pass	Pass	Pass	Include
23460	Gadsden, AL	Pass	Pass	Pass	Include
23540	Gainesville, FL	Pass	Pass	Pass	Include
23580	Gainesville, GA	Pass	Pass	Pass	Include
23900	Gettysburg, PA	Fail	Fail	Pass	Exclude
24020	Glens Falls, NY	Fail	Fail	Pass	Exclude
24140	Goldsboro, NC	Fail	Fail	Pass	Exclude
24220	Grand Forks, ND-MN	Pass	Pass	Pass	Include
24260	Grand Island, NE	Fail	Fail	Pass	Exclude
24300	Grand Junction, CO	Pass	Pass	Pass	Include
24340	Grand Rapids-Wyoming, MI	Pass	Pass	Pass	Include
24420	Grants Pass, OR	Fail	Fail	Pass	Exclude
24500	Great Falls, MT	Fail	Fail	Pass	Exclude
24540	Greeley, CO	Pass	Pass	Pass	Include
24580	Green Bay, WI	Pass	Pass	Pass	Include
24660	Greensboro-High Point, NC	Pass	Pass	Pass	Include
24780	Greenville, NC	Pass	Pass	Pass	Include
24860	Greenville-Anderson-Mauldin, SC	Pass	Pass	Pass	Include
25020	Guayama, PR	Fail	Fail	Pass	Exclude
25060	Gulfport-Biloxi-Pascagoula, MS	Pass	Pass	Pass	Include
25180	Hagerstown-Martinsburg, MD-WV	Pass	Fail	Fail	Exclude
25220	Hammond, LA	Fail	Fail	Pass	Exclude
25260	Hanford-Corcoran, CA	Fail	Fail	Pass	Exclude
25420	Harrisburg-Carlisle, PA	Pass	Pass	Pass	Include

CBSA_ OMB	MSA Name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA Eligible for Selection
25500	Harrisonburg, VA	Pass	Fail	Fail	Exclude
25540	Hartford-West Hartford-East Hartford, CT	Pass	Pass	Pass	Include
25620	Hattiesburg, MS	Pass	Pass	Pass	Include
25860	Hickory-Lenoir-Morganton, NC	Pass	Pass	Pass	Include
25940	Hilton Head Island-Bluffton-Beaufort, SC	Pass	Pass	Pass	Include
26140	Homosassa Springs, FL	Pass	Pass	Pass	Include
26300	Hot Springs, AR	Pass	Pass	Pass	Include
26380	Houma-Thibodaux, LA	Pass	Pass	Pass	Include
26420	Houston-The Woodlands-Sugar Land, TX	Pass	Pass	Pass	Include
26580	Huntington-Ashland, WV-KY-OH	Pass	Pass	Pass	Include
26620	Huntsville, AL	Pass	Pass	Pass	Include
26820	Idaho Falls, ID	Pass	Pass	Pass	Include
26900	Indianapolis-Carmel-Anderson, IN	Pass	Pass	Pass	Include
26980	Iowa City, IA	Pass	Pass	Pass	Include
27060	Ithaca, NY	Fail	Fail	Pass	Exclude
27100	Jackson, MI	Pass	Pass	Pass	Include
27140	Jackson, MS	Pass	Pass	Pass	Include
27180	Jackson, TN	Pass	Fail	Fail	Exclude
27260	Jacksonville, FL	Pass	Pass	Pass	Include
27340	Jacksonville, NC	Fail	Fail	Pass	Exclude
27500	Janesville-Beloit, WI	Pass	Pass	Pass	Include
27620	Jefferson City, MO	Pass	Pass	Pass	Include
27740	Johnson City, TN	Pass	Fail	Fail	Exclude
27780	Johnstown, PA	Pass	Pass	Pass	Include
27860	Jonesboro, AR	Pass	Pass	Pass	Include
27900	Joplin, MO	Pass	Pass	Pass	Include
27980	Kahului-Wailuku-Lahaina, HI	Fail	Fail	Pass	Exclude
28020	Kalamazoo-Portage, MI	Pass	Pass	Pass	Include
28100	Kankakee, IL	Pass	Pass	Pass	Include
28140	Kansas City, MO-KS	Pass	Pass	Pass	Include
28420	Kennewick-Richland, WA	Pass	Pass	Pass	Include
28660	Killeen-Temple, TX	Pass	Pass	Pass	Include
28700	Kingsport-Bristol-Bristol, TN-VA	Pass	Pass	Pass	Include
28740	Kingston, NY	Fail	Fail	Pass	Exclude
28940	Knoxville, TN	Pass	Pass	Pass	Include
29020	Kokomo, IN	Fail	Fail	Pass	Exclude
29100	La Crosse-Onalaska, WI-MN	Pass	Pass	Pass	Include
29180	Lafayette, LA	Pass	Pass	Pass	Include

CBSA_ OMB	MSA Name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA Eligible for Selection
29200	Lafayette-West Lafayette, IN	Pass	Pass	Pass	Include
29340	Lake Charles, LA	Pass	Pass	Pass	Include
29420	Lake Havasu City-Kingman, AZ	Pass	Pass	Pass	Include
29460	Lakeland-Winter Haven, FL	Pass	Pass	Pass	Include
29540	Lancaster, PA	Pass	Fail	Fail	Exclude
29620	Lansing-East Lansing, MI	Pass	Pass	Pass	Include
29700	Laredo, TX	Pass	Fail	Pass	Exclude
29740	Las Cruces, NM	Pass	Pass	Pass	Include
29820	Las Vegas-Henderson-Paradise, NV	Pass	Pass	Pass	Include
29940	Lawrence, KS	Fail	Fail	Pass	Exclude
30020	Lawton, OK	Pass	Pass	Pass	Include
30140	Lebanon, PA	Pass	Fail	Pass	Exclude
30300	Lewiston, ID-WA	Fail	Fail	Pass	Exclude
30340	Lewiston-Auburn, ME	Pass	Pass	Pass	Include
30460	Lexington-Fayette, KY	Pass	Pass	Pass	Include
30620	Lima, OH	Pass	Pass	Pass	Include
30700	Lincoln, NE	Pass	Pass	Pass	Include
30780	Little Rock-North Little Rock-Conway, AR	Pass	Pass	Pass	Include
30860	Logan, UT-ID	Fail	Fail	Pass	Exclude
30980	Longview, TX	Pass	Pass	Pass	Include
31020	Longview, WA	Fail	Fail	Pass	Exclude
31080	Los Angeles-Long Beach-Anaheim, CA	Pass	Pass	Pass	Include
31140	Louisville/Jefferson County, KY-IN	Pass	Pass	Pass	Include
31180	Lubbock, TX	Pass	Pass	Pass	Include
31340	Lynchburg, VA	Pass	Pass	Pass	Include
31420	Macon, GA	Pass	Pass	Pass	Include
31460	Madera, CA	Fail	Fail	Pass	Exclude
31540	Madison, WI	Pass	Pass	Pass	Include
31700	Manchester-Nashua, NH	Pass	Pass	Pass	Include
31740	Manhattan, KS	Fail	Fail	Pass	Exclude
31860	Mankato-North Mankato, MN	Fail	Fail	Pass	Exclude
31900	Mansfield, OH	Pass	Pass	Pass	Include
32420	Mayagüez, PR	Fail	Fail	Pass	Exclude
32580	McAllen-Edinburg-Mission, TX	Pass	Pass	Fail	Exclude
32780	Medford, OR	Pass	Pass	Pass	Include
32820	Memphis, TN-MS-AR	Pass	Pass	Pass	Include
32900	Merced, CA	Fail	Fail	Pass	Exclude
33100	Miami-Fort Lauderdale-West Palm Beach, FL	Pass	Pass	Pass	Include

CBSA_ OMB	MSA Name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA Eligible for Selection
33140	Michigan City-La Porte, IN	Pass	Pass	Pass	Include
33220	Midland, MI	Pass	Pass	Pass	Include
33260	Midland, TX	Pass	Fail	Pass	Exclude
33340	Milwaukee-Waukesha-West Allis, WI	Pass	Pass	Pass	Include
33460	Minneapolis-St. Paul-Bloomington, MN-WI	Pass	Pass	Pass	Include
33540	Missoula, MT	Pass	Pass	Pass	Include
33660	Mobile, AL	Pass	Pass	Pass	Include
33700	Modesto, CA	Pass	Pass	Pass	Include
33740	Monroe, LA	Pass	Pass	Pass	Include
33780	Monroe, MI	Pass	Pass	Pass	Include
33860	Montgomery, AL	Pass	Pass	Pass	Include
34060	Morgantown, WV	Pass	Pass	Pass	Include
34100	Morristown, TN	Fail	Fail	Pass	Exclude
34580	Mount Vernon-Anacortes, WA	Pass	Fail	Pass	Exclude
34620	Muncie, IN	Pass	Pass	Pass	Include
34740	Muskegon, MI	Pass	Pass	Pass	Include
34820	Myrtle Beach-Conway-North Myrtle Beach, SC-NC	Pass	Pass	Pass	Include
34900	Napa, CA	Pass	Fail	Fail	Exclude
34940	Naples-Immokalee-Marco Island, FL	Pass	Pass	Pass	Include
34980	Nashville-Davidson--Murfreesboro--Franklin, TN	Pass	Pass	Pass	Include
35100	New Bern, NC	Pass	Pass	Pass	Include
35300	New Haven-Milford, CT	Pass	Pass	Pass	Include
35380	New Orleans-Metairie, LA	Pass	Pass	Pass	Include
35620	New York-Newark-Jersey City, NY-NJ-PA	Pass	Pass	Pass	Include
35660	Niles-Benton Harbor, MI	Pass	Pass	Pass	Include
35840	North Port-Sarasota-Bradenton, FL	Pass	Pass	Pass	Include
35980	Norwich-New London, CT	Pass	Pass	Pass	Include
36100	Ocala, FL	Pass	Pass	Fail	Exclude
36140	Ocean City, NJ	Fail	Fail	Pass	Exclude
36220	Odessa, TX	Pass	Pass	Pass	Include
36260	Ogden-Clearfield, UT	Pass	Pass	Pass	Include
36420	Oklahoma City, OK	Pass	Pass	Pass	Include
36500	Olympia-Tumwater, WA	Pass	Pass	Pass	Include
36540	Omaha-Council Bluffs, NE-IA	Pass	Pass	Pass	Include
36740	Orlando-Kissimmee-Sanford, FL	Pass	Pass	Fail	Exclude
36780	Oshkosh-Neenah, WI	Fail	Fail	Pass	Exclude
36980	Owensboro, KY	Pass	Pass	Pass	Include
37100	Oxnard-Thousand Oaks-Ventura, CA	Pass	Pass	Fail	Exclude

CBSA_ OMB	MSA Name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA Eligible for Selection
37340	Palm Bay-Melbourne-Titusville, FL	Pass	Pass	Pass	Include
37460	Panama City, FL	Pass	Pass	Pass	Include
37620	Parkersburg-Vienna, WV	Pass	Pass	Pass	Include
37860	Pensacola-Ferry Pass-Brent, FL	Pass	Pass	Pass	Include
37900	Peoria, IL	Pass	Pass	Pass	Include
37980	Philadelphia-Camden-Wilmington, PA-NJ-DE-MD	Pass	Pass	Pass	Include
38060	Phoenix-Mesa-Scottsdale, AZ	Pass	Pass	Pass	Include
38220	Pine Bluff, AR	Fail	Fail	Pass	Exclude
38300	Pittsburgh, PA	Pass	Pass	Pass	Include
38340	Pittsfield, MA	Pass	Fail	Pass	Exclude
38540	Pocatello, ID	Fail	Fail	Pass	Exclude
38660	Ponce, PR	Fail	Fail	Pass	Exclude
38860	Portland-South Portland, ME	Pass	Pass	Pass	Include
38900	Portland-Vancouver-Hillsboro, OR-WA	Pass	Pass	Pass	Include
38940	Port St. Lucie, FL	Pass	Pass	Pass	Include
39140	Prescott, AZ	Pass	Pass	Pass	Include
39300	Providence-Warwick, RI-MA	Pass	Pass	Pass	Include
39340	Provo-Orem, UT	Pass	Pass	Pass	Include
39380	Pueblo, CO	Pass	Pass	Pass	Include
39460	Punta Gorda, FL	Pass	Pass	Pass	Include
39540	Racine, WI	Fail	Fail	Pass	Exclude
39580	Raleigh, NC	Pass	Pass	Pass	Include
39660	Rapid City, SD	Pass	Pass	Pass	Include
39740	Reading, PA	Pass	Pass	Pass	Include
39820	Redding, CA	Pass	Pass	Pass	Include
39900	Reno, NV	Pass	Pass	Pass	Include
40060	Richmond, VA	Pass	Pass	Pass	Include
40140	Riverside-San Bernardino-Ontario, CA	Pass	Pass	Pass	Include
40220	Roanoke, VA	Pass	Pass	Pass	Include
40340	Rochester, MN	Pass	Pass	Pass	Include
40380	Rochester, NY	Pass	Pass	Pass	Include
40420	Rockford, IL	Pass	Pass	Pass	Include
40580	Rocky Mount, NC	Pass	Pass	Pass	Include
40660	Rome, GA	Pass	Pass	Pass	Include
40900	Sacramento--Roseville--Arden-Arcade, CA	Pass	Pass	Pass	Include
40980	Saginaw, MI	Pass	Pass	Pass	Include
41060	St. Cloud, MN	Pass	Pass	Pass	Include
41100	St. George, UT	Pass	Pass	Pass	Include

CBSA_ OMB	MSA Name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA Eligible for Selection
41140	St. Joseph, MO-KS	Pass	Pass	Pass	Include
41180	St. Louis, MO-IL	Pass	Pass	Pass	Include
41420	Salem, OR	Pass	Pass	Pass	Include
41500	Salinas, CA	Pass	Pass	Pass	Include
41540	Salisbury, MD-DE	Pass	Pass	Pass	Include
41620	Salt Lake City, UT	Pass	Pass	Pass	Include
41660	San Angelo, TX	Pass	Pass	Pass	Include
41700	San Antonio-New Braunfels, TX	Pass	Pass	Fail	Exclude
41740	San Diego-Carlsbad, CA	Pass	Pass	Pass	Include
41860	San Francisco-Oakland-Hayward, CA	Pass	Pass	Pass	Include
41900	San Germán, PR	Fail	Fail	Pass	Exclude
41940	San Jose-Sunnyvale-Santa Clara, CA	Pass	Pass	Pass	Include
41980	San Juan-Carolina-Caguas, PR	Fail	Fail	Pass	Exclude
42020	San Luis Obispo-Paso Robles-Arroyo Grande, CA	Pass	Pass	Pass	Include
42100	Santa Cruz-Watsonville, CA	Pass	Fail	Fail	Exclude
42140	Santa Fe, NM	Pass	Pass	Pass	Include
42200	Santa Maria-Santa Barbara, CA	Pass	Pass	Pass	Include
42220	Santa Rosa, CA	Pass	Pass	Pass	Include
42340	Savannah, GA	Pass	Pass	Pass	Include
42540	Scranton--Wilkes-Barre--Hazleton, PA	Pass	Pass	Pass	Include
42660	Seattle-Tacoma-Bellevue, WA	Pass	Pass	Pass	Include
42680	Sebastian-Vero Beach, FL	Pass	Pass	Pass	Include
42700	Sebring, FL	Pass	Pass	Pass	Include
43100	Sheboygan, WI	Fail	Fail	Pass	Exclude
43300	Sherman-Denison, TX	Pass	Pass	Pass	Include
43340	Shreveport-Bossier City, LA	Pass	Pass	Pass	Include
43420	Sierra Vista-Douglas, AZ	Pass	Fail	Fail	Exclude
43580	Sioux City, IA-NE-SD	Pass	Pass	Pass	Include
43620	Sioux Falls, SD	Pass	Pass	Pass	Include
43780	South Bend-Mishawaka, IN-MI	Pass	Fail	Fail	Exclude
43900	Spartanburg, SC	Pass	Pass	Pass	Include
44060	Spokane-Spokane Valley, WA	Pass	Pass	Pass	Include
44100	Springfield, IL	Pass	Pass	Pass	Include
44140	Springfield, MA	Pass	Pass	Fail	Exclude
44180	Springfield, MO	Pass	Pass	Pass	Include
44220	Springfield, OH	Fail	Fail	Pass	Exclude
44300	State College, PA	Fail	Fail	Pass	Exclude
44420	Staunton-Waynesboro, VA	Pass	Pass	Pass	Include

CBSA_ OMB	MSA Name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA Eligible for Selection
44700	Stockton-Lodi, CA	Pass	Pass	Pass	Include
44940	Sumter, SC	Fail	Fail	Fail	Exclude
45060	Syracuse, NY	Pass	Pass	Pass	Include
45220	Tallahassee, FL	Pass	Pass	Pass	Include
45300	Tampa-St. Petersburg-Clearwater, FL	Pass	Pass	Pass	Include
45460	Terre Haute, IN	Pass	Pass	Pass	Include
45500	Texarkana, TX-AR	Pass	Pass	Fail	Exclude
45540	The Villages, FL	Pass	Pass	Pass	Include
45780	Toledo, OH	Pass	Pass	Pass	Include
45820	Topeka, KS	Pass	Pass	Pass	Include
45940	Trenton, NJ	Pass	Pass	Pass	Include
46060	Tucson, AZ	Pass	Pass	Pass	Include
46140	Tulsa, OK	Pass	Pass	Pass	Include
46220	Tuscaloosa, AL	Pass	Pass	Pass	Include
46340	Tyler, TX	Pass	Pass	Pass	Include
46520	Urban Honolulu, HI	Pass	Pass	Pass	Include
46540	Utica-Rome, NY	Pass	Pass	Pass	Include
46660	Valdosta, GA	Pass	Fail	Pass	Exclude
46700	Vallejo-Fairfield, CA	Pass	Fail	Fail	Exclude
47020	Victoria, TX	Pass	Pass	Pass	Include
47220	Vineland-Bridgeton, NJ	Pass	Fail	Pass	Exclude
47260	Virginia Beach-Norfolk-Newport News, VA-NC	Pass	Pass	Fail	Exclude
47300	Visalia-Porterville, CA	Pass	Pass	Pass	Include
47380	Waco, TX	Pass	Pass	Pass	Include
47460	Walla Walla, WA	Fail	Fail	Pass	Exclude
47580	Warner Robins, GA	Pass	Pass	Pass	Include
47900	Washington-Arlington-Alexandria, DC-VA-MD-WV	Pass	Pass	Pass	Include
47940	Waterloo-Cedar Falls, IA	Pass	Pass	Pass	Include
48060	Watertown-Fort Drum, NY	Fail	Fail	Pass	Exclude
48140	Wausau, WI	Pass	Pass	Pass	Include
48260	Weirton-Steubenville, WV-OH	Pass	Pass	Pass	Include
48300	Wenatchee, WA	Pass	Pass	Pass	Include
48540	Wheeling, WV-OH	Pass	Pass	Pass	Include
48620	Wichita, KS	Pass	Pass	Pass	Include
48660	Wichita Falls, TX	Pass	Fail	Fail	Exclude
48700	Williamsport, PA	Pass	Pass	Pass	Include
48900	Wilmington, NC	Pass	Pass	Pass	Include
49020	Winchester, VA-WV	Pass	Pass	Pass	Include

CBSA_ OMB	MSA Name	Rule 1: 75+ AMIs	Rule 2: 75+ non-BPCI AMI	Rule 3: <50% BPCI AMI	MSA Eligible for Selection
49180	Winston-Salem, NC	Pass	Pass	Pass	Include
49340	Worcester, MA-CT	Pass	Pass	Pass	Include
49420	Yakima, WA	Pass	Pass	Pass	Include
49620	York-Hanover, PA	Pass	Pass	Pass	Include
49660	Youngstown-Warren-Boardman, OH-PA	Pass	Pass	Pass	Include
49700	Yuba City, CA	Pass	Pass	Pass	Include
49740	Yuma, AZ	Pass	Pass	Pass	Include

b. Proposed Selection Approach

We propose the selection of 98 MSAs through the use of simple random selection from the 294 eligible MSAs.

Simple random selection is often considered to be an appropriate default approach to experimental design unless there is a compelling reason to depart from it. One common alternative approach is to perform random selection separately within subgroups. Selection within subgroups can be a useful approach to limiting differences between intervention and control groups to improve statistical power or for facilitating over or under sampling to allow the evaluation to examine effects of the intervention on particular types of MSAs or because those types of MSAs are of particular interest for policy reasons.

In CJR, we used a stratified random assignment approach in which we organized MSAs into strata based on MSA population size and historic LEJR episode payments. Under the CJR model, we believed a stratified approach was appropriate due to wide regional variation in prices, primarily associated with the use of post-acute services. The stratified approach served as a means to oversample in higher-expense MSAs as these areas have both the most need for and the most opportunity under the CJR model.

In assessing whether stratification would be proposed for the EPMs, we assessed a

variety of factors described later in this section. Absent stratification, the rate at which a particular type of MSA will appear in the sample will be proportional to how often in appears among eligible MSAs. If a particular type of MSA is relatively common, it is likely to occur often enough that we do not need to deliberately over-sample for it. In the end, our analyses did not provide sufficient evidence that it is necessary to create selection subgroups of MSAs to guide the selection approach. As a result, we are proposing to use simple random selection from the entire pool of eligible MSAs.

(1) Factors Considered but Not Used

We considered a variety of possible MSA characteristics for possible use in classifying sub-groups. Though we did consider many of these variables important, we believe that a simple random selection, where warranted, is preferable.

Some of the factors we considered that we are not proposing to use in the selection methodology include the following:

- Measures associated with AMI-episode and CABG episode wage-adjusted spending, respectively. In considering how to operationalize such measures, we considered a number of alternatives including average total episode spending payments in an MSA, average episode spending associated with the initial hospital stay(s) and average episode spending occurring in the period after discharge from the initial hospital.

- Measures associated with variation in practice patterns associated with AMI and CABG episodes. In considering how to operationalize this measure, we considered a number of alternatives including the extent to which both an AMI and a CABG episode are associated with having a transfer hospital stay at the beginning of the episode, and the extent to which CABG

hospitalizations occur following a hospital transfer from either within or from outside the same MSA.

- Measures associated with relative market share of providers with respect to AMI and/or CABG episodes, including the presence or absence of regional referral centers and the number of providers with the capacity to perform CABGs or otherwise treat complex cardiac patients.

- Health care supply measures of providers in the MSA including acute or post-acute bed counts, and number of relevant physician specialties such as cardiologists and cardiothoracic surgeons.

- MSA-level demographic measures such as: (1) average income; (2) distributions of population by age, gender or race; (3) percent dually eligible; and (4) percent with specific health conditions or other demographic composition measures.

- Measures associated with the degree to which a market might be more capable or ready to implement care-redesign activities. Examples of market-level characteristics that might be associated with anticipated ease of implementation include the MSA-level EHR meaningful-use levels, managed-care penetration, ACO penetration, and experience with other bundling efforts.

Though these measures are not proposed to be part of the selection process, we acknowledge that these and other market-level factors may be important to the proper understanding of the evaluation of the impact of EPMs. We intend to consider these and other measures in determining which MSAs are appropriate comparison markets for the evaluation and for possible subgroup analysis or risk-adjustment purposes. The evaluations will include beneficiary-, provider-, and market-level characteristics in how they will examine the

performance of these proposed EPMs.

(2) Sample-Size Calculations and the Number of Selected MSAs

Our analyses of the necessary sample size led us to propose the selection of 98 MSAs, out of the 294 MSAs eligible for selection and 384 total MSAs, to participate in both the AMI and CABG EPMs. In this section, we discuss the assumptions and modeling that went into our proposal to test these EPMs in 98 MSAs. The discussion of the method of selection of these 98 MSAs is addressed in the following section. In coming to the decision to target 98 MSAs, we are proposing an approach that limits the size of the intervention to the greatest degree possible, while still ensuring that we have sufficient statistical power to reliably evaluate the effects of the EPMs. Going below this threshold would jeopardize our ability to be confident in our results and to be able to generalize from the EPMs to the larger national context.

In calculating the necessary size of the AMI and CABG EPMs, a key consideration was to have sufficient power to be able to detect the desired size impact. The larger the anticipated size of the impact, the fewer MSAs we would have to sample in order to observe it. However, a model sized to be able to only detect large impacts runs the risk of not being able to draw conclusions if the size of the change is less than anticipated. The measure of interest used in estimating sample size requirements for the both the AMI and the CABG EPMs was wage-adjusted total episode spending. The data used for the wage-adjusted total episode spending is the 3-year data pull previously described that covers AMI and CABG episodes with admission dates from July 1, 2012, through December 31, 2014. For the purposes of the sample-size calculation, we aim to be able to reliably identify between a 2-percent and 3-percent reduction in wage-adjusted episode spending after 1 year of experience. We chose this range because those numbers represent the anticipated amount of the discount proposed to apply under

various conditions of the AMI and CABG EPMs' implementation.

The next consideration in calculating the necessary sample size is the degree of certainty we will need for the statistical tests that will be performed. In selecting the right sample size, there are two types of errors that need to be considered: "false positives" and "false negatives." A false positive occurs if a statistical test concludes that a model was successful (that is, saved money) when it in fact was not. A false negative occurs if a statistical test fails to find statistically-significant evidence that the model was successful, when it in fact was successful. In considering the minimum sample size needs of the AMI and CABG EPMs, a standard guideline in the statistical literature suggests calibrating statistical tests to generate no more than a 5--percent chance of a false positive and selecting the sample size to ensure no more than a 20-percent chance of a false negative. In contrast, the proposed sample size for this project was based on a 10-percent chance of a false positive and no more than a 30-percent chance of a false negative in order to minimize reduce sample size requirements to the greatest degree possible.

A third consideration in the sample-size calculation was the appropriate unit of selection and whether it is necessary to base the calculation on the number of MSAs, the number of hospitals, or the number of episodes. We are proposing to base the sample size calculation at the MSA level. The proposed EPMs are an example of what is known as a "nested comparative study." Under a nested comparative study, assignment to an intervention or comparison arms of the study is based on membership in pre-existing, identifiable group where the groups are not formed at random, but rather through some physical, social, geographic, or other connection among their members. Because these groups are not formed at random, individual members of each group are likely to share important commonalities. In the context of the proposed EPMs spending and outcomes for patients cared for within a given MSA are relatively similar to one

another due to such factors as the existence of common practice or referral patterns, the underlying health in the population, and the availability of providers in an area.

In statistical terms, these commonalities create a positive correlation (called an intra-class correlation) among hospitals or beneficiaries in the same MSA. Due to that intra-class correlation, the variability of any aggregate statistic—such as the estimated difference in outcomes between the intervention and comparison arms of the study—has two components -- (1) variability attributable to variation among hospitals or beneficiaries in a given MSA; and (2) variability attributable to differences between MSAs. An accurate power analysis must account for both components of variability.

In determining the necessary sample size, we take into consideration the degree to which commonalities within MSAs exist and the number of independent beneficiaries and hospitals expected to be included in the EPM within each MSA. As part of this process, we empirically examined the number of beneficiaries, the number of hospitals, and the number of MSAs, as well as the level of correlation in episode payments between each level. Based on this empirical examination, we determined that the correlation was high enough that the degree of variability would be primarily driven by the number of MSAs in the model, indicating that the MSA is the appropriate unit of analysis for the power calculations.

Using the aforementioned assumptions, a power calculation for AMI was run which indicated that at 98 MSAs we would be able to reliably detect a 3-percent reduction in wage-adjusted episode spending after 1 year with a false-positive rate of 10 percent and a false-negative rate of between 20 percent and 40 percent. We are targeting a false-negative rate of 30 percent. The extent to which this rate can be lowered will depend on the ability of evaluation models to substantially reduce variation through risk adjustment and modeling. We

believe it is prudent to choose a sample size where the targeted amount is in the middle of this expected band.

We separately assessed the sample-size needs associated with CABG episodes. At 98 MSAs, we anticipate being able to detect a 2.25-percent reduction in wage-adjusted episode expenditures after 1 year with a false-positive rate of 10 percent and a false-negative rate of between 20-40 percent. The effective number of MSAs where the CABG EPM will be tested will be reduced because approximately 6 percent of eligible MSAs had no CABG episodes in the reference year. However, our power calculations do not lead us to believe we need to increase the sample size based on this fact. The number of CABG MSAs can experience this reduction and maintain equivalent levels of power to the AMI episodes.

(3) Method of Selecting MSAs

As previously discussed, we are seeking to choose 98 MSAs from our pool of eligible MSAs through simple random selection. We propose to make the selection in the final rule using SAS Enterprise Guide 7.1 software to run a computer algorithm SAS Enterprise Guide 7.1 and the computer algorithm used to conduct selection represents an industry-standard for generating advanced analytics and provides a rigorous, standardized tool by which to satisfy the requirements of randomized selection. The key SAS commands employed include a "PROC SURVEYSELECT" statement coupled with the "METHOD=SRS" option used to specify simple random sampling as the sample selection method. A random number seed will be generated using the birthdate of the person executing the program.[37]

We seek comment on our proposal to implement the AMI and CABG models in the

[37] For more information on this procedure and the underlying statistical methodology, please reference SAS support documentation at: http://support.sas.com/documentation/cdl/en/statug/63033/HTML/default/viewer.htm#statug_surveyselect_sect003.htm/.

selected MSAs, some of which may overlap with MSAs where the CJR and SHFFT models also are being implemented.

C. Episode Definition for the EPMs

1. Background

Episode payment models incentivize improvement in the coordination and quality of care experienced by a Medicare beneficiary, as well as episode efficiency, by bundling payment for services furnished to the beneficiary for specific clinical conditions over a defined period of time. A key model design feature is the definition of the episodes included in the model. The definition of episodes has two significant dimensions -- (1) a clinical dimension that describes which clinical conditions and associated services are included in the model; and (2) a time dimension that describes the beginning, middle, and end of the model.

2. Overview of Three Proposed Episode Payment Models

We propose three new EPMs—AMI, CABG, and SHFFT—that each begin with a hospitalization and extend 90 days after hospital discharge. The proposed AMI model generally includes beneficiaries discharged under an AMI MS-DRG (280-282), representing admission to an IPPS hospital for AMI that is treated with medical management, or an IPPS admission for a PCI MS-DRG (246-251) with an International Classification of Diseases (ICD)-Clinical Modification (CM) AMI diagnosis code describing an initial AMI diagnosis in the principal or a secondary diagnosis code position.

The proposed CABG model generally includes beneficiaries discharged under a CABG MS-DRG (231-236), representing an IPPS admission for this coronary revascularization procedure irrespective of AMI diagnosis. The proposed SHFFT model generally includes beneficiaries discharged under hip and femur procedures except major joint MS-DRG (480-482),

representing an IPPS admission for a hip fixation procedure in the setting of a hip fracture.

One reason these particular episodes were chosen for the proposed EPMs is that the initiation of treatment for each of the three clinical conditions included in an episode occurs almost exclusively during a hospitalization, which we believe would minimize the possibility of shifting beneficiaries in or out of the EPM based on the site-of-service where treatment is initiated. The majority of evaluation and treatment for AMI is performed in the inpatient hospital setting, commonly beginning when beneficiaries present with symptoms to the emergency department of a hospital. Patients experiencing an AMI are almost uniformly admitted to the hospital for further evaluation and management.[38] Although PCIs can be performed and may be paid by Medicare in the hospital outpatient setting in addition to being performed during a hospitalization, the majority of patients experiencing an AMI who are candidates for procedural revascularization receive PCI procedures during the initial hospitalization for AMI where evaluation also occurs.[39] CABG procedures are furnished exclusively in the inpatient hospital setting. We note that all of the Current Procedural Terminology (CPT) codes that physicians report for CABG are listed on the hospital Outpatient Prospective Payment System (OPPS) inpatient-only list in Addendum E of the 2016 OPPS final rule with comment period that is posted on the CMS Web site.[40] The hip fixation procedures performed in the SHFFT model also are predominantly furnished in the inpatient hospital setting, and we further note that almost all of the CPT codes that describe these procedures also are on

[38] Amsterdam et al. 2014 AHA/ACC Guideline for the Management of Patients with Non-ST-Elevation Acute Coronary Syndromes. Circulation. 2014; 130:e344-e426.

[39] Episodes for beneficiaries with AMI initiated by all U.S. IPPS hospitals not in Maryland and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule, that end in CY 2014.

[40] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1633-FC.html.

the OPPS inpatient-only list.

Hospitals' ability to identify EPM beneficiaries during the hospitalization that begins the episode (hereinafter the anchor hospitalization) also is an important consideration in developing episode payment models that, like the CJR model, rely upon MS-DRG assignment for IPPS claims following their submission in order to identify beneficiaries for model inclusion. This is especially important for medical management of conditions for which the predictability of the ultimate MS-DRG for the hospitalization is less certain than for surgical or procedural MS-DRGs. AMI represents a relative exception among medical conditions as it is associated with specific clinical and laboratory features that enable hospitals to identify beneficiaries with AMI during the anchor hospitalization whom would likely be included in an AMI model episode through their ultimate discharge under an AMI MS-DRG. We note that ICD-CM coding rules allow AMI diagnosis codes in both the primary and secondary position to map to AMI MS-DRGs.[41] In the case of procedural episodes such as CABG, SHFFT, and AMI model episodes for beneficiaries treated with PCI, the MS-DRG for the procedure performed would determine the ultimate MS-DRG assignment for the hospitalization unless additional surgeries higher in the MS-DRG hierarchy also are reported.[42] Therefore, we propose these three EPMs for clinical conditions where MS-DRG assignment is likely to be certain and known during the anchor hospitalization, even though treatment for AMI may involve only medical management. We believe hospitals participating in the proposed EPMs would be able to identify

[41] Medical Severity Diagnosis Related Groups (MS-DRGs): Definitions Manual. Version 33.0A. 3M Health Information Systems. (October 1, 2015). https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Final-Rule-Data-Files.html.

[42] Medical Severity Diagnosis Related Groups (MS-DRGs): Definitions Manual. Version 33.0A. 3M Health Information Systems. (October 1, 2015). https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Final-Rule-Data-Files.html

beneficiaries in EPM episodes through their AMI, CABG, and SHFFT episode MS-DRGs during the anchor hospitalization, allowing active coordination of EPM beneficiary care during and after hospitalization.

3. Clinical Dimensions of AMI, CABG, and SHFFT Model Episodes

As we stated in the CJR model Final Rule, we believe that a straightforward approach for hospitals and other providers to identify Medicare beneficiaries in these episode payment models would be important for the care redesign that is required for EPM success, as well as for operationalization of the proposed payment and other EPM policies (80 FR 73299). Therefore, as in the CJR model, we propose that an EPM episode would be initiated by an admission to an acute care hospital for an anchor hospitalization paid under EPM-specific MS-DRGs under the IPPS (80 FR 73300).

a. Definition of the Clinical Conditions Included in AMI, CABG, and SHFFT Model Episodes

(1) AMI (Medical Management and PCI) Model

We propose the AMI model to incentivize improvements in the coordination and quality of care, as well as episode efficiency, for beneficiaries treated for AMI with either medical management or coronary artery revascularization with PCI. We propose to define beneficiary inclusion in the AMI model by discharge under an AMI MS-DRG (280–282), representing those individuals admitted with AMI who receive medical therapy but no revascularization, and discharge under a PCI MS-DRG (246–251) with an ICD-10-CM diagnosis code of AMI on the IPPS claim for the anchor hospitalization in the principal or secondary diagnosis code position. We note that we would use AMI International Classification of Diseases, 9th revision clinical modification (ICD-9-CM) diagnosis codes to identify historical episodes for setting AMI model-episode benchmark prices in the early performance years of the AMI model. The

Uniform Hospital Discharge Data Set (UHDDS) defines the principal diagnosis for hospitalization as "that condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care" and other (secondary) diagnoses as "all conditions that coexist at the time of admission, that develop subsequently, or that affect the treatment received and/or the length of stay. Diagnoses that relate to an earlier episode which have no bearing on the current hospital stay are to be excluded."[43] We propose to include those beneficiaries discharged under PCI MS-DRGs with an AMI ICD-10-CM diagnosis code in the principal or secondary diagnosis code position to ensure that beneficiaries with an AMI that is not chiefly responsible for occasioning the hospitalization are included in the AMI model because the AMI itself is likely to substantially influence the hospitalization and post-discharge recovery (and be responsible for leading to the PCI) even if an AMI ICD-10-CM diagnosis code is reported in a secondary diagnosis code position. For example, a beneficiary receiving a PCI with an ICD-10-CM diagnosis code of pneumonia in the principal position and an AMI ICD-10-CM diagnosis code in a secondary position would be included in the AMI model, which would be appropriate because the course of the beneficiary's recovery and management during the AMI model episode would be primarily associated with the AMI and PCI. While pneumonia is typically an acute illness that may sometimes result in hospitalization, underlying chronic conditions may increase the likelihood that a beneficiary would be hospitalized for pneumonia, a condition that is more commonly treated on an outpatient basis. AMI in association with a hospitalization for pneumonia would represent a sentinel event for the beneficiary resulting from underlying CAD that signals a need for a heightened focus on medical management of CAD and other beneficiary risk factors for future cardiac events and that may themselves have increased

[43] http://www.cdc.gov/nchs/data/icd/icd10cm_guidelines_2014.pdf.

the beneficiary's risk for pneumonia. Thus, care coordination and management in the 90 days post-hospital discharge for these beneficiaries would be focused on managing CAD and the beneficiary's cardiac function after the AMI.

We acknowledge that this proposal to identify beneficiaries included in the AMI model through a combination of MS-DRGs and AMI ICD-CM diagnosis codes represents a modification of the CJR model episode definition methodology. The CJR model defined episodes based on MS-DRGs alone, specifically MS-DRG 469 (Major joint replacement or reattachment of lower extremity with Major Complications or Comorbidities (MCC)) and MS-DRG 470 (Major joint replacement or reattachment of lower extremity without MCC), because the anchor hospitalization for the CJR model was defined by admission for a surgical procedure alone (80 FR 73280). However, the proposed AMI model is defined by admission for a medical condition that includes a range of treatment options, including medical treatment and PCI. Therefore, to identify beneficiaries admitted for AMI and treated with PCI requires ICD-CM diagnosis codes paired with MS-DRGs to identify the subset of PCI MS-DRG cases associated with AMI that would otherwise be excluded from an AMI model based solely on AMI MS-DRGs.

For the purposes of defining historical AMI model episodes, we propose to exclude beneficiaries discharged under PCI MS-DRGs with an AMI ICD-9-CM diagnosis code in the principal or secondary position if there is an intracardiac ICD-9-CM procedure code in any procedure code field. Intracardiac procedure codes do not represent PCI procedures indicated for the treatment of the coronary artery obstruction that results in AMI, but instead represent a group of procedures indicated for treating congenital cardiac malformations, cardiac valve disease, and cardiac arrhythmias. These intracardiac procedures are performed within the heart chambers

rather than PCI procedures for AMI that are performed within the coronary blood vessels. To reflect this clinical distinction, the FY 2016 IPPS update removed intracardiac procedures from MS-DRGs 246-251 and assigned them to new MS-DRGs 273 and 274 (80 FR 49367). Therefore, to be consistent with our proposed definition of AMI model episodes that initiate with PCI MS-DRGs 246-251 (not with MS-DRGs 273 and 274) and an AMI ICD-9-CM diagnosis code in the principal or secondary position, we are proposing to define historical AMI model episodes for beneficiaries discharged under PCI MS-DRGS 246-251 as those that do not include the ICD-9-CM procedure codes in Table 2. These codes are also posted on the CMS Web site at https://innovation.cms.gov/inititatives/epm.

TABLE 2: PROPOSED ICD-9-CM PROCEDURE CODES IN ANY POSITION ON THE IPPS CLAIM FOR PCI MS-DRGS (246-251) THAT DO NOT DEFINE HISTORICAL AMI MODEL EPISODES

ICD-9-CM Procedure Code	ICD-9-CM Procedure Code Description
35.52	Repair of atrial septal defect with prosthesis, closed technique
35.96	Percutaneous balloon valvuloplasty
35.97	Percutaneous mitral valve repair with implant
37.26	Catheter based invasive electrophysiologic testing
37.27	Cardiac mapping
37.34	Excision or destruction of other lesion or tissue of heart, endovascular approach
37.36	Excision, destruction, or exclusion of left atrial appendage
37.90	Insertion of left atrial appendage device

In FY 2014, there were approximately 395,000 beneficiaries discharged from a short-term acute care hospitalization (excluding Maryland) with an AMI ICD-9-CM diagnosis code in the principal or secondary position on the IPPS claim. Of these beneficiaries, 58 percent were discharged under MS-DRGs that would initiate an AMI model episode, specifically an AMI MS-DRG (33 percent) and PCI MS-DRG (25 percent). Five percent of beneficiaries were discharged from CABG MS-DRGs and 3 percent were discharged from AMI MS-DRGs

representing death during the hospitalization. The remaining 34 percent of beneficiaries with an AMI ICD-CM diagnosis code in the principal or secondary position were distributed across over approximately 300 other MS-DRGs, with the septicemia MS-DRGs accounting for 8 percent and the remainder accounting for 3 percent or less of beneficiaries with an AMI ICD-CM diagnosis code on the IPPS claim.[44] We note that the AMI ICD-9-CM diagnosis code was most commonly in a secondary position for discharges from these other MS-DRGs, likely representing beneficiaries hospitalized for another condition who experienced an AMI during that hospitalization. We note that CMS's AMI quality measures used in the Hospital Inpatient Quality Reporting (HIQR) Program are based on all beneficiaries discharged under any MS-DRG who have an AMI ICD-CM diagnosis code only in the principal position, reflecting the measures' focus on the most homogeneous beneficiary population with AMI as the condition responsible for occasioning the hospital admission. This is in contrast with our proposed use of an AMI ICD-10-CM diagnosis code in the principal or a secondary position for the AMI model in order to identify those beneficiaries receiving a PCI whose hospitalization and post-discharge recovery and management would primarily be associated with the PCI and AMI.

The proposed specifications for AMI episodes, including ICD-9-CM AMI diagnosis codes for historical episodes used to set the initial AMI model-episode benchmark prices and ICD-10-CM AMI diagnosis codes for the proposed performance years of the model, are displayed in Table 3. The ICD-9-CM intracardiac procedure codes used to exclude inpatient claims with PCI MS-DRGS 246-251 from anchoring AMI model historical episodes used to set initial AMI model-episode benchmark prices are displayed in Table 3.

Based on Medicare claims data for historical AMI episodes ending in CYs 2012-2014,

[44] Inpatient claims from all U.S. IPPS hospitals not in Maryland were derived from the October 2013 – September 2014 Inpatient Claims File located in the Chronic Conditions Warehouse.

the annual number of potentially eligible beneficiary discharges for the AMI model nationally was approximately 168,000.[45] This number is less than the approximately 229,000 discharges for beneficiaries with AMI discharged from AMI MS-DRGs 280-282 and PCI MS-DRGs 246-251 that could be expected to be included in the AMI model for several reasons. Discharges do not result in historical episodes when a beneficiary does not meet the beneficiary care inclusion criteria discussed in section III.C.4.a.(1) of this proposed rule; is not discharged alive from PCI MS-DRGS 246-251; is discharged from a transfer hospital during a chained anchor hospitalization; or is discharged from a readmission during an AMI model episode that does not initiate new model episodes.

The proposed list of ICD-9-CM and ICD-10-CM AMI diagnosis codes used to identify beneficiaries discharged under a PCI MS-DRG (MS-DRGs 246-251) in historical episodes and during the performance years of the model that will be included in the AMI model episodes are discussed in section III.C.4.a.(2) of this proposed rule. To make changes to this list as necessary based on annual ICD-10-CM coding changes or to address issues raised by the public throughout the EPM performance years, we propose implementing the following sub-regulatory process, which mirrors the sub-regulatory process as described in the CJR model final rule for updating hip fracture ICD-9-CM and ICD-10-CM diagnosis codes (80 FR 73340) and for updating the exclusions list (80 FR 73305 and 73315). We propose to use this process on an annual, or more frequent, basis to update the AMI ICD-10-CM diagnosis code list and to address issues raised by the public. As part of this process we propose the following standard when revising the list of ICD-10-CM diagnosis codes representing AMI: the ICD-10-CM diagnosis code is sufficiently specific that it represents an AMI. We propose to then post a list of potential AMI ICD-10-CM

[45] Episodes for AMI beneficiaries initiated by all U.S. IPPS hospitals not in Maryland and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule, that began in CYs 2012-2014.

diagnosis codes to the CMS Web site at https://innovation.cms.gov/inititatives/epm to allow for public input on our planned application of these standards, and then adopt the AMI ICD-10-CM diagnosis code list with posting to the CMS Web site of the final AMI ICD-CM diagnosis code list after our consideration of the public input. We would provide sufficient time for public input based on the complexity of potential revisions under consideration, typically at least 30 days, and, while we would not respond to individual comments as would be required in a regulatory process, we could discuss the reasons for our decisions about changes in response to public input with interested stakeholders.

The proposals for identifying the beneficiaries included in the AMI model and the sub-regulatory process for updating the AMI ICD-10-CM diagnosis code list are included in § 512.100(c)(1) and (d), respectively. We seek comment on our proposals to identify beneficiaries included in the AMI model and the sub-regulatory process for updating the AMI ICD-10-CM diagnosis code list. The proposal to exclude inpatient claims with PCI MS-DRGS 246-251 from anchoring AMI model historical episodes used to set initial AMI model-episode benchmark prices when there is an ICD-9-CM intracardiac procedure code on the claim is included in § 512.100(d)(4). We seek comment on our proposal to exclude inpatient claims with PCI MS-DRGS 246-251 from anchoring AMI model historical episodes used to set initial AMI model-episode benchmark prices when there is an ICD-9-CM intracardiac procedure code on the claim.

(2) CABG Model

We propose the CABG model to incentivize improvements in the coordination and quality of care, as well as episode efficiency, for beneficiaries treated with CABG irrespective of AMI during the CABG hospitalization, thereby including beneficiaries undergoing elective

CABG in the CABG model as well as beneficiaries with AMI who have a CABG during their initial AMI treatment. The CABG model is similar to the CJR model in that the anchor hospitalization is defined by admission for a surgical procedure, which is defined by the MS-DRGs for that procedure alone (80 FR 73280). All CABG procedures are performed in the inpatient hospital setting. Thus, we propose to include beneficiaries admitted and discharged from an anchor hospitalization paid under CABG MS-DRGs (231-236) under the IPPS in the CABG model. Based on Medicare claims data for historical CABG episodes beginning in CYs 2012-2014, the annual number of potentially eligible beneficiary discharges for the CABG model nationally was approximately 48,000.[46]

The proposal for identifying beneficiaries included in the CABG model is included in § 512.100(c)(2). We seek comment on our proposal to identify beneficiaries included in the CABG model.

(3) SHFFT (Excludes Lower Extremity Joint Replacement) Model

We propose the SHFFT model to incentivize improvements in the coordination and quality of care, as well as episode efficiency, for beneficiaries treated surgically for hip and femur fractures, other than hip arthroplasty. Together, the CJR and SHFFT models cover all surgical treatment options (that is, hip arthroplasty and fixation) for Medicare beneficiaries with hip fracture.

The SHFFT model is similar to the CJR model in that the anchor hospitalization is defined by admission for a surgical procedure, which is defined by the MS-DRGs for that procedure alone (80 FR 73280). Additionally, most SHFFT procedures are furnished in the inpatient hospital setting, consisting primarily of hip fixation procedures, with or without

[46] Episodes for CABG beneficiaries initiated by all U.S. IPPS hospitals not in Maryland and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule, that began in CYs 2012-2014.

reduction of the fracture, as well as open and closed surgical approaches. Thus, we propose to include beneficiaries admitted and discharged from an anchor hospitalization paid under SHFFT MS-DRGs (480-482) under the IPPS in the SHFFT model. Based on Medicare claims data for historical SHFFT episodes beginning in CYs 20122014, the annual number of potentially eligible beneficiary discharges for the SHFFT model nationally was approximately 109,000.[47]

The proposal for identifying beneficiaries included in the SHFFT model is included in § 512.100(c)(3). We seek comment on our proposal to identify beneficiaries included in the SHFFT model.

b. Definition of the Related Services Included in EPM Episodes

The general principles for the proposed definition of related services are the same for the AMI, CABG, and SHFFT models, so we address them in a single discussion in this section. Like the CJR model, we are interested in testing inclusive AMI, CABG, and SHFFT model episodes to incentivize comprehensive, coordinated, patient-centered care for the beneficiary throughout the episode (80 FR 73303). Therefore, we propose to exclude Medicare items and services furnished during the EPM episodes only when unrelated to the EPM episode diagnosis and procedures based on clinical rationale that would result in standard exclusions from all of the episodes in a single EPM. Thus, we propose to include all items and services paid under Medicare Part A and Part B unless they fall under an exclusion because they are unrelated to the EPM episodes.

Also like the CJR model, we propose that the items and services ultimately included in the EPM episodes after the exclusions are applied are called related items and services, and that Medicare spending for related items and services be included in the historical data used to set

[47] Episodes for SHFFT beneficiaries initiated by all U.S. IPPS hospitals not in Maryland and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that began in CYs 2012-2014.

EPM-episode benchmark prices and in the calculation of actual EPM episode payments that would be compared against the quality-adjusted target price to assess the performance of EPM participants (80 FR 73303 and 73315). Additionally, we propose that Medicare spending for unrelated items and services (excluded from the EPMs' episode definitions) would not be included in the historical data used to set EPM-episode benchmark prices or in the calculation of actual EPM episode payments. We propose that related items and services for EPM episodes would include the following items and services paid under Medicare Part A and Part B, after the EPM-specific exclusions are applied:

- Physicians' services.
- Inpatient hospital services.
- Inpatient psychiatric facility (IPF) services.
- Long-Term Care Hospital (LTCH) services.
- Inpatient Rehabilitation Facility (IRF) services.
- Skilled Nursing Facility (SNF) services.
- Home Health Agency (HHA) services.
- Hospital outpatient services.
- Independent outpatient therapy services.
- Clinical laboratory services.
- Durable medical equipment.
- Part B drugs.
- Hospice.

We note that inpatient hospital services would include services paid through IPPS operating and capital payments. The AMI, CABG, and SHFFT model episodes also could

include certain per-member-per-month model payments as discussed in section III.D.6.d. of this proposed rule. These proposed items and services for the EPMs are the same items and services included in CJR model episodes (80 FR 73303 and 73315).

Similar to the CJR model and for the reasons explained in the CJR Final Rule, we propose to exclude drugs that are paid outside of the MS-DRGs included in the EPM episode definitions, specifically hemophilia clotting factors, identified by CPT code, diagnosis code, and revenue center on IPPS claims, from the EPM episodes (80 FR 73303 and 73315). Hemophilia clotting factors, in contrast to other drugs that are administered during a hospitalization and paid through the MS-DRG, are paid separately by Medicare in recognition that clotting factors are costly and essential to appropriate care of certain beneficiaries. Therefore, we believe there are no EPM episode efficiencies to be gained in the variable use of these high cost drugs.

We also propose to exclude IPPS new technology add-on payments for drugs, technologies, and services from these EPM episodes, excluding them from both the actual historical episode data used to set EPM-episode benchmark prices and from actual EPM episode payments that are reconciled to the quality-adjusted target prices like the CJR model (80 FR 73303-73304 and 73315). This would apply to both the anchor hospitalization and any related readmissions during the EPM episodes. New technology add-on payments are made separately and in addition to the MS-DRG payment under the IPPS for specific new drugs, technologies, and services that substantially improve the diagnosis or treatment of Medicare beneficiaries and would be inadequately paid under the MS-DRG system. We believe it would not be appropriate for the EPM to potentially diminish beneficiaries' access to new technologies or to burden hospitals who choose to use these new drugs, technologies, or services with concern about these payments counting toward EPM participants' actual EPM

episode payment. Additionally, new drugs, technologies, or services approved for the add-on payments vary unpredictably over time in their application to specific clinical conditions.

Finally, we propose to exclude OPPS transitional pass-through payments for medical devices as defined in § 419.66 from the EPM episodes because, through the established OPPS review process, we have determined that these technologies have a substantial cost but also lead to substantial clinical improvement for Medicare beneficiaries. This proposal also is consistent with the CJR model final exclusions policy (80 FR 73308 and 73315).

We propose to follow the same general principles in determining other proposed excluded Part A and Part B services from the EPM episodes that we use in the CJR model in order to promote coordinated, high-quality, patient-centered care (80 FR 73304). These include identifying excluded (unrelated) services rather than included (related) services based on clinical review. We would operationalize these principles for the new EPMs, as we do for the CJR model, by excluding unrelated inpatient hospital admissions during the EPM episode by identifying MS-DRGs for exclusion on an EPM-specific basis (80 FR 73304 through 73312 and 73315). We would further exclude unrelated Part B services during the EPM episode based on the diagnosis code on the claim by identifying categories of ICD-CM codes for exclusion (identified by code ranges) on an EPM-specific basis. ICD-9-CM diagnosis code exclusions would apply to historical episodes used to construct EPM-episode benchmark prices, while ICD-10-CM diagnosis code exclusions would apply to EPM episodes during the EPMs' performance years. We propose to identify unrelated Part B services and readmissions based on the BPCI Model 2 Part B exclusions lists that apply to the anchor MS-DRG that initiates the EPM episode, or to the price MS-DRG if it is different than the anchor MS-DRG as described further in section III.D.4.b.(2)(a) of this proposed rule. This proposal is consistent with our use

of the BPCI Model 2 LEJR ICD-9-CM, ICD-10-CM, and MS-DRG exclusions lists in the CJR model (80 FR 73304 and 73315).

The BPCI episode-specific exclusions lists were initially developed more than 3 years ago for BPCI through a collaborative effort of CMS staff, including physicians from medical and surgical specialties, coding experts, claims processing experts, and health services researchers. The lists have been shared with thousands of entities and individuals participating in episodes in one or more phases of BPCI, and have undergone refinement in response to stakeholder input about specific diagnoses for exclusion, resulting in only minimal changes over the last 3 years. Thus, the BPCI exclusions lists have been vetted broadly in the health care community; refined based on input from a wide variety of providers, researchers and other stakeholders; and successfully operationalized in the BPCI models. We propose their use in the AMI, CABG, and SHFFT models based on our confidence related to our several years of experience that these definitions are reasonable and workable for AMI, CABG, and SHFFT model episodes, for both providers and CMS, and based on our rulemaking for the CJR model. We note that the BPCI Model 2 exclusions lists for the 48 clinical conditions being tested in the BPCI models include lists that apply to every MS-DRG that could be an anchor MS-DRG (or price MS-DRG, if applicable) for the proposed AMI, CABG, and SHFFT model episodes.

Similar to the CJR model, we propose to include in EPM episodes all Part A services furnished post-hospital discharge during the EPM episode, as these services are typically intended to be comprehensive in nature (80 FR 73304 and 73315). We specifically propose to exclude unrelated hospital readmissions for MS-DRGs that group to the following categories of diagnoses: oncology, trauma medical admissions, surgery for chronic conditions unrelated to a

condition likely to have been affected by care furnished during the EPM episode, and surgery for acute conditions unrelated to a condition resulting from or likely to have been affected by care during the EPM episode. The rationale for these exclusions is the same as the rationale for their exclusion in the CJR model (80 FR 73304).

Specifically with respect to Part B services, similar to the CJR model, we propose to exclude acute disease diagnoses unrelated to a condition resulting from or likely to have been affected by care during the EPM episode, and certain chronic disease diagnoses, as specified by CMS on a diagnosis-by-diagnosis basis, depending on whether the condition was likely to have been affected by care during the EPM episode or whether substantial services were likely to be provided for the chronic condition during the EPM episode (80 FR 73305 and 73315). Thus, we would include all Part B services with principal diagnosis codes on the associated Part B claims that are directly related (clinically and per coding conventions) to EPM episodes, claims for diagnoses that are related to the quality and safety of care furnished during EPM episodes, and claims for services for diagnoses that are related to preexisting chronic conditions such as diabetes, which may be affected by care furnished during EPM episodes.

In general, the anchor MS-DRG that initiates the AMI, CABG, or SHFFT episode would determine the exclusions list that applies to the EPM episode. For example, AMI model episodes may have different exclusions lists applied based on whether the AMI model episode is initiated by admission to the participant hospital that results in discharge from an AMI anchor MS-DRG or a PCI anchor MS-DRG with AMI ICD-10-CM diagnosis code. If a price MS-DRG applies to the AMI model episode that includes a chained anchor hospitalization as described in section III.D.4.b.(2)(a) of this proposed rule, the exclusions list that applies to the price MS-DRG would apply to the AMI model episode. Complete lists of proposed excluded

MS-DRGs for readmissions and proposed excluded ICD-CM codes for Part B services furnished during EPM episodes after EPM beneficiary discharge from an anchor or chained anchor hospitalization in the AMI, CABG, and SHFFT models are posted on the CMS Web site at https://innovation.cms.gov/initiatives/epm.

Like the CJR model policy, we propose that these exclusion lists would be updated by sub-regulatory guidance on an annual basis, at a minimum, to reflect annual changes to ICD-10-CM coding and annual changes to the MS-DRGs under the IPPS, as well as to address any other issues that are brought to our attention throughout the course of the EPMs' performance period (80 FR 73304 through 73305 and 73315). The standards for this updating process reflect the aforementioned general principles for determining excluded services. That is, we propose to not exclude any items or services that are directly related to the EPM episode diagnosis or procedure (for example, a subsequent admission for heart failure or repeat revascularization) or the quality or safety of care (for example, sternal wound infection following CABG); or to chronic conditions that may be affected by the EPM diagnosis or procedure and the post-discharge care (for example, diabetes). We propose to exclude items and services for chronic conditions that are generally not affected by the EPM diagnosis or procedure and the post-discharge care (for example, prostate removal for cancer), and for acute clinical conditions not arising from existing EPM episode-related chronic clinical conditions or complications from the EPM episode (for example, appendectomy).

Similar to the CJR model, we propose that the potential revised exclusions, which could include additions to or deletions from the exclusions lists, would be posted to the CMS Web site to allow for public input (80 FR 73305 and 73315). Through the process for public input on potential revised exclusions and then posting of the final revised exclusions, we propose to

provide information to the public about when the revisions would take effect and to which episodes they would apply.

The proposal for included services for an EPM is included in § 512.210(a). The proposal for excluded services from the EPM episode is included in § 512.210(b). The proposal for updating the lists of excluded services for EPMs is included in § 512.210(c). We seek comment on our proposals for included and excluded services for the AMI, CABG, and SHFFT models and updating the lists of excluded services.

4. EPM Episodes

a. Beneficiary Care Inclusion Criteria and Beginning of EPM Episodes

(1) General Beneficiary Care Inclusion Criteria

Because of the clinical variability leading up to these EPM episodes and the challenge of identifying unrelated services given the multiple chronic conditions experienced by many EPM beneficiaries, we propose to follow the CJR model precedent and not begin an EPM episode prior to the anchor hospitalization (80 FR 73315 and 73318). We propose that all services that are already included in the IPPS payment based on established Medicare policies (for example, 3-day payment window payment policies) would be included in these EPM episodes, and that the defined population of Medicare beneficiaries whose care would be included in the EPMs would meet all of the following criteria on admission to the anchor or chained anchor hospitalization:

- Enrolled in Medicare Part A and Part B.
- Eligible for Medicare not on the basis of end-stage renal disease.
- Not enrolled in any managed care plan (for example, Medicare Advantage, Health Care Prepayment Plans, cost-based health maintenance organizations).

- Not covered under a United Mine Workers of America health plan, which provides health care benefits for retired mine workers.
- Have Medicare as their primary payer.
- Not aligned to an ACO in the Next Generation ACO model or an ACO in a track of the Comprehensive ESRD Care Initiative incorporating downside risk for financial losses.
- Not under the care of an attending or operating physician, as designated on the inpatient hospital claim, who is a member of a physician group practice that initiates BPCI Model 2 episodes at the EPM participant for the MS-DRG that would be the anchor MS-DRG under the EPM.
- Not already in any BPCI model episode.
- Not already in an AMI, SHFFT, CABG or CJR model episode with an episode definition that does not exclude the MS-DRG that would be the anchor MS-DRG under the applicable EPM.

For a discussion of our proposal to exclude certain ACO-aligned beneficiaries from EPM episodes, we refer to section III.D.6.c.(3) of this proposed rule. For a discussion of our proposals for addressing potential overlap of beneficiaries in episode payment models that are relevant to these last two criteria, we refer to sections III.D.6.c.(1) and (2) of this proposed rule.

The proposal for beneficiary care inclusion policies is included in § 512.230. We seek comment on our proposal of beneficiary care inclusion policies.

(2) Beginning AMI Model Episodes

We propose that, as long as the beneficiary meets the general beneficiary care inclusion criteria, then an AMI model episode would begin with admission of a Medicare beneficiary to an IPPS hospital for the following MS-DRGs, where the specific MS-DRG is called the anchor

MS-DRG for the episode:

- AMI MS-DRGs--

++ 280 (Acute myocardial infarction, discharged alive with MCC);

++ 281 (Acute myocardial infarction, discharged alive with CC); and

++ 282 (Acute myocardial infarction, discharged alive without CC/MCC).

- PCI MS-DRGs, when the claim includes an AMI ICD-10-CM diagnosis code in the principal or secondary position on the IPPS claim as specified in Table 3--

++ 246 (Percutaneous cardiovascular procedures with drug-eluting stent with MCC or 4+ vessels/stents);

++ 247 (Percutaneous cardiovascular procedures with drug-eluting stent without MCC);

++ 248 (Percutaneous cardiovascular procedures with non-drug-eluting stent with MCC or 4+ vessels/stents);

++ 249 (Percutaneous cardiovascular procedures with non-drug-eluting stent without MCC);

++ 250 (Percutaneous cardiovascular procedures without coronary artery stent with MCC); and

++ 251 (Percutaneous cardiovascular procedures without coronary artery stent without MCC).

Table 3 displays the ICD-9-CM codes that we propose to use to identify historical AMI episodes for beneficiaries discharged from PCI MS-DRGs, as well as the ICD-10-CM diagnosis codes that would be used to identify AMI model episodes for beneficiaries discharged from PCI MS-DRGs throughout the duration of the AMI model. The proposed sub-regulatory process for updating this AMI ICD-10-CM diagnosis code list is described previously in

section III.C.3.a.(1) of this proposed rule.

We first identified the ICD-9-CM diagnosis codes for the initial AMI episode-of-care that were historically used to report care for a newly diagnosed AMI patient admitted to the hospital. These codes all have a fifth digit of "1" and were applicable until the patient was discharged from acute medical care, including for any transfers to and from other acute care facilities that occurred. These AMI ICD-9-CM diagnosis codes would be used to identify historical AMI episodes for developing AMI model-episode benchmark prices for anchor PCI MS-DRGs. We propose to cross-walk the ICD-9-CM diagnosis codes for the initial AMI episode-of-care to the ICD-10-CM diagnosis codes that would be reported for similar beneficiaries during the AMI model performance years. The proposed crosswalk in Table 3 is consistent with the crosswalk CMS posted for public comment regarding ICD-9-CM to ICD-10-CM diagnosis codes used for HIQR Program measures, including AMI quality measures.[48]

TABLE 3: PROPOSED ICD-9-CM AND ICD-10-CM AMI DIAGNOSIS CODES IN THE PRINCIPAL OR SECONDARY POSITION ON THE IPPS CLAIM FOR PCI MS-DRGS (246-251) THAT INITIATE AMI MODEL EPISODES

ICD-9-CM Diagnosis Code	ICD-9-CM Description	ICD-10-CM Diagnosis Code	ICD-10-CM Description
410.01	Acute myocardial infarction of anterolateral wall, initial episode of care	121.09	ST elevation (STEMI) myocardial infarction involving other coronary artery of anterior wall
		122.0	Subsequent ST elevation (STEMI) myocardial infarction of anterior wall
410.11	Acute myocardial infarction of other anterior wall, initial	121.01	ST elevation (STEMI) myocardial infarction involving left main coronary artery

48 https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/HIQR-ICD9-to-ICD10-Tables.pdf.

ICD-9-CM Diagnosis Code	ICD-9-CM Description	ICD-10-CM Diagnosis Code	ICD-10-CM Description
	episode of care	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	121.21	ST elevation (STEMI) myocardial infarction involving left circumflex coronary artery

ICD-9-CM Diagnosis Code	ICD-9-CM Description	ICD-10-CM Diagnosis Code	ICD-10-CM Description
	episode of care	121.29	ST elevation (STEMI) myocardial infarction involving other sites
		122.8	Subsequent ST elevation (STEMI) myocardial infarction of other sites
410.91	Acute myocardial infarction of unspecified site, initial episode of care	121.3	ST elevation (STEMI) myocardial infarction of unspecified site
		122.9	Subsequent ST elevation (STEMI) myocardial infarction of unspecified site

The proposal for beginning AMI model episodes is included in § 512.240(a)(1). We seek comment on our proposal to begin AMI model episodes.

(3) Beginning CABG Model Episodes

We propose that, as long as a beneficiary meets the general beneficiary care inclusion criteria, a CABG model episode would begin with the admission of a Medicare beneficiary to an IPPS hospital for a CABG that is paid under the following CABG MS-DRGs and the specific MS-DRG is called the anchor MS-DRG for the episode:

- 231 (Coronary bypass with percutaneous transluminal coronary angioplasty (PTCA) with MCC).
- 232 (Coronary bypass with PTCA without MCC).
- 233 (Coronary bypass with cardiac catheterization with MCC).
- 234 (Coronary bypass with cardiac catheterization without MCC).
- 235 (Coronary bypass without cardiac catheterization with MCC).
- 236 (Coronary bypass without cardiac catheterization without MCC).

The proposal for beginning CABG episodes is included in § 512.240(b)(1). We seek comment on our proposal to begin CABG model episodes.

(4) Beginning SHFFT Episodes

We propose that as long as a beneficiary meets the general inclusion criteria, a SHFFT model episode would begin with the admission of a Medicare beneficiary to an IPPS hospital for surgical treatment of hip or femur fracture (other than joint replacement) that is paid under the following SHFFT MS-DRGs and where the specific MS-DRG is called the anchor MS-DRG for the episode:

- 480 (Hip and femur procedures except major joint with MCC).
- 481 (Hip and femur procedures except major joint with complication or comorbidity (CC).
- 482 (Hip and femur procedures except major joint without CC or MCC).

The proposal for beginning SHFFT model episodes is included in § 512.240(c)(1). We seek comment on our proposal to begin SHFFT model episodes.

(5) Special Policies for Hospital Transfers of Beneficiaries with AMI

The asymmetric distribution of cardiac care across hospitals makes transfer, either from an inpatient admission or from the emergency department (without inpatient admission) of one hospital to another, a common consideration in the treatment course for beneficiaries with an initial diagnosis of AMI. Therefore, transfer for cardiac care is an important consideration for the AMI and CABG models.

The availability of revascularization and intensive cardiac care are particularly important considerations in the transfer of beneficiaries with an AMI. A substantial portion of hospitals do not have revascularization capability (that is, a cardiac catheterization lab for PCI or cardiothoracic surgeons who can perform CABG) or cardiovascular intensive care units (CVICU) and, therefore, must transfer beneficiaries to provide access to these services. In the

PCI and CABG examples, the discharge from the transfer hospital that accepted the beneficiary would result in discharge under the MS-DRGs for PCI (246-251) or CABG (231-236). For the CVICU example, the transfer hospital's discharge MS-DRG would be AMI (280-282). There is evidence of the asymmetric distribution of cardiac care in the 2014 IPPS and critical access hospital claims data: while 4,332 hospitals submitted at least one claim for an AMI MS-DRG, only 1,755 (41 percent) and 1,156 (27 percent) of these hospitals filed at least one claim for PCI or CABG MS-DRGs, respectively.[49]

The potential transfer scenarios are best illustrated by the care pathways experienced by beneficiaries with AMI. These beneficiaries typically present to a hospital's emergency department where the evaluation identifies the AMI diagnosis and determines the initial indicated treatments. Depending on the beneficiary's clinical needs and the hospital's treatment capacity, the beneficiary could be --

- Admitted to the initial treating hospital, with no transfer to another hospital during the initial hospitalization for AMI. We refer to this scenario as no transfer;
- Admitted to the initial treating hospital and later transferred to a transfer hospital. We refer to this scenario as inpatient-to-inpatient transfer and the transfer hospital as an i-i transfer hospital; or
- Transferred from the initial treating hospital to a transfer hospital without admission to the initial treating hospital. We refer to this scenario as outpatient-to-inpatient transfer and the transfer hospital as an o-i transfer hospital.

Our proposals and alternatives considered for these scenarios are described in detail in this section. In our proposals for AMI or CABG model episodes for initial AMI care, our

[49] AMI, CABG and PCI MS-DRG inpatient claims from all U.S. IPPS hospitals and CAHs derived from the 2014 Geographic Variations Inpatient Claims File located in the Chronic Conditions Warehouse.

overarching policy is that every AMI or CABG model episode would begin at the first AMI or CABG model participant to which the beneficiary is admitted for an AMI MS-DRG, PCI MS-DRG with an AMI ICD-CM diagnosis code, or CABG MS-DRG. The AMI or CABG model participant where the episode begins would then be financially responsible for the AMI or CABG model episode unless the episode is canceled.

Based on our analysis of Medicare claims data, about 75 percent of historical AMI episodes and CABG episodes for beneficiaries with AMI begin through the emergency department of the hospital where the anchor hospitalization for the AMI or CABG model episode would occur. In another 18 percent of historical AMI episodes and CABG episodes for beneficiaries with AMI, the anchor hospitalization occurs at a transfer hospital following an emergency department visit at another hospital without admission to that hospital for an MS-DRG that would initiate an AMI or CABG model episode.[50]

In each of these scenarios, policies to determine which episode type applies, the beginning of the episode, and the specific hospital with financial responsibility for the episode must be determined (for example, AMI or CABG, if CABG is provided as an initial treatment in an outpatient-to-inpatient or inpatient-to-inpatient scenario). In this section, we discuss each of the scenarios in detail and provide a summary of the scenarios in Table 4.

In the no transfer scenario, the episode would begin upon admission to an AMI or CABG model participant under circumstances that meet the criteria discussed in sections III.C.4.a.(1) and (2) or (3) of this proposed rule, and the AMI or CABG model episode that applies would be determined by the specific MS-DRG for the anchor hospitalization. Financial responsibility for the episode would be attributed to the sole treating hospital involved in the

[50] Episode for beneficiaries with AMI initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that end in CY 2014.

initial AMI care. Under this proposal, the treating hospital's quality measure performance would determine the effective discount factor to be applied to the AMI or CABG model benchmark episode price for the episode at reconciliation as described in section III.D.4.b.(10) of this proposed rule.

The inpatient-to-inpatient transfer scenario has several potential outcomes. If the beneficiary initially presents for AMI care to a hospital that is not an AMI model participant and is admitted and then transferred to an i-i transfer hospital that is an AMI or CABG model participant, the episode would first initiate at the i-i transfer hospital and, therefore, the i-i transfer hospital would be financially responsible for the AMI or CABG model episode. The i-i transfer hospital's quality measure performance would determine the effective discount factor to be applied to the AMI or CABG model benchmark episode price for the episode at reconciliation as described in section III.D.4.b.(10) of this proposed rule.

Conversely, if a beneficiary initially presents for AMI care to an AMI model participant and is admitted and then transferred to an i-i transfer hospital (hereinafter a chained anchor hospitalization) and the i-i transfer hospital is not an AMI or CABG model participant, the episode would initiate at the initial treating hospital and would only be canceled for beneficiaries discharged from the i-i transfer hospital under MS-DRGs that are not anchor MS-DRGs for AMI or CABG model episodes is discussed in section III.C.4.b. of this proposed rule. The initial treating hospital's quality measure performance would determine the effective discount factor to be applied to the AMI or CABG model benchmark episode price for the episode at reconciliation as described in section III.D.4.b.(10) of this proposed rule. We also refer to section III.D.4.b.(2)(a) of this proposed rule for further discussion of price MS-DRGs that may differ from the anchor MS-DRG in AMI model episodes that include a chained anchor

hospitalization, in order to provide pricing adjustments for episodes where the initial treating hospital is responsible for the AMI model episode.

Inpatient-to-inpatient transfers between AMI and CABG model participant hospitals are further considered in this section and specifically include beneficiaries experiencing an AMI who are transferred for revascularization (that is, PCI or CABG) or a higher level of medical AMI care. We note that of all beneficiaries experiencing an AMI in historical episodes, about half received no revascularization (PCI or CABG) during the anchor hospitalization or the 90-day post-hospital discharge period, about 40 percent received a PCI, and less than 10 percent had CABG surgery.[51] Moreover, three-quarters of CABG procedures and over 90 percent of PCIs for beneficiaries experiencing an AMI occurred at the hospital that first admitted the beneficiary for an inpatient hospitalization.[52]

However, given the asymmetric distribution of cardiac care capacity there will be beneficiaries who initiate an AMI model episode by admission to an initial treating hospital but then require transfer to an i-i transfer hospital for additional treatment during the AMI model episode, resulting in a chained anchor hospitalization. For historical AMI episodes ending in CY 2014, only about 12 percent of beneficiaries who would have initiated an AMI model episode through admission and assignment to an AMI MS-DRG at the initial treating hospital were transferred to an i-i transfer hospital, with 30 percent and 20 percent receiving PCI or CABG, respectively, at the i-i transfer hospital. Another 20 percent were discharged from the i-i transfer hospital in the chained anchor hospitalization under an AMI MS-DRG. The remaining 30 percent of beneficiaries were discharged from the i-i transfer hospital in the

[51] Episodes for beneficiaries with AMI initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule, and that end in CY 2014.
[52] Episodes for beneficiaries with AMI initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule, and that end in CY 2014.

chained anchor hospitalization under other MS-DRGs that would not have initiated AMI or CABG model episodes, including cardiac valve surgery, septicemia, and renal failure. From the perspective of hospital capacity and transfer patterns, most hospitals transferred less than 10 percent of beneficiaries initiating a historical AMI episode under an AMI MS-DRG at the first admitting hospital, and only a handful of hospitals transferred the majority of their patients in this scenario.[53] This small number of hospitals that transferred the majority of their patients includes a range of urban and rural hospitals with 50 to 250 beds.

The need to transfer a beneficiary in an AMI model episode during the anchor hospitalization for appropriate care that results in a chained anchor hospitalization where the hospitals are both AMI or CABG model participants raises considerations about whether attribution of the AMI model episode should be to the first treating hospital that admitted the beneficiary or the i-i transfer hospital, as well as considerations about the specific model (AMI or CABG) for attribution of the episode in some circumstances. For example, if the first treating hospital initiates an AMI model episode by admitting a beneficiary and then transfers the beneficiary to another hospital where the beneficiary is treated and ultimately discharged from acute care, ending the chained anchor hospitalization under a CABG MS-DRG, then we need to determine whether the beneficiary would be included in the AMI or CABG model, which hospital assumes financial responsibility for the beneficiary's episode, and under what circumstances, if any, would the AMI model episode be canceled if a transfer occurs.

In considering the model episode that includes the beneficiary's care and accountability for the beneficiary in inpatient-to-inpatient transfer scenarios between AMI and CABG model participant hospitals that result in a chained anchor hospitalization for AMI, several factors are

[53] Episodes for AMI beneficiaries initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that end in CY 2014.

relevant, including the timing of final discharge disposition of the beneficiary, including to post-acute care; the location of the post-acute care; the identity and location of the physician who is most responsible for managing the beneficiary's care after discharge; and consistency across other CMS transfer policies. We note that while 64 percent of CABG beneficiaries in historical episodes received post-acute care services following discharge from the anchor hospitalization (most commonly home health services – 43 percent received home health services only and 13 percent a combination of home health and SNF services), only 36 percent of historical AMI beneficiaries received post-acute services.[54] Of further relevance for beneficiaries with an AMI diagnosis is that significant follow up care is usually performed by cardiologists who manage the patient's underlying cardiovascular disease, rather than the interventional cardiologist or cardiothoracic surgeon that perform the revascularization procedure. PCI procedures, billed by interventional cardiologists, have a 0-day global period, reflecting that follow up care is not typically furnished by interventional cardiologists. We further note that patients in commercial programs that require travel to regional centers of excellence for CABG generally only stay in the remote location away from the patient's home for a week or so post-hospital discharge. We expect that beneficiaries hospitalized for treatment of AMI, even if they are transferred to a revascularization hospital resulting in a chained anchor hospitalization, would receive most follow up care in their local communities, a view that was supported by many commenters on the CJR model proposed rule who asserted that many patients requiring post-acute care prefer to return to their home communities for that care following hospital discharge (80 FR 23457). Finally, consistency across other CMS program policies when a beneficiary with an AMI experiences an inpatient-to-inpatient transfer is

[54] Episodes for AMI and CABG beneficiaries initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that end in CY 2014.

relevant to developing policies for the proposed AMI and CABG models. Specifically, we note that the Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for AMI (NQF #2431) measure used in the hospital value-based purchasing (HVBP) Program attributes payments for transferred beneficiaries to the hospital that admitted the patient for the initial AMI hospitalization.[55]

Based on these considerations, we propose that once an AMI model episode is initiated at an AMI model participant hospital through an inpatient hospitalization, the AMI model episode would continue under the financial responsibility of that participant hospital, regardless of whether the beneficiary is transferred to another AMI or CABG model participant hospital for further medical management of AMI, or for a PCI or CABG during a chained anchor hospitalization. Under this proposal, the initial treating hospital's quality measure performance would determine the effective discount factor to be applied to the AMI model benchmark episode price for the episode at reconciliation as described in section III.D.4.b.(10) of this proposed rule. Our proposal to cancel AMI model episodes for beneficiaries discharged from the i-i transfer hospital under MS-DRGs that are not anchor MS-DRGs for AMI or CABG model episodes is discussed in section III.C.4.b. of this proposed rule. We also refer to section III.D.4.b.(2)(a) of this proposed rule for further discussion of price MS-DRGs that may differ from the anchor MS-DRG in AMI model episodes that include a chained anchor hospitalization, in order to provide pricing adjustments for episodes where the initial treating hospital is responsible for the AMI model episode.

We note that we do not propose to cancel the AMI model episode even if the transfer

55 https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

and admission to the i-i transfer hospital would otherwise initiate a CABG model episode at the i-i transfer hospital. We believe that once the AMI model episode has been initiated, all related care during the episode (including hospital care for transfers and related readmissions for CABG) should be fully attributed to the AMI model episode in the manner described in this section for the episode and that the first hospital that initiated the AMI model episode should be financially responsible for the AMI episode. Therefore, we do not propose to cancel the AMI model episode if a CABG is performed during a chained anchor hospitalization, nor do we propose that a beneficiary could simultaneously be in an AMI and CABG model episode for overlapping periods of time due to the different MS-DRGs that apply during the chained anchor hospitalization. Instead, we would make an AMI model episode pricing adjustment for these circumstances by paying the AMI model participant based on a price MS-DRG that is different from the anchor MS-DRG to reflect Medicare payment for the CABG as discussed in section III.D.4.b.(2)(a) of this proposed rule.

We considered several alternatives to our proposal for AMI model episode attribution for inpatient-to-inpatient transfer scenario where both hospitals are AMI or CABG model participants. First, we considered canceling the AMI model episode initiated at the initial treating hospital when a transfer occurs, and basing any AMI or CABG model episode initiation on the MS-DRG for the final i-i transfer hospital admission in the chained anchor hospitalization as long as that latter hospital is an AMI or CABG model participant. This would place financial responsibility for the episode on the i-i transfer hospital if the beneficiary goes on to be discharged from acute care at that hospital. Attributing episodes under this alternative policy would assign beneficiaries to the final i-i transfer hospital for the AMI or CABG model episode based on the model episode definitions in sections III.C.4.a.(2) and (3) of this proposed

rule. That is, if the beneficiary is discharged from the final admission in the chained anchor hospitalization under an AMI MS-DRG or a PCI MS-DRG, then the AMI model episode initiated at the initial treating hospital would be canceled and the i-i transfer hospital accepting the beneficiary on referral would initiate an AMI model episode. Similarly, if the beneficiary is discharged from the final admission in the chained anchor hospitalization under a CABG MS-DRG, then the AMI model episode initiated at the first hospital would be canceled and the i-i transfer hospital accepting the beneficiary on referral would initiate a CABG model episode. Under this alternative, the i-i transfer hospital's quality measure performance would determine the effective discount factor to be applied to the AMI or CABG model benchmark episode price for the episode at reconciliation as described in section III.D.4.b.(10) of this proposed rule. However, we do not propose this alternative because we believe that post-acute care and care management following hospital discharge are more likely to be effectively provided near the beneficiary's home community, rather than near the i-i transfer hospital accepting the beneficiary upon referral.

Second, we considered proposing an episode hierarchy such that, during a chained anchor hospitalization, the most resource-intensive MS-DRG during the whole chained anchor hospitalization would determine the model episode and the financially responsible hospital for the episode. For example, if we establish CABG, PCI, and AMI MS-DRGs in descending order of inpatient hospital resource-intensity, we would initiate a model episode based on the most resource-intensive MS-DRG during the chained anchor hospitalization and attribute the model episode to the hospital discharging the beneficiary under that MS-DRG. Under this scenario, either the initial treating or i-i transfer hospital's quality measure performance would determine the effective discount factor to be applied to the AMI or CABG model benchmark episode price

for the episode at reconciliation as described in section III.D.4.b.(10) of this proposed rule, depending on the specific hospital discharging the beneficiary under the most resource-intensive MS-DRG during the chained anchor hospitalization. However, we do not propose this alternative because we believe, like the first alternative we considered, this could frequently lead to episode responsibility being attributed to the i-i transfer hospital when the local hospital first caring for the beneficiary with AMI may be better positioned to coordinate care in the beneficiary's home community.

Thus, our proposal would place responsibility for care during the 90-day post-hospital discharge period in the AMI model episode on the AMI model participant hospital to which the beneficiary initially presented for AMI care and was admitted, rather than on the i-i transfer hospital to which the beneficiary was transferred after initiating the AMI model episode. Given the broad episode definition of AMI model episodes, we believe that the post-discharge care required following hospitalization that includes CABG, PCI, or medical management is best coordinated and managed by the hospital that originally admitted the beneficiary for the AMI. Such post-discharge care could include follow up for adherence to cardiac rehabilitation referral and management of the beneficiary's underlying CAD and comorbidities. Even in the case of the more common surgical complications of CABG, such as wound infection, the beneficiary commonly would be admitted to the local hospital for treatment.

We further propose that, as discussed in section III.I.3 of this proposed rule, hospitals may be collaborators in the AMI, CABG, and SHFFT models in order to increase the financial alignment of hospitals and other EPM collaborators with EPM participants that are financially responsible for EPM episodes. Therefore, we expect that community hospital participants in the AMI model would be able to enter into collaboration agreements with i-i transfer hospitals

accepting AMI model beneficiaries on referral to allow sharing of episode reconciliation payments or repayment responsibility with the i-i transfer hospitals if those hospitals play a significant role in care redesign of AMI or CABG care pathways or management of beneficiaries throughout AMI or CABG model episodes, including during the 90 days post-hospital discharge. We expect that community hospitals would need to coordinate closely with i-i transfer hospitals accepting AMI model beneficiaries on referral as the beneficiaries in AMI model episodes are discharged from those hospitals, in order to improve the quality and efficiency of AMI model episodes. This coordination could potentially be enhanced if i-i transfer hospitals are AMI model collaborators with financial incentives that are aligned with those of the AMI model participants through sharing arrangements.

The proposal for AMI model episode attribution in circumstances that involve inpatient-to-inpatient transfers of beneficiaries with AMI is included in § 512.240(a)(2). We seek comment on our proposal for AMI model episode attribution in circumstances that involve inpatient-to-inpatient transfers of beneficiaries with AMI, including comment on the alternatives considered.

In the outpatient-to-inpatient transfer scenario where a beneficiary with AMI is transferred from the emergency department of the initial treating hospital without admission to that hospital as an inpatient to an o-i transfer hospital for admission, we propose that the AMI or CABG model episode would begin at the o-i transfer hospital based on the MS-DRG (and AMI ICD-CM diagnosis code if a PCI MS-DRG applies) that is assigned to that anchor hospitalization. That is, if a beneficiary receives initial AMI care in a hospital emergency department without admission and is transferred to an AMI or CABG model participant (the o-i transfer hospital) for admission, then the AMI or CABG model episode would begin in the first

hospital involved in the beneficiary's AMI or CABG care that admits the beneficiary as an inpatient, specifically the o-i transfer hospital. Therefore, the o-i transfer hospital would be financially responsible for the AMI or CABG model episode. This proposed attribution is in accordance with the proposed AMI and CABG model rules, as discussed in sections III.C.4.a.(2) and (3) of this proposed rule, that initiate an AMI model episode with a hospitalization that results in discharge from an AMI MS-DRG or PCI MS-DRG with an AMI ICD-CM diagnosis code in the principal or secondary position from an AMI model participant or a CABG model episode with a hospitalization that results in discharge from a CABG MS-DRG. Under this proposal, the o-i transfer hospital's quality measure performance would determine the effective discount factor to be applied to the AMI or CABG model benchmark episode price for the episode at reconciliation as described in section III.D.4.b.(10) of this proposed rule. Under this proposal, regardless of whether the initial treating hospital is an AMI or CABG model participant, an AMI or CABG model episode would only be initiated at the o-i transfer hospital if that hospital is an AMI or CABG model participant.

We considered an overarching alternative policy that would begin every AMI or CABG model episode at the first AMI or CABG model participant at which either:

- The beneficiary presented to the emergency department for initial AMI care before being transferred to an o-i transfer hospital; or
- The beneficiary was admitted for an AMI MS-DRG, PCI MS-DRG with an AMI ICD-CM diagnosis code, or a CABG MS-DRG.

The AMI or CABG model participant where the episode begins would then be financially responsible for the AMI or CABG model episode unless the episode is canceled. Under this alternative, there would no changes to our proposals for attributing episodes with no

transfers or inpatient-to-inpatient transfers.

However, under this alternative, if the beneficiary presented for initial AMI care to the emergency department of an AMI or CABG model participant, the AMI or CABG model episode would begin at this initial treating hospital when a beneficiary is transferred from the emergency department for his or her first inpatient hospitalization which occurs at an o-i transfer hospital. This would place financial responsibility for the AMI or CABG model episode on the initial treating hospital despite the fact that the beneficiary was transferred from that hospital without being admitted, and the initial treating hospital's quality measure performance would determine the effective discount factor to be applied to the AMI or CABG model benchmark episode price for the episode at reconciliation as described in section III.D.4.b.(10) of this proposed rule.

Identifying the emergency department visit at the initial treating hospital would require using Field (Form Locator) 15 – Point of Origin for Admission or Visit code on the CMS 1450 IPPS claim from the o-i transfer hospital to identify transfer from another hospital and linking that claim to the hospital outpatient claims from the initial treating hospital for the emergency department visit and other hospital outpatient services that occurred within a certain period of time prior to the o-i transfer hospital admission and that are related to the AMI care. The episode would be assigned to the AMI model even if the beneficiary received a CABG at the o-i transfer hospital, and we would assign financial responsibility for the AMI model episode to the initial treating hospital. Under this alternative, the initial treating hospital's quality measure performance would determine the effective discount factor to be applied to the AMI model benchmark episode price for the episode at reconciliation as described in section III.D.4.b.(10) of this proposed rule. We would also need to identify other types of related services to include

in the episode that would begin prior to the o-i transfer hospital admission, such as physicians' services for care in the emergency department.

This alternative would have the benefit of consistently including all care in each AMI or CABG model episode that occurs following presentation of a beneficiary with AMI to the emergency department of an AMI or CABG model participant in the AMI or CABG model episode, regardless of whether an AMI or CABG model episode involves no transfer, o-i transfer, or i-i transfer. However, because this alternative would begin the AMI model episode prior to the initial hospital admission, we would need to establish additional policies for identifying the beneficiaries who initiate these episodes and define the timeframe and services that would be included in the AMI or CABG model episode prior to admission to the o-i transfer hospital.

We do not propose this alternative because we believe the policies necessary to begin the AMI or CABG model episode at the first treating hospital when an inpatient hospitalization does not occur would be complex, challenging to operationalize, and require assumptions about the relationship of care to the AMI based solely on administrative claims data that are insufficient to ensure we can accurately identify related care. We believe it remains problematic to define the services to be included in AMI or CABG model episodes if those services precede an inpatient hospitalization that would otherwise initiate the AMI or CABG model episode. For example, we would need to define the timeframe for beginning an AMI or CABG model episode with an emergency department visit for AMI that results in a transfer to the o-i transfer hospital, as well as the Part A and Part B services to be included in the AMI or CABG model episode that would result. As we discuss in section III.C.4.a.(1) of this proposed rule, we do not propose to begin any EPM episode prior to the anchor hospitalization because of

the clinical variability leading up to all EPM episodes and the challenge of identifying unrelated services prior to the inpatient hospitalization. Thus, we do not propose to make an exception for transfers from the emergency department of the initial treating AMI or CABG model participant hospital when the beneficiary with AMI is not admitted to that hospital.

We seek comment on the proposal for AMI and CABG model episode initiation and attribution for the outpatient-to-inpatient transfer scenario, as well as the alternative considered that would begin an episode upon presentation of a beneficiary for initial AMI care to the emergency department of an AMI or CABG model participant when the care results in an outpatient-to-inpatient transfer.

Table 4 provides a summary of our proposals for episode initiation and attribution at the beginning of AMI care for no transfer, inpatient-to-inpatient transfer, and outpatient-to-inpatient transfer scenarios, including a description of how these relate to the participation in the AMI or CABG models of hospitals providing initial AMI care.

TABLE 4: PROPOSED INITIATION AND ATTRIBUTION OF AMI AND CABG MODEL EPISODES THAT INVOLVE NO TRANSFER, OR OUTPATIENT-TO-INPATIENT OR INPATIENT-TO-INPATIENT TRANSFERS AT THE BEGINNING OF AMI CARE

Scenario	Episode Initiation and Attribution
No transfer (participant): Beneficiary admitted to an initial treating hospital that is a participant in the AMI or CABG model for an AMI MS-DRG, PCI MS-DRG with AMI ICD-CM diagnosis code, or CABG MS-DRG.	Initiate AMI or CABG model episode based on anchor hospitalization MS-DRG. Attribute episode to the initial treating hospital.
No transfer (nonparticipant): Beneficiary admitted to an initial treating hospital that is not a participant in the AMI or CABG model for an AMI MS-DRG, PCI MS-DRG with AMI ICD-CM diagnosis code, or CABG MS-DRG.	No AMI or CABG model episode is initiated.
Inpatient-to-inpatient transfer (nonparticipant to participant): Beneficiary admitted to an	Initiate AMI or CABG model episode based on the MS-DRG at i-i transfer hospital.

Scenario	Episode Initiation and Attribution
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.	Attribute episode to the i-i transfer hospital.
Inpatient-to-inpatient transfer (participant to participant or participant to nonparticipant): Beneficiary admitted to an initial treating hospital that is an AMI or CABG model participant for an AMI MS-DRG, PCI MS-DRG with AMI ICD-CM diagnosis code, or CABG MS-DRG and later transferred to an i-i transfer hospital for an AMI, PCI, or CABG MS-DRG, regardless of whether the i-i transfer hospital is an AMI or CABG model participant.	Initiate AMI or CABG model episode based on anchor hospitalization MS-DRG at initial treating hospital. If the chained anchor hospitalization results in a final AMI, PCI, or CABG MS-DRG, calculate episode benchmark price based on the AMI, PCI or CABG MS-DRG with the highest IPPS weight. If the final MS-DRG is not an AMI, PCI, or CABG MS-DRG, cancel the episode. Attribute episode to the initial treating hospital.
Outpatient-to-inpatient transfer (nonparticipant to participant or participant to participant): Beneficiary transferred without admission from the initial treating hospital, regardless of whether the initial treating hospital is an AMI or CABG model participant, to a o-i transfer hospital that is an AMI or CABG model participant and is discharged from the o-i transfer hospital for an AMI MS-DRG, PCI MS-DRG with AMI ICD-CM diagnosis code, or CABG MS-DRG.	Initiate AMI or CABG model episode based on anchor hospitalization MS-DRG at o-i transfer hospital. Attribute episode to the o-i transfer hospital.
Outpatient-to-inpatient transfer (participant to nonparticipant): Beneficiary transferred without admission from the initial treating hospital that is an AMI or CABG participant to an o-i transfer hospital that is not an AMI or CABG model participant.	No AMI or CABG model episode is initiated.

b. Middle of EPM Episodes

Similar to the CJR model, we propose that once an EPM episode begins, it would continue until the end of the episode as described in the following section, unless certain circumstances arise during the episode (80 FR 73318). When an EPM episode is canceled, we propose that the services furnished to beneficiaries prior to and following the EPM episode

cancellation would continue to be paid by Medicare as usual but there would be no actual EPM episode spending calculation that would be reconciled against the EPM quality-adjusted target price.

Specifically, we propose that the following circumstances occurring during an EPM episode would cancel the EPM episode:

- The beneficiary ceases to meet any of the general beneficiary inclusion criteria described in section III.C.4.a.(1) of this proposed rule, except the three criteria regarding inclusion in other episode payment model episodes.
- The beneficiary dies during the anchor hospitalization.
- The beneficiary initiates any BPCI model episode.

For purposes of cancellation of EPM episodes for beneficiary overlap with other episode payment models, we propose that if a beneficiary in an EPM episode would initiate any BPCI model episode, the EPM episode would be canceled. We refer to section III.D.6.c.(1) of this proposed rule for further discussion of our proposals addressing potential overlap of beneficiaries in the proposed EPMs with BPCI. We also refer to section III.D.6.c.(3) of this proposed rule for discussion of our proposal to cancel EPM episodes for beneficiaries who become aligned with specified ACOs during EPM episodes.

Our proposal to only cancel the EPM episode if a beneficiary dies during the anchor hospitalization differs from the final CJR model policy that cancels an episode if a beneficiary dies any time during the episode (80 FR 73318). As discussed in the CJR model Final Rule for LEJR episode, we believe that it also would be appropriate to cancel an episode in the AMI, CABG, and SHFFT models when a beneficiary dies during the anchor hospitalization as there would be limited incentives for efficiency that could be expected during the anchor

hospitalization itself (80 FR 73318). We agreed with commenters on the CJR model proposed rule that we should cancel CJR model episodes for death any time during those episodes, because beneficiary deaths following LEJR would be uncommon and expected to vary unpredictably, leading to extremely high or low episode spending that was not typical for a LEJR episode. A recent analysis that pooled results from 32 studies showed the incidence of mortality during the first 30 and 90 days following hip replacement to be 0.30 percent and 0.65 percent, respectively, confirming our expectation of low mortality rates during LEJR episodes.[56] In contrast, the 30-day national CABG and AMI mortality rates as displayed on Hospital Compare are significantly higher at approximately 3 percent and 14 percent respectively.[57] Several CMS programs use 30-day mortality measures for CABG and AMI as measures of hospital quality, and these measures are proposed for use in the pay-for-performance methodology for the CABG and AMI models as discussed in section III.E.3.f. of this proposed rule. Similarly, a 2009 study shows a 30-day hip fracture mortality rate for Medicare beneficiaries of approximately 5 percent, significantly higher than the mortality rate following LEJR procedures.[58] Thus, we would expect that deaths during SHFFT model episodes would be more common than in CJR model episodes. Because beneficiaries in AMI, CABG, and SHFFT model episodes are at significant risk of death during these episodes that extends 90 days post-hospital discharge, we consider mortality to be a harmful beneficiary outcome that should be targeted for improvement through care redesign incentivized by the EPMs for these clinical conditions. Therefore, we do not believe it would be appropriate to

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[56] Berstock JR, Beswick AD, Lenguerrand E, Whitehouse MR, Blom AW. Mortality after total hip replacement surgery: A systematic review. Bone & Joint Research. 2014; 3(6):175-182. doi:10.1302/2046-3758.36.2000239.
[57] https://www.medicare.gov/hospitalcompare/search.html.
[58] Brauer CA, Coca-Perraillon M, Cutler DM, Rosen AB. Incidence and Mortality of Hip Fractures in the United States. JAMA. 2009;302(14):1573-1579. doi:10.1001/jama.2009.1462.

exclude beneficiaries from AMI, CABG, or SHFFT model episodes who die any time during the episode like we do in the CJR model. Instead, we propose to maintain beneficiary episodes in the EPMs even if death occurs during the episodes, meaning we would calculate actual EPM episode spending when beneficiaries die following discharge from the anchor hospitalization but within the 90-day post-hospital discharge episode duration and reconcile it against the quality-adjusted target price. We believe this proposal would encourage EPM participants to actively manage EPM beneficiaries to reduce their risk of death, especially as death is often preceded by expensive care for emergencies and complications. Because of the higher mortality rates for all of the proposed EPM episodes than for LEJR episodes in the CJR model, we do not consider mortality following hospital discharge to be atypical and, therefore, we propose to cancel EPM episodes only for death during the anchor hospitalization.

We further propose that the following circumstances also would cancel an AMI model episode in the circumstances of a chained anchor hospitalization when the beneficiary is discharged from acute care under an MS-DRG from the final transfer hospital in the chained anchor hospitalization that could not, itself, initiate an AMI or CABG model episode, regardless of whether the final transfer hospital is an AMI or CABG model participant (that is, the episode would be canceled if the final transfer hospital MS-DRG is any MS-DRG other than an AMI MS-DRG, PCI MS-DRG, or CABG MS-DRG);

While we would begin an AMI model episode with the first hospitalization in the chained anchor hospitalization that would initiate an episode as discussed in section III.C.4.a.(5) of this proposed rule, we understand that a variety of types of care at i-i transfer hospitals could occur following the discharge from the hospital that began the AMI model episode during the chained anchor hospitalization, most commonly further medical management of AMI and

revascularization that could be appropriately included in the AMI model episode. We further note that less than 0.2 percent of beneficiaries in historical AMI episodes have more than one inpatient-to-inpatient transfer during the chained anchor hospitalization.[59] However, in some cases transfer to another hospital during an AMI episode could result in a final i-i transfer hospital MS-DRG for care that would not itself have initiated an AMI (or CABG) model episode if all inpatient hospital care were furnished at a single hospital. For example, a beneficiary in an AMI model episode could be transferred to another hospital where the beneficiary undergoes cardiac valve surgery or treatment for renal failure or stroke. In some of these cases, further treatment at the i-i transfer hospital could be due to potentially avoidable complications resulting from insufficient care management during the AMI model episode that is initiated at the first hospital. In other cases the care at the i-i transfer hospital could be unavoidable and clinically appropriate, resulting from the beneficiary's evolving AMI or other associated chronic conditions and the specific capabilities of the hospital that initiated the AMI model episode. Therefore, we believe it would be most appropriate to cancel AMI model episodes under the circumstances when a beneficiary in an AMI model episode is discharged from acute care under an MS-DRG from the final i-i transfer hospital in the chained anchor hospitalization that is not an AMI, PCI, or CABG MS-DRG that could initiate an AMI or CABG model episode (that is, the episode would be canceled if the final transfer hospitalization MS-DRG is any MS-DRG other than an AMI, PCI, or CABG MS-DRG). We note that we would not require an AMI ICD-10-CM diagnosis code on all claims in a chained anchor hospitalization for a beneficiary in an AMI model episode in order to provide to an adjusted payment at the price MS-DRG for the AMI model episode as discussed in section

[59] Episodes for AMI beneficiaries initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that end in CY 2014.

III.D.4.b.(2)(a) of this proposed rule. We also would not cancel the AMI model episode if an AMI ICD-10-CM diagnosis code is not on the claim for the final transfer hospitalization, as long as the discharge is under an AMI, PCI, or CABG MS-DRG. Because the beneficiary would be in an AMI model episode during a chained anchor hospitalization, we would treat the beneficiary who is transferred to an i-i transfer hospital according to all policies that apply to the diagnosis of AMI in the CABG and AMI models, regardless of whether an AMI ICD-10-CM diagnosis code was on the PCI or CABG MS-DRG claim from the final i-i transfer hospital. Overall, this proposal would treat the hospital that initiated the AMI model episode and then transferred the beneficiary most similarly to a hospital that furnished all of the beneficiary's inpatient care itself, with respect to whether or not the beneficiary's care is ultimately included as an episode in the AMI model.

Finally, we do not propose to cancel an AMI episode altogether for a CABG readmission during the 90-day post-hospital discharge period or cancel the AMI model episode and initiate a CABG model episode because planned CABG readmission following an anchor hospitalization that initiates an AMI model episode may be an appropriate clinical pathway for certain beneficiaries. Instead, we propose to provide an adjusted AMI model-episode benchmark price that includes a CABG readmission in such circumstances so as not to financially penalize participant hospitals for relatively uncommon, costly, clinically appropriate care patterns for beneficiaries in AMI model episodes. We refer to section III.D.4.b.(2)(c) of this proposed rule for discussion of the adjusted AMI model-episode benchmark price that would apply in the case of CABG readmission during an AMI model episode.

The proposals for cancellation of EPM episodes are included in § 512.240(a)(3), (b)(2), and (c)(2). We seek comment on our proposals for cancellation of EPM episodes.

c. End of EPM Episodes

(1) AMI and CABG Models

We propose a 90-day post-hospital discharge episode duration for AMI model episodes. AMI in general, whether managed medically or with revascularization, has a lengthy recovery period, during which the beneficiary has a higher than average risk of additional cardiac events and other complications, as well as higher utilization of diagnostic testing and related cardiac procedures. AMI frequently serves as a sentinel event that marks the need for a heightened focus on medical management of coronary artery disease and other beneficiary risk factors for future cardiac events, cardiac rehabilitation over multiple months, and beneficiary education and engagement. Given the broad episode definition for AMI model episodes that includes beneficiaries receiving both medical and PCI management for an acute event, we do not believe that an episode longer than 90 days would be feasible due to the higher risk of including unrelated services in the episode beyond several months after hospital discharge. However, we believe that 90-day post-hospital discharge episodes would provide substantial incentives for aggressive medical management, cardiac rehabilitation, and beneficiary education and engagement, whereas a shorter episode duration would have less effect. We acknowledge that ongoing disease management for beneficiaries with cardiovascular disease must extend long after the conclusion of the proposed AMI model episodes. Nevertheless, we believe the proposed 90-day post-hospital discharge episode duration remains appropriate for an episode payment model focused around a hospitalization. We expect that the medical management and care coordination during AMI model episodes would continue to be provided as beneficiaries transition out of AMI model episodes, potentially into a primary care medical home or other model or program with accountability for population health, such as an ACO.

We further note based on analysis of historical episodes that about 10 percent of beneficiaries hospitalized with AMI who received a CABG received the CABG between 2 and 90 days post-discharge from the anchor hospitalization (these beneficiaries would be in AMI model episodes), while the remaining 90 percent of CABGs for beneficiaries hospitalized with AMI were provided during the initial hospitalization (these beneficiaries would in CABG model episodes). In contrast, fewer than 3 percent of those AMI model beneficiaries who received an inpatient or outpatient PCI during an AMI model episode received the PCI between 2 and 90 days post-discharge from the anchor hospitalization, while more than 97 percent received the PCI during the anchor hospitalization.[60] We refer to section III.D.4.b.(2)(c) of this proposed rule for further discussion of pricing adjustments and alternatives considered for setting EPM-episode benchmark prices for AMI model episodes where PCI or CABG occurs during the AMI episode but post-discharge from the anchor or chained anchor hospitalization.

Finally, for similar reasons, we believe CABG model episodes should extend 90 days post-hospital discharge. About one-third of CABG procedures are performed in the context of a hospital admission for AMI, leading to the same considerations discussed previously in this section around the appropriate episode duration for beneficiaries with AMI. The remaining CABG model beneficiaries are likely to have significant ischemic heart disease, making the occurrence of CABG itself a sentinel event, like AMI, that marks the need for a heightened focus on medical management of CAD and other beneficiary risk factors for future cardiac events, cardiac rehabilitation over multiple months, and beneficiary education and engagement. Moreover, CABG procedures have 90-day global periods under the Physician Fee Schedule, consistent with the lengthy period of recovery associated with major chest surgery. Thus, a

[60] Episodes for AMI beneficiaries initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that end in CY 2014.

90-day post-hospital discharge episode duration is consistent with the recovery period from CABG surgery. We acknowledge that ongoing disease management for beneficiaries with cardiovascular disease must extend long after the conclusion of the proposed CABG model episodes. Nevertheless, we believe the proposed 90-day post-hospital discharge episode duration remains appropriate for an episode payment model focused around a hospitalization. We expect that the medical management and care coordination during CABG model episodes would continue to be provided as beneficiaries transition out of CABG model episodes, potentially into a primary care medical home or other model or program with accountability for population health, such as an ACO.

As in the CJR model, we propose that the day of discharge from the anchor hospitalization counts as day 1 of the post-hospital discharge period (80 FR 73324). However, in the case of an AMI model episode that includes a chained anchor hospitalization, we would count the day of discharge from the final hospitalization in the chained anchor hospitalization as day 1 of the post-hospital discharge period. Since the post-hospital discharge period is intended to extend 90 days for recovery following hospital discharge, we believe it is appropriate under these circumstances to begin the 90-day count when the beneficiary is ultimately discharged from acute care for the first time during the AMI model episode. However, the hospital that initiated the AMI model episode in the chained anchor hospitalization would continue to be responsible in the AMI model for the episode discussed previously in section III.C.4.a.(5) of this proposed rule.

The proposals for the end of AMI and CABG model episodes are included in §§ 512.240(a)(1) and (b)(1), respectively. We seek comment on our proposals to end AMI and CABG model episodes.

(2) SHFFT Model

We believe that SHFFT model beneficiaries are similar to CJR model beneficiaries who undergo hip replacement for fracture. We believe that the same episode duration as the CJR model of 90 days is appropriate for SHFFT model episodes in order to include the full time for recovery of function for these beneficiaries, which extends beyond 60 days based on patterns of post-acute care provider use (80 FR 73319 through 73324). Therefore, we propose a 90-day post-hospital discharge duration for SHFFT model episodes.

The proposal for the end of SHFFT model episodes are included in § 512.240(c)(1). We seek comment on our proposal to end SHFFT model episodes.

III. Provisions of the Proposed Regulations

D. Methodology for Setting EPM Episode Prices and Paying EPM Participants in the AMI, CABG, and SHFFT Models

1. Background

a. Overview

We propose that the AMI, CABG, and SHFFT models would provide incentives for EPM participants to work with other health care providers and suppliers to improve the quality and efficiency of care for Medicare beneficiaries by paying EPM participants or holding them responsible for repaying Medicare based on EPM participants' performance with respect to the quality and spending for AMI, CABG, and SHFFT episodes in a manner similar to the CJR model. Given the general similarity between the design of the CJR model and these EPMs, there is precedent for adopting the general payment and pricing parameters used under the CJR model, with modification to appropriately pay for EPM episodes that include the different clinical conditions treated in AMI, CABG, and SHFFT model episodes. The following sections describe our proposals for the:

- Performance year, retrospective episode payments, and two-sided risk EPMs.
- Adjustments to actual EPM-episode payments and to historical episode payments used to set episode prices.
- EPM episode price-setting methodologies.
- Process for reconciliation.
- Adjustments for overlaps with other Innovation Center models and CMS programs.
- Limits or adjustments to EPM participants' financial responsibility.

b. Key Terms for EPM Episode Pricing and Payment

For purposes of ease of understanding of the technical discussion that follows around EPM episode pricing and payment, we are providing the following definitions of terms that are used in sections that precede their technical definition and cross-references to other sections of this proposed rule for more detailed discussion of the policies associated with these terms.

- Anchor hospitalization - hospitalization that initiates an EPM episode and has no subsequent inpatient-to-inpatient transfer chained anchor hospitalization.
- Chained anchor hospitalization - an anchor hospitalization that initiates an AMI model episode and has at least one subsequent inpatient-to-inpatient transfer.
- Anchor MS-DRG - MS-DRG assigned to the first hospitalization discharge, which initiates an EPM episode.
- Price MS-DRG - for EPM episodes without a chained anchor hospitalization, the price MS-DRG is the anchor MS-DRG. For AMI model episodes with a chained anchor hospitalization, the price MS-DRG is the MS-DRG assigned to the AMI model episode according to the hierarchy described in III.D.4.b.(2)(i).
- Episode benchmark price - dollar amount assigned to EPM episodes based on historical EPM-episode data (3 years of historical Medicare payment data grouped into EPM episodes according to the EPM episode definitions as discussed in sections III.C.3. and III.C.4. of this proposed rule) prior to the application of the effective discount factor, as described throughout sections III.D.4.b through e. of this proposed rule.
- CABG readmission AMI model episode benchmark price - episode benchmark price assigned to certain AMI model episodes with price MS-DRG 280-282 or 246-251 and with a readmission for MS-DRG 231-236, as described in sections III.D.4.b.(2)(c) and III.D.4.e. of this proposed rule.

- Quality-adjusted target price - dollar amount assigned to EPM episodes as the result of reducing the episode benchmark price by the EPM participant's effective discount factor based on the EPM participant's quality performance, as described in sections III.D.4.b.(10) and III.E.3.f. of this proposed rule.

- Excess EPM-episode spending - dollar amount corresponding to the amount by which actual EPM-episode payments for all EPM episodes attributed to an EPM participant exceed the quality-adjusted target prices for the same EPM episodes, as discussed in section III.D.2.c. of this proposed rule.

2. Performance Years, Retrospective Episode Payments, and Two-Sided Risk EPMs

a. Performance Period

Consistent with the methodology for the CJR model, we propose 5 performance years (PYs) for the EPMs, which would include EPM episodes for the periods displayed in the following Table 5:

TABLE 5: PERFORMANCE YEARS FOR EPMS

Performance Year (PY)	Calendar Year	EPM Episodes Included in Performance Year
1	2017	EPM episodes that start on or after July 1, 2017 and end on or before December 31, 2017
2	2018	EPM episodes that end between January 1, 2018 and December 31, 2018, inclusive
3	2019	EPM episodes that end between January 1, 2019 and December 31, 2019, inclusive
4	2020	EPM episodes that end between January 1, 2020 and December 31, 2020, inclusive
5	2021	EPM episodes that end between January 1, 2021 and December 31, 2021, inclusive

As displayed in Table 5, some EPM episodes that would begin in a given calendar year may be captured in the following performance year due to some EPM episodes ending after

December 31st of a given calendar year. For example, EPM episodes beginning in December 2017 and ending in March 2018 would be part of performance year 2. We believe that the proposed period of time for the EPMs, which generally aligns with the performance period for other Innovation Center models, for example, the CJR and Pioneer ACO models, should be sufficient to test and gather the data needed to evaluate the EPMs (80 FR 73325). In contrast, we would be concerned whether an EPM with fewer than 5 performance years would be sufficient for these purposes.

We also recognize that our proposal would allow only 6 months of EPM episodes for PY1 as compared to 9 months for the CJR model. We considered extending the first PY, for example, to 18 months. As discussed further in section III.D.2.c. of this proposed rule, however, we are instead proposing to delay the requirement for participants to begin accepting downside risk until the second quarter of PY2. As such, EPM participants would have a comparable transition period to that of CJR participants with respect to when they must accept downside risk while still allowing us to make timely reconciliation payments to EPM participants as well as to most effectively align EPM reconciliation with the reconciliation processes for other models and programs with which the EPMs overlap (for example., the Shared Savings Program, Pioneer ACO model, Comprehensive Primary Care Initiative, and Oncology Care Model). We believe that it is important to synchronize the timing of reconciliation for EPMs with other efforts that need this information when making their financial calculations. We seek comment on this proposal.

b. Retrospective Payment Methodology

Consistent with the CJR model, we propose to apply a retrospective payment methodology to the proposed EPMs (80 FR 73329). Under this proposal, all providers and

suppliers caring for Medicare beneficiaries in EPM episodes would continue to bill and be paid as usual under the applicable Medicare payment systems. After the completion of an EPM performance year, Medicare claims for services furnished to EPM beneficiaries would be grouped into EPM episodes and aggregated, and EPM participants' actual EPM episode-payments compared to quality-adjusted target prices (which account for the level of EPM episode quality), as described in section III.D.5.a. of this proposed rule. Based on an EPM participant's performance (taking into account quality and spending), we would determine if Medicare would make a payment to the participant (reconciliation payment), or if the participant owes money to Medicare (resulting in Medicare repayment).

We considered an alternative option of paying for EPM episodes prospectively by paying one lump sum amount to the EPM participant for the expected spending for the EPM episode which extends 90 days post-hospital-discharge. However, as was the case when we established regulations for the CJR model, we continue to believe that such an option would be challenging to implement at this time given the payment infrastructure changes for both EPM participants and Medicare that would need to be developed to pay and manage prospective episode payments under these EPMs (80 FR 73329). Moreover, we continue to believe that a retrospective payment approach can accomplish the objective of testing episode payments in a broad group of hospitals, including financial incentives to streamline care delivery around that episode, without requiring core billing and payment changes by providers and suppliers, which would create substantial administrative burden.

We seek comment on this proposal.

c. Two-Sided Risk EPMs

As we did for the CJR model, we propose to establish two-sided risk for hospitals

participating in the EPMs. Under this proposal, for each of performance years 1 through 5, we would make EPM-episode reconciliation payments to EPM participants that achieve reduced actual EPM payments relative to their quality-adjusted target prices (80 FR 73229-7333). Likewise, beginning with episodes ending in the second quarter of performance year 2 and extending through each of performance years 3 through 5, we would hold EPM participants responsible for repaying Medicare when their actual EPM-episode payments exceed their quality-adjusted target prices. As such, our proposal differs from CJR in that we are proposing a modestly shorter period in which EPM participants would accept downside risk in order to allow them a comparable transition period to that of CJR participants in which to do so. Accordingly, we will refer to the two portions of performance year 2 as --

- Performance Year 2 (NDR) or 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. We believe that our proposal to establish two-sided risk would provide appropriate incentives for EPM participants to improve their care quality and efficiency under the EPMs. We also continue to believe, as we indicated in the CJR Final Rule, that we would diminish these incentives if we instead proposed to establish one-sided risk, in which an EPM participant could qualify for a reconciliation payment but not be held responsible for Medicare repayments (80 FR 73329). In recognition that EPM participants may need to make infrastructure, care coordination and delivery, and financial preparations for the EPMs, which can take several months or longer to implement, we do believe that it is reasonable

to delay EPM participant responsibility for repaying excess EPM-episode spending in performance year 1 to more strongly align EPM-participant incentives with care quality. Thus, similar to what we did for the CJR model, we are proposing to phase-in this repayment responsibility beginning in the second quarter of EPM performance year 2 as displayed in Table 6.

We refer to section III.E.3.f. of this proposed rule for additional information on the effective discount factors used to calculate quality-adjusted target prices, as well as the quality categories that determine an EPM participant's effective discount factor that would be applied to the EPM benchmark episode price at reconciliation to calculate the repayment amount during the phase-in period in EPM performance year 2 (quarters 2 through 4) and performance year 3. Table 6 also presents the phase-in of the proposed stop-loss limits and discount percentages, which are discussed in detail in section III.D.7.b. and III.D.4.b.(10) of this proposed rule.

We seek comment on this proposal.

TABLE 6: STOP-LOSS THRESHOLDS AND DISCOUNT PERCENTAGE RANGES FOR MEDICARE REPAYMENTS BY PY

	PY1	**PY2 (NDR)**	**PY2 (DR)**	**PY3**	**PY4**	**PY5**
Stop-loss threshold	n/a as no downside risk in PY1 and PY2 (DR)		5%	10%	20%	20%
Discount percentage (range) for Repayment, Depending on Quality Category			0.5%-2.0%	0.5%-2.0%	1.5%-3.0%	1.5%-3.0%

*Stop-loss thresholds for certain hospitals, including rural and sole-community hospitals are 3% for PY2 (DR) and 5% for PY3-PY5.

3. Adjustments to Actual EPM-Episode Payments and to Historical Episode Payments used to Set Episode Prices

a. Overview

We propose to calculate actual EPM-episode payments and historical episode payments (3 years of historical Medicare payment data grouped into EPM episodes according to the EPM episode definitions as discussed in sections III.C.3. and III.C.4. of this proposed rule) to calculate EPM quality-adjusted target prices for each performance year of the EPMs as we did for the CJR model—that is, for each non-cancelled EPM episode, we would calculate these amounts based on Medicare payments for Parts A and B claims for services included in the EPM episode definition. As was the case for the CJR model, we also propose to include certain payment adjustments in the EPMs for: (1) special payment provisions under existing Medicare payment systems; (2) payments for services that straddle episodes; and (3) high payment episodes (80 FR 73330 through 73336). We also propose to additionally include an adjustment for reconciliation payments and Medicare repayments when updating EPM participant episode benchmark and quality-adjusted target prices (80 FR 73330 through 73331). We refer to section III.D.6. of this proposed rule for discussion of adjustments for overlaps with other Innovation Center models and CMS programs.

b. Special Payment Provisions

Many of the existing Medicare payment systems have special payment provisions that have been created by regulation or statute to improve quality and efficiency in service delivery. IPPS hospitals are subject to incentives under the HRRP, the HVBP Program, the Hospital-Acquired Condition (HAC) Reduction Program, and the HIQR Program and Outpatient Quality Reporting (OQR) Program. IPPS hospitals and CAHs are subject to the Medicare

Electronic Health Record (EHR) Incentive Program. Additionally, the majority of IPPS hospitals receive additional payments for Medicare Disproportionate Share Hospital (DSH) and Uncompensated Care, and IPPS teaching hospitals can receive additional payments for Indirect Medical Education (IME). IPPS hospitals that meet certain requirements related to low volume Medicare discharges and distance from another hospital receive a low volume add-on payment. Also, some IPPS hospitals qualify to be sole community hospitals (SCHs) or Medicare Dependent Hospitals (MDHs), and they may receive enhanced payments based on cost-based hospital-specific rates for services; whether a SCH or MDH receives enhanced payments may vary year to year, in accordance with § 419.43(g) and § 412.108(g), respectively.

Medicare payments to providers of post-acute care services, including IRFs, SNFs, IPFs, HHAs, LTCHs, and hospice facilities, are conditioned, in part, on whether the provider satisfactorily reports certain specified data to CMS: Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP); Skilled Nursing Facility Quality Reporting Program (SNF QRP); Inpatient Psychiatric Facility Quality Reporting Program (IPF QRP); Home Health Quality Reporting Program (HH QRP); Long-Term Care Hospital Quality Reporting Program (LTCH QRP); and Hospice Quality Reporting Program. Additionally, IRFs located in rural areas receive rural add-on payments, IRFs serving higher proportions of low-income beneficiaries receive increased payments according to their low-income percentage (LIP), and IRFs with teaching programs receive increased payments to reflect their teaching status. SNFs receive higher payments for treating beneficiaries with human immunodeficiency virus (HIV). HHAs located in rural areas also receive rural add-on payments.

Ambulatory Surgical Centers (ASCs) have their own Quality Reporting Program (ASC QRP). Physicians also have a set of special payment provisions based on quality and reporting:

Medicare EHR Incentive Program for Eligible Professionals; Physician Quality Reporting System (PQRS); and Physician Value-based Modifier Program.

Consistent with how we determine payments under the CJR model, we propose to adjust both the actual and historical EPM-episode payments used to set EPM-episode benchmark and quality-adjusted target prices by excluding these special payments from EPM-episode calculations using the CMS Price Standardization methodology (80 FR 73333). We believe that in applying this methodology to exclude these payments from our calculations, we would best maintain appropriate incentives for both the proposed EPMs and the existing incentive programs. Also, not excluding add-on payments based on the characteristics of providers caring for EPM beneficiaries, such as more indigent patients, having low Medicare hospital volume, being located in a rural area, supporting greater levels of physician training, and having a greater proportion of beneficiaries with HIV, from actual EPM-episode payments could inappropriately result in certain EPM participants that receive more add-on payments having worse episode payment performance compared to quality-adjusted target prices than what their performance would otherwise have been. Additionally, not excluding enhanced payments for MDHs and SCHs could result in higher or lower quality-adjusted target prices just because EPM participants received their enhanced payments in 1 historical year but not the other, regardless of actual utilization. We also believe that excluding special payments would ensure an EPM participant's actual episode payment performance is not artificially improved or worsened because of payment reduction penalties or incentives or enhanced or add-on payments, the effects of which we are not intending to test under the proposed models. In addition to the various incentives, enhanced payments, and add-on payments, sequestration came into effect for Medicare payments for discharges on or after April 1, 2013, per the Budget Control Act of 2011 and delayed by the

American Taxpayer Relief Act of 2012. Sequestration applies a 2-percent reduction to Medicare payment for most Medicare FFS services.

For more information on the CMS Price (Payment) Standardization Detailed Methodology, we refer to the QualityNet Web site at http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350 and to 80 FR 73331.

Accordingly, we propose to exclude these special payments from EPM-episode calculations using the CMS Price Standardization methodology at § 512.300(e)(2). We seek comment on our proposal to exclude special payments using the CMS Price Standardization methodology.

c. Services that Straddle Episodes

A service that straddles an EPM episode is one that begins before the start of or continues beyond the end of an EPM episode that extends 90 days post-hospital discharge. Under the CJR model, we prorate payments so that they include only the portion of the payment that is included in the CJR model episode, using separate approaches to prorate payments under each payment system, for example, IPPS, non-IPPS and other inpatient services, and home health services (80 FR 73333 through 73335). We propose to apply the CJR model methodologies for prorating payments when calculating actual EPM-episode payments and when calculating historical EPM-episode payments used to set EPM-episode benchmark and quality-adjusted target prices. We believe these methodologies would most accurately account for spending within EPM episodes under the proposed EPMs.

The proposed methodologies for prorating payments are included in § 512.300(f). We seek comment on our proposed methodologies for prorating payments.

d. High-Payment EPM Episodes

For the CJR model, we defined a high-payment episode as an episode with payments 2 standard deviations or more above the mean calculated at the regional level (80 FR 73336 through 73337). As with the CJR model, we propose applying a high-payment episode ceiling when calculating actual EPM-episode payments and when calculating historical EPM-episode payments used to set EPM-episode benchmark and quality-adjusted target prices. We propose to apply the ceiling according to the following groupings that align with our proposed EPM price-setting methodology.

First, for SHFFT model episodes, we propose to calculate and apply the ceiling separately for each SHFFT price MS-DRG at the regional level.

Second, for AMI model episodes with price MS-DRGs 280-282 or 246-251 without readmission for CABG MS-DRGs, we propose to calculate and apply the ceiling separately for each price MS-DRG at the regional level.

Third, for CABG model episodes, we propose to apply ceilings separately to the payments that occurred during the anchor hospitalization of the CABG model episode and to the payments that occurred after the anchor hospitalization. For the anchor hospitalization portion of CABG model episodes, we propose to calculate and apply the ceiling separately by each price MS-DRG in 231-236 at the regional level. For the post-anchor hospitalization portion we propose to calculate and apply the ceiling separately for the following groupings at the regional level:

- With AMI ICD-CM diagnosis code on the anchor inpatient claim and price MS-DRG with major complication or comorbidity (231, 233, or 235).
- With AMI ICD-CM diagnosis code on the anchor inpatient claim and price MS-DRG

without major complication or comorbidity (232, 234, or 236).

- Without AMI ICD-CM diagnosis code on the anchor inpatient claim and price MS-DRG with major complication or comorbidity (231, 233, or 235).
- Without AMI ICD-CM diagnosis code on the anchor inpatient claim and price MS-DRG without major complication or comorbidity (232, 234, or 236).

Fourth, for AMI model episodes with price MS-DRG 231-236, we propose to apply ceilings separately to the payments that occurred during the chained anchor hospitalization and to the payments that occurred after the chained anchor hospitalization. For the anchor hospitalization portion of the episode, we propose to apply the regional level ceiling calculated for the anchor hospitalization portion of a CABG model episode for the corresponding price MS-DRG, as described previously. For the post-anchor hospitalization portion of the episode, we propose to apply the regional level ceiling calculated for the post-anchor hospitalization portion of a CABG model episode for the corresponding price MS-DRG with AMI diagnosis.

Fifth, for AMI model episodes with price MS-DRG 280-282 or 246-251 and with readmission for CABG MS-DRGs, we propose to apply the ceiling separately to the payments during the CABG readmission and all other payments during the episode. For payments during the CABG readmission portion of the AMI model episode we propose to apply the regional level ceiling calculated for the anchor hospitalization portion of a CABG model episode for the corresponding CABG readmission MS-DRG, as described previously. For all other payments during the AMI model episode, we propose to apply the regional level ceiling calculated for AMI model episodes with price MS-DRG 280-282 or 246-251 and without readmission for CABG MS-DRGs corresponding to the AMI price MS-DRG.

We believe that this ceiling would protect EPM participants from variable repayment risk

for especially-high payment EPM episodes where the clinical scenarios for these cases each year may differ significantly and unpredictably.

The proposal for capping high payment EPM episodes is included in § 512.300(e)(1). We seek comment on our proposal to cap high payment EPM episodes.

e. Treatment of Reconciliation Payments and Medicare Repayments when Calculating Historical EPM-Episode Payments to Update EPM-Episode Benchmark and Quality-Adjusted Target Prices

For the CJR model, we exclude CJR model reconciliation payments and Medicare repayments from the expenditure data used to update historical claims when calculating CJR model target prices, although we received comments on the proposed rule encouraging us to include these payments. For example, commenters supported their inclusion because CJR-participating hospitals otherwise would be providing care coordination services that would not be paid directly or accounted for under applicable Medicare FFS payments systems and thus might be funded through reconciliation payments. Further, by excluding reconciliation payments from our calculations, commenters suggested that we may underestimate their actual resource costs when updating target prices for the care necessary during episodes. The CJR Final Rule discussed our view that including reconciliation payments would have the effect of Medicare paying CJR model participant hospitals their target prices, regardless of whether such participant was below, above, or met their episode target price. We also noted that we had not discussed any alternatives in the CJR model proposed rule, and that we might consider including these payments in updating historical claims through future rulemaking (80 FR 73332).

After further consideration, we are proposing to include both reconciliation payments and Medicare repayments when calculating historical EPM-episode payments to update

EPM-episode benchmark and quality-adjusted target prices. We concur with the views expressed by commenters on the CJR model proposed rule that including these payments would more fully recognize the total resource costs of care under an EPM than would their exclusion. As indicated in section V.5 of this proposed rule, we are also proposing to modify our policy for the CJR model to also include reconciliation payments and Medicare repayments when updating target prices under that model We also considered an option where we would include only reconciliation payments when updating but not Medicare repayments; however, we believe this option would not achieve our intention of more fully capturing the costs of care under the EPM. We would further note that the inclusion of both reconciliation payments and Medicare repayments could have differential effects on an EPM participant's benchmark and quality-adjusted target prices based on whether or not it received a reconciliation payment or made a Medicare repayment. For example, all else equal, including an EPM reconciliation payment when updating an EPM participant's EPM-episode benchmark and quality-adjusted target prices would modestly increase the quality-adjusted target prices in performance years 3 through 5 in comparison to not including the reconciliation payment. Conversely, all else equal, including a Medicare repayment when updating an EPM participant's EPM-episode benchmark and quality-adjusted target prices would reduce the next performance year's quality-adjusted target price in comparison to not including the Medicare repayment.

Following analogous logic, we also propose to include BPCI Net Payment Reconciliation Amounts in our calculations when updating EPM-episode benchmark and quality-adjusted target prices. We would note, however, that the effects of these proposals would largely be confined to PY3 of the EPMs and diminish as EPM-participant historical EPM-episode updates are eventually determined based on regional payments in subsequent years of the EPMs. This is

because the net sum of EPM reconciliation payments, Medicare repayments, and BPCI Net Payment Reconciliation Amounts would represent a small portion of the total historical EPM- episode payments captured in regional pricing.

When updating EPM-episode benchmark and quality adjusted target prices for CABG model episodes, we propose to apportion EPM reconciliation payments and BPCI Net Reconciliation Payment Amounts proportionally to the anchor hospitalization and post-anchor hospitalization portions of CABG model historical episodes. We also propose to calculate the proportions based on regional average historical episode payments that occurred during the anchor hospitalization portion of CABG model episodes and regional average historical episode payments that occurred during the post-anchor anchor hospitalization portion of CABG model episodes that were initiated during the 3 historical years. This aligns with the general proposal to calculate the CABG model-episode benchmark price as the sum of the corresponding CABG anchor hospitalization benchmark price and the corresponding CABG post-anchor hospitalization benchmark price, as discussed in III.D.4.b.(2)(ii) and III.D.4.d. of this proposed rule.

The proposal to include both reconciliation payments and Medicare repayments when calculating historical EPM-episode payments to update EPM-episode benchmark and quality-adjusted target prices is included in § 512.300(c)(8). We seek comment on our proposal to include both reconciliation payments and Medicare repayments when calculating historical EPM- episode payments to update EPM-episode benchmark and quality-adjusted target prices.

4. EPM-Episode Price-Setting Methodologies

a. Overview

Whether an EPM participant receives a reconciliation payment or is made responsible to

repay Medicare under the proposed EPM is based on the EPM participant's actual EPM- episode payments relative to quality-adjusted target prices, as well as the EPM participant's eligibility for reconciliation payment based on acceptable, good, or excellent quality performance. While our proposals for relating EPM participant quality performance to EPM payments are further discussed in section III.E.3.f of this proposed rule, the remainder of this section will discuss the proposed approach to establishing EPM-episode benchmark and quality-adjusted target prices.

For the purposes of price-setting, any references in this proposed rule to AMI ICD-CM diagnosis codes means those ICD-9-CM and ICD-10-CM diagnosis codes for historical EPM episodes or ICD-10-CM diagnosis codes for EPM episodes during the EPM performance years that can be found in the specific EPM episode definitions parameters spreadsheet. Also, for the purposes of price-setting, any references in this proposed rule to intracardiac ICD-CM procedure codes means those ICD-9-CM procedure codes for historical EPM episodes that can be found in the specific EPM episode definitions parameters spreadsheet. The EPM episode definitions parameters spreadsheets are posted on the CMS web site at https://innovation.cms.gov/inititatives/epm.

We propose to establish EPM-episode benchmark and quality-adjusted target prices for each EPM participant based on the following MS-DRGs and diagnoses included in the AMI, CABG, and SHFFT models as discussed in sections III.C.3 and III.C.4. of this proposed rule:

(1) AMI model

- AMI MS-DRGs --

++ 280 (Acute myocardial infarction, discharged alive with MCC);

++ 281 (Acute myocardial infarction, discharged alive with CC);

++ 282 (Acute myocardial infarction, discharged alive without CC/MCC); and

- PCI MS-DRGs, when the claim includes an AMI ICD-CM diagnosis code in the principal or secondary position on the inpatient claim and when the claim does not include an intracardiac ICD-CM procedure code in any position on the inpatient claim --

++ 246 (Perc cardiovasc proc with drug-eluting stent with MCC or 4+ vessels/stents);

++ 247 (Perc cardiovasc proc with drug-eluting stent without MCC);

++ 248 (Perc cardiovasc proc with non-drug-eluting stent with MCC or 4+ vessels/stents);

++ 249 (Perc cardiovasc proc with non-drug-eluting stent without MCC);

++ 250 (Perc cardiovasc proc without coronary artery stent with MCC); and

++ 251 (Perc cardiovasc proc without coronary artery stent without MCC).

(2) CABG model DRGs --

- 231 (Coronary bypass with PTCA with MCC);
- 232 (Coronary bypass with PTCA without MCC);
- 233 (Coronary bypass with cardiac cath with MCC);
- 234 (Coronary bypass with cardiac cath without MCC);
- 235 (Coronary bypass without cardiac cath with MCC); and
- 236 (Coronary bypass without cardiac cath without MCC).

(3) SHFFT model DRGs --

- 480 (Hip and femur procedures except major joint with MCC);
- 481 (Hip and femur procedures except major joint with CC); and
- 482 (Hip and femur procedures except major joint without CC or MCC).

We propose to generally apply the CJR model methodology to set EPM-episode benchmark and quality-adjusted target prices, with the addition of some adjustments based on

the specific clinical conditions and care patterns for EPM episodes included in the AMI, CABG, and SHFFT models (80 FR 73337 through 73338). The proposed price-setting methodology incorporates the following features:

- Set different EPM benchmark and quality-adjusted target prices for EPM episodes based on the assigned price MS-DRG in one of the included MS-DRGs to account for patient and clinical variations that impact EPM participants' costs of providing care. Inpatient claims with PCI MS-DRGs 246-251 that contain an intracardiac ICD-CM procedure code in any position would not anchor an historical episode, nor be considered when assigning a price MS-DRG. This is because beginning in FY 2016, inpatient claims containing an intracardiac ICD-10-CM procedure code in any position no longer map to MS-DRGs 246-251.

- Adjust EPM benchmark and quality-adjusted target prices for certain EPM episodes involving chained anchor hospitalizations, specific readmissions, or the presence of an AMI ICD-CM diagnosis code for CABG MS-DRGs.

- Use 3 years of historical Medicare FFS payment data grouped into EPM episodes according to the EPM episode definitions in sections III.C.3 and III.C.4. of this proposed , termed historical EPM episodes and historical EPM-episode payments. The specific set of 3 historical years would be updated every other performance year.

- Apply Medicare payment system (for example, IPPS, OPPS, IRF PPS, SNF, MPFS.) updates to the historical EPM-episode data to ensure we incentivize EPM participants based on historical utilization and practice patterns, not Medicare payment system rate changes that are beyond such participants' control. Because different Medicare payment system updates become effective at two different times of the year, we would calculate one set of EPM-benchmark and quality-adjusted target prices for EPM episodes initiated between January 1 and September 30

and another set for EPM episodes initiated between October 1 and December 31.

- Blend together EPM-participant hospital-specific and regional historical EPM-episode payments, transitioning from primarily hospital-specific to completely regional pricing over the course of the 5 performance years, to incentivize both historically-efficient and less-efficient EPM participants to furnish high quality, efficient care in all years of the EPM Regions would be defined as each of the nine U.S. Census divisions.
- Normalize for hospital-specific wage-adjustment variations in Medicare payment systems when combining hospital-specific and regional historical EPM episodes.
- Pool together EPM episodes by groups of price MS-DRGs to allow a greater volume of historical cases and allow us to set more stable prices.
- Apply an effective discount factor on EPM-episode benchmark prices to serve as Medicare's portion of reduced expenditures from the EPM episode, with any remaining portion of reduced Medicare spending below the quality-adjusted target price potentially available as reconciliation payments to the EPM participant where the anchor hospitalization occurred.
- Further discussion on each of the proposed features and sequential steps to calculate EPM-episode benchmark and quality-adjusted target prices can be found in sections III.D.4.b through e. of this proposed rule, which immediately follow.

We also propose to calculate and communicate EPM-episode benchmark and quality-adjusted target prices to EPM participants prior to the performance period in which the prices apply (that is, prior to January 1, 2018, for prices covering EPM episodes that start between January 1, 2018, and September 30, 2018; prior to October 1, 2018, for prices covering EPM episodes that start between October 1, 2018, and December 31, 2018). We believe that prospectively communicating EPM-episode benchmark and quality-adjusted target prices to

EPM participants would help them make infrastructure, care coordination and delivery, and financial refinements they may deem appropriate to prepare for the new episode target prices under the model.

The proposal to prospectively communicate quality-adjusted target prices are included in § 512.300(c)(9). We seek comment on our proposal to prospectively communicate these prices.

b. EPM-Episode Benchmark and Quality-Adjusted Target Price Features

(1) Risk-Stratifying EPM-Episode Benchmark Prices based on MS–DRG and Diagnosis

To account for some of the clinical and resource variations that would be expected to occur under the EPMs, we propose generally to apply the episode pricing methodology that was applied to the CJR model to develop the EPM-episode benchmark prices, hereinafter called the standard EPM-episode benchmark price. In addition, for each EPM participant, we propose to risk-stratify and establish special EPM-episode benchmark prices for episodes in different pricing scenarios as described in this section, as well as sections III.D.4.c. through e. of this proposed rule. For purposes of this proposed rule, risk-stratification means the methodology for developing the EPM-episode benchmark price that accounts for clinical and resource variation in historical EPM episodes so that the quality-adjusted target price (calculated from the EPM-episode benchmark price) can be compared to actual EPM episode payments for EPM beneficiaries with similar care needs to those in historical EPM episodes.

For the SHFFT model, we propose to set the price MS-DRG equal to the anchor MS-DRG. We propose to calculate standard SHFFT model-episode benchmark prices based on price MS-DRGs following the general payment methodology that was applied to the CJR model with risk stratification according to the anchor MS-DRG (80 FR 73337 through 73358).

Similarly, for AMI model episodes without chained anchor hospitalizations and without

readmissions for CABG MS-DRGs, we propose to set the price MS-DRG equal to the anchor MS-DRG. We propose to calculate standard AMI model-episode benchmark prices based on price MS-DRGs following the general payment methodology that was applied to the CJR model with risk stratification according to the anchor MS-DRG (80 FR 73337 through 73358). We propose to apply the CJR model payment methodology separately to AMI model episodes with anchor AMI MS-DRGs 280-282 and anchor PCI MS-DRGs 246-251 with a corresponding AMI ICD-CM diagnosis code on the inpatient claim for the anchor hospitalization and without an intracardiac ICD-CM procedure code in any position on the inpatient claim for the anchor hospitalization.

For episodes in the AMI model with chained anchor hospitalizations and no readmissions for CABG MS-DRGs, we propose to set the price MS-DRG based on the hierarchy described in section III.D.4.b.(2)(a) and to calculate AMI model-episode benchmark prices based on price MS-DRGs as described in sections III.D.4.b.(2)(a) and III.D.4.c.of this proposed rule.

For AMI model episodes without chained anchor hospitalizations and with readmissions for CABG MS-DRGs, we propose to set the price MS-DRG as the anchor MS-DRG and to calculate CABG readmission AMI model-episode benchmark prices as described in sections III.D.4.b.(2)(b),III.D.4.b.(2)(c), and III.D.4.e of this proposed rule.

For AMI model episodes with chained anchor hospitalizations that do not include CABG MS-DRGs and with readmissions for CABG MS-DRGs, we propose to set the price MS-DRG based on the hierarchy described in section III.D.4.b.(2)(a) and to calculate CABG readmission AMI model-episode benchmark prices as described in sections III.D.4.b.(2)(b), III.D.4.b.(2)(c), and III.D.4.e. of this proposed rule.

For CABG model episodes, we propose to set the price MS-DRG as the anchor MS-DRG

and to calculate CABG model-episode benchmark prices as the sum of the CABG anchor hospitalization portion price and the CABG post-anchor hospitalization portion price, which would be calculated by applying the general payment methodology that was applied to the CJR model separately to the expenditures that occurred during the anchor hospitalization of the CABG model episode and to the expenditures that occurred after the anchor hospitalization as discussed in sections III.D.4.b.(2)(b) and III.D.4.d. of this proposed rule (80 FR 73337 through 73358).

Finally, we propose that after assigning an EPM-episode benchmark price to each EPM episode, the EPM-episode quality-adjusted target price would be the EPM-episode benchmark price reduced by the effective discount factor for the corresponding EPM that corresponds to the EPM participant's quality category, as discussed in sections III.D.4.b.(10) and III.E.3.f.of this proposed rule.

(2) Adjustments to Account for EPM-Episode Price Variation

We also have considered further adjustments to account for clinical and resource variation that could affect EPM participants' costs for EPM episodes. As was the case for the CJR model, we continue to believe that no standard risk adjustment approach that is widely-accepted throughout the nation exists for the proposed EPM episodes (80 FR 73338 through 73339). Thus, we are not proposing to make risk adjustments based on beneficiary-specific demographic characteristics or clinical indicators. Likewise, we continue to believe that CMS Hierarchical Condition Categories (HCC) used to adjust for risk in the Medicare Advantage program would not be appropriate for risk-adjusting EPM episodes as such categories are used to predict total Medicare expenditures in an upcoming year for MA plans and may not be appropriate for use in predicting expenditures over a shorter period of time, such as

the EPM episodes. Further, the validity of HCC scores for predicting Medicare expenditures for shorter episodes-of-care or specifically for the AMI, CABG, and SHFFT model episodes that we are proposing has not been determined. Thus, we do not propose to risk-adjust EPM-episode benchmark or quality-adjusted target prices using HCC scores for the currently proposed EPMs. We refer to the CJR Final Rule for additional discussion of our assessment of risk-adjustment options for the CJR model, which informs our views on their appropriateness for the proposed EPMs (80 FR 73338 through 73340).

However, we believe there are circumstances that could account for spending variation in EPM episodes where certain pricing adjustments could be appropriate. We have identified several scenarios where increased EPM-episode efficiencies would be limited for certain groups of EPM beneficiaries and a standard EPM-episode benchmark price based on the anchor MS-DRG would, therefore, not account for circumstances where clinically-appropriate care could consistently result in higher EPM-episode payments. For example, as discussed in section III.C.4.a.(5) of this proposed rule, variation could arise from the asymmetric distribution of cardiac care across hospitals, which makes transfers, either from a hospitalization or from the emergency department (without inpatient admission) of one hospital to another, a common consideration in the treatment course for beneficiaries with an initial diagnosis of AMI, resulting in a chained anchor hospitalization for inpatient-to-inpatient transfers. Alternately, we recognize that certain episodes involving hospital readmissions for clinically-appropriate planned follow-up care may have higher episode spending than episodes with a single hospitalization or with chained anchor hospitalizations involving transfers that do not have any readmissions. Further, a beneficiary who has a CABG in the context of hospitalization for an AMI may have different spending in the 90 days post-hospital-discharge due to different health needs than a

beneficiary who has an elective CABG. Accordingly, we propose specific policies and payment adjustments in recognition of the systematic, consistent variation in EPM-episode spending that could result from such circumstances.

(a) Adjustments for Certain AMI Model Episodes with Chained Anchor Hospitalizations

In section III.C.4.a.(5) of this proposed rule, we proposed that once an AMI model episode is initiated at an AMI model participant, the AMI model episode continues under the responsibility of that specific participant, regardless of whether the beneficiary is transferred to another hospital for further medical management of AMI or revascularization through PCI or CABG during a chained anchor hospitalization. Given there could be significant differences between the discharge MS-DRG from the hospital that initiates the AMI episode and the hospital to which a beneficiary is transferred, as well as the Medicare payment associated with these different MS-DRGs and the post-discharge spending for these beneficiaries, we believe it would be appropriate to adjust the AMI model-episode benchmark prices for certain AMI model episodes involving a chained anchor hospitalization.

More specifically, we believe that it would be appropriate to make an adjustment when a final hospital discharge MS-DRG in the chained anchor hospitalization is an anchor MS-DRG under either the AMI or CABG model. Thus, for episodes involving a chained anchor hospitalization with a final discharge diagnosis of any of AMI MS-DRG 280-282, PCI MS-DRG 246-251 without an intracardiac ICD-CM procedure code in any position on the inpatient claim, or CABG MS-DRG 231-236, we propose to set a chain-adjusted AMI model-episode benchmark price or "price MS-DRG" based on the AMI, PCI, or CABG MS-DRG in the chained anchor admission with the highest IPPS weight. If a CABG MS-DRG occurs in a chained anchor hospitalization that was initiated with an AMI MS-DRG or PCI MS-DRG without an

intracardiac ICD-CM procedure code in any position on the corresponding inpatient claim, we propose that the AMI model episode would begin with and be attributed to the first hospital, and we propose to set the price MS-DRG to the CABG MS-DRG in the chained anchor hospitalization with the highest IPPS weight.

If the price MS-DRG is an AMI or PCI MS-DRG, we propose to set the episode benchmark price as the standard AMI model-episode benchmark price for the price MS-DRG, subject to a possible adjustment for readmission for CABG MS-DRGs, as described in section III.D.4.b.(2)(c) of this proposed rule. If the price MS-DRG is a CABG MS-DRG, we propose to set the AMI model-episode benchmark price as the CABG model-episode benchmark price for the corresponding CABG MS-DRG, with no further adjustment in the event of a readmission for CABG MS-DRGs.

Table 7 displays the weights for CABG, PCI, and AMI MS-DRGs established in the FY 2016 IPPS final rule, which are subject to change each FY through the annual IPPS rulemaking (80 FR 49325 through 49886).

TABLE 7: FY 2016 IPPS WEIGHTS FOR MS-DRGS 231-236, 246-251, AND 280-282.

MS-DRG	MS-DRG Title	Weights
231	CORONARY BYPASS W PTCA W MCC	7.8056
232	CORONARY BYPASS W PTCA W/O MCC	5.7779
233	CORONARY BYPASS W CARDIAC CATH W MCC	7.3581
234	CORONARY BYPASS W CARDIAC CATH W/O MCC	4.9076
235	CORONARY BYPASS W/O CARDIAC CATH W MCC	5.8103
236	CORONARY BYPASS W/O CARDIAC CATH W/O MCC	3.8013
246	PERC CARDIOVASC PROC W DRUG-ELUTING STENT W MCC OR 4+ VESSELS/STENTS	3.2494
247	PERC CARDIOVASC PROC W DRUG-ELUTING STENT W/O MCC	2.1307
248	PERC CARDIOVASC PROC W NON-DRUG-ELUTING STENT W MCC OR 4+ VES/STENTS	3.0696
249	PERC CARDIOVASC PROC W NON-DRUG-ELUTING STENT W/O MCC	1.9140
250	PERC CARDIOVASC PROC W/O CORONARY ARTERY STENT W MCC	2.6975
251	PERC CARDIOVASC PROC W/O CORONARY ARTERY STENT W/O MCC	1.6863
280	ACUTE MYOCARDIAL INFARCTION, DISCHARGED ALIVE W MCC	1.6971
281	ACUTE MYOCARDIAL INFARCTION, DISCHARGED ALIVE W CC	1.0232
282	ACUTE MYOCARDIAL INFARCTION, DISCHARGED ALIVE W/O CC/MCC	0.7557

We believe that this proposal could minimize potential disincentives to AMI model participants from transferring patients when different or higher levels of care are needed. This is because the AMI model-episode benchmark prices we set would be more representative of the AMI spending based on the totality of care furnished during the chained anchor hospitalization and post-discharge period within the AMI model episode and for which the AMI model participants would be held accountable. We also believe that our proposal could encourage AMI model participants that frequently transfer patients after admission to improve their efficiency and the quality of care by transferring beneficiaries needing higher levels of care prior to hospital

admission and managing those beneficiaries admitted to reduce the need for later transfers.

As an alternative, we also considered an approach where we would set the target price taking into consideration IPPS payments for both the MS-DRG assigned to the first admission in the chained anchor hospitalization and the MS-DRG assigned to the final admission in the chained anchor hospitalization. We could apply this approach to all AMI model participant hospitals or to only a subset of hospitals based on special situations that could lead to more common transfer scenarios that are unavoidable, such as small bed-size, rural location, interventional or cardiac surgery capacity, or other characteristic of the hospitals. All AMI model episodes involving chained anchor hospitalizations would include at least two IPPS payments for the chained anchor hospitalization, compared to one IPPS payment for most AMI episodes with only an anchor hospitalization that does not result in an inpatient-to-inpatient transfer. The alternative approach would likely result in a higher AMI-model episode benchmark price than under our proposal for AMI model episodes including a chained anchor hospitalization. Therefore, we believe this alternative approach could have the effect of further reducing potential disincentives to hospitals from transferring patients when different or a higher level of care is needed; however, we are not convinced this approach would ultimately improve care quality and efficiency under the AMI model.

First, we are concerned that this alternative approach could serve as an incentive for hospitals to admit and then transfer patients when doing so might not be medically necessary, which would neither enhance care quality nor efficiency. A recent study showed that non-procedure hospitals, defined as hospitals that lack onsite cardiac catheterization and coronary revascularization facilities, vary substantially in their use of the transfer process for

Medicare beneficiaries admitted with AMI.[61] Beneficiaries transferred from hospitals that had a high transfer rate experienced greater use of invasive cardiac procedures after admission to the transfer hospital than beneficiaries transferred from hospitals with a low transfer rate. However, higher transfer rates were not associated with a significantly lower risk-standardized mortality rate at 30 days, and at one year, there was only a 1.1 percent mortality rate difference between hospitals with higher and lower transfer rates. As such, we believe this alternative approach could be appropriate for only a subset of AMI model participant hospitals based on specific hospital characteristics that could lead to a higher frequency of unavoidable transfers for AMI model beneficiaries rather than appropriate for hospitals overall. In addition, if we were to adopt this alternative approach, we believe it would also be necessary to incorporate methods for monitoring changes in the frequency of AMI model participant hospital patient transfers over the model's performance years, as well as assessing the appropriateness of those transfers. For example, to address changes in transfer frequency, we might compare how often an AMI model participant hospital transferred a beneficiary following an inpatient admission within each performance year relative to the frequency of transfers during its initial 3-year historical period. To address appropriateness of transfers, we might consider reviewing and comparing a sample of a hospital's transfers within a performance year as compared to the historical period. Furthermore, we might also propose future changes to this approach where changes in the frequency or appropriateness of transfers were identified.

Second, in contrast to our proposal, we believe that this alternative approach would not have the benefit of encouraging AMI model participant hospitals to make an early decision and

[61] Barreto-Filho J, Wang Y, Rathore SS, et al. Transfer Rates From Nonprocedure Hospitals After Initial Admission and Outcomes Among Elderly Patients With Acute Myocardial Infarction. JAMA Intern Med. 2014;174(2):213-222. doi:10.1001/jamainternmed.2013.11944.

transfer patients prior to rather than following inpatient admission when doing so prior to admission would be appropriate for the beneficiary's clinical circumstances and the hospital's capabilities. While we recognize that in some cases, an AMI model beneficiary admitted to the initial treating hospital may need to be transferred to a referral hospital that can provide a different or higher level of care, we believe it is important that the AMI model's payment methodology support the goal of rapid decision-making by the AMI model participant hospital about the AMI model beneficiary's care pathway based on clinical guidelines that often incorporate a time dimension in the guidelines for care.

Thus, on balance, we believe our proposed methodology would best establish appropriate incentives to improve care quality and efficiency under the AMI model by encouraging timely decisions about admission to the initial treating hospital and incentivizing only those transfers that are necessary to meet AMI model beneficiary's health care during the course of their hospitalization. Our proposal would adjust the AMI model-episode benchmark price that applies to the episode when a chained anchor hospitalization occurs and results in more costly care at the transfer hospital than would be expected based on the anchor MS-DRG at the initial treating hospital who would be accountable for the episode under the AMI model, thus accounting for the care at the referral hospital.

In contrast, some chained anchor hospitalizations could begin an episode based on an MS-DRG that anchors an episode in the model such as an AMI MS-DRGs that subsequently also includes an MS-DRG that does not anchor an episode under the model (for example, heart failure, renal failure, or cardiac valve replacement). Some of these non-anchor MS-DRGs could be related to the AMI episode but are unavoidable, for example, cardiac valve surgery, while others could potentially reflect complications resulting from inadequate care management during

the episode (for example, heart or renal failure).

As discussed in section III.C.4.b. of this proposed rule, we propose to cancel an AMI model episode when the final MS-DRG in a chained anchor hospitalization is from an MS-DRG that would not an anchor MS-DRG under the AMI or CABG model. We believe that, in tandem, these proposals would allow for appropriate pricing of AMI model episodes that continue and include chained anchor hospitalizations.

The proposals to establish pricing for AMI model episodes involving chained anchor hospitalizations are included in § 512.300(c)(7)(i). We seek comment on our proposals for pricing AMI episodes involving chained anchor hospitalizations and the alternative proposals we considered. We also seek comment on the alternative considered that would account for both the MS-DRGs at the first and last hospitals caring for the AMI model beneficiary during the chained anchor hospitalization in setting the AMI-model episode benchmark price for episodes involving a chained anchor hospitalization. In particular, under such an alternative, we seek comment on the clinical circumstances in which inpatient-to-inpatient transfers are unavoidable and whether or not there are hospital characteristics that would lead us to expect higher frequencies of unavoidable inpatient-to-inpatient transfers for AMI model beneficiaries than hospitals overall. We also seek comment on how we could discourage unintended consequences under this alternative, such as less timely decisions about the most appropriate hospital to treat the beneficiary and increased beneficiary transfers that are unnecessary or inappropriate for improved quality of AMI model episode care.

(b) Adjustments for CABG Model Episodes

Among Medicare beneficiaries historically discharged under a CABG MS-DRG, average episode spending was substantially higher for those beneficiaries who also had AMI ICD-CM

diagnosis codes on their inpatient claims ($57,000) than those who did not ($44,000).[62] About 30 percent of CABG beneficiaries had AMI ICD-CM diagnosis codes on their claims, while about 70 percent did not, and this percentage of CABG beneficiaries with AMI varied substantially across IPPS hospitals furnishing CABG procedures.[63] While average spending, in total, was substantially higher for CABG beneficiaries with AMI than without AMI, average spending during the anchor hospitalization was not substantially higher. Rather, much of this variation in CABG model episode spending occurred after discharge from the anchor hospitalization and correlated both with the presence of AMI and whether the CABG beneficiary was discharged from the anchor hospitalization in a CABG MS-DRG with major complication or comorbidity (MS-DRGs 231, 233, or 235) as opposed to a CABG MS-DRG without major complication or comorbidity (MS-DRGs 232, 234, or 236). Specifically, we found that average CABG episode spending after discharge from the anchor hospitalization was --

- $9,000 for non-AMI CABG beneficiaries discharged from MS-DRGs 232, 234, or 236;
- $11,000 for CABG beneficiaries with AMI discharged from MS-DRGs 232, 234, or 236;
- $16,000 for non-AMI CABG beneficiaries discharged from MS-DRGs 231, 233, or 235; and
- $20,000 for CABG beneficiaries with AMI discharged from MS-DRGs 231, 233, or

[62] Episodes for CABG model beneficiaries initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule, that began in CYs 2012-2014.
[63] Episodes for CABG model beneficiaries initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule, that began in CYs 2012-2014.

235.[64]

Thus, for CABG model episodes, we propose to set CABG model-episode benchmark prices by first splitting historical CABG model-episode expenditures into expenditures that occurred during anchor hospitalizations and expenditures that occurred after discharge from the anchor hospitalizations.

We propose to calculate the CABG anchor hospitalization benchmark price by following the general payment methodology that was applied to the CJR model, with expenditures limited to those that occurred during the anchor hospitalization and risk stratification according to the price CABG MS-DRG (80 FR 73337 through 73358).

We also propose to calculate the CABG post-anchor hospitalization benchmark price by following the general payment methodology that was applied to the CJR model, with expenditures limited to those that occurred after the anchor hospitalization and risk-stratification according to the presence of an AMI ICD-CM diagnosis code on the anchor inpatient claim and whether the price MS-DRG is a CABG MS-DRG with major complication or comorbidity (231, 233, or 235) or a CABG MS-DRG without major complication or comorbidity (232, 234, or 236) (80 FR 73337 through 73358).

We propose that the CABG model-episode benchmark price for an episode would be the sum of the corresponding CABG anchor hospitalization benchmark price and the corresponding CABG post-anchor hospitalization benchmark price, as discussed in this section and in III.D.4.d.

The proposals to establish pricing for CABG model episodes are included in § 512.300(c)(7)(ii). We seek comment on our proposals to establish pricing for CABG model episodes.

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[64] Episodes for CABG model beneficiaries initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule, that began in CYs 2012-2014.

(c) Adjustments for Certain AMI Model Episodes with CABG Readmissions

In section III.C.4.b of this proposed rule, we discuss AMI model episodes where a beneficiary is discharged from an AMI model participant under an AMI MS-DRG and is later readmitted for a CABG. In that section, we did not propose to cancel the AMI model episode altogether for a CABG readmission during the 90-day post-hospital discharge period or cancel the AMI model episode and initiate a CABG model episode because planned CABG readmission following an anchor hospitalization that initiates an AMI episode may be an appropriate clinical pathway for certain beneficiaries. For example, we noted that historically approximately 10 percent of those AMI beneficiaries who received CABGs during AMI episodes would receive the CABGs between 2 and 90 days post-discharge from the anchor hospitalization, and most of those readmissions did not occur through hospital emergency departments. Even though CABG readmissions are not excluded from AMI model episodes (because they are clinically-related to the AMI model episode), we propose to provide an adjusted AMI model-episode benchmark price in such circumstances so as not to financially penalize AMI model participants for relatively uncommon, costly, clinically-appropriate care patterns for AMI model beneficiaries. Accordingly, we are proposing to establish an adjusted CABG-readmission AMI model- benchmark episode price for AMI model episodes with a price MS-DRG of 280-282 or 246-251 that have readmission for a CABG MS-DRG 231-236.

Specifically, if a CABG readmission occurs during an AMI model episode with a price MS-DRG of 280-282 or 246-251, we propose to calculate a CABG-readmission AMI model- episode benchmark price equal to the sum of the standard AMI model-episode benchmark price corresponding to the price MS-DRG (AMI MS-DRGs 280-282 or PCI MS-DRGs 246-251) and the CABG anchor hospitalization benchmark price corresponding to the

MS-DRG of the CABG readmission. Because the adjustment would be based on the anchor hospitalization benchmark price, which does not include costs associated with the post-discharge period for CABG, this adjustment approach would avoid "double counting" post-discharge costs. Because adjusting for spending that occurred during a CABG readmission accounts for most of the spending variation between AMI model episodes with a CABG readmission and AMI model episodes without a CABG readmission, we propose no additional adjustment to the price for AMI model episodes with a CABG readmission.

In the event of any other readmission other than CABG during an AMI model episode that is not excluded from the AMI model episode definition, we would apply the usual rules of EPM-episode pricing that would include the spending for the related readmission in the actual AMI model-episode spending, without other adjustments. Fewer than 3 percent of those AMI model beneficiaries who receive inpatient or outpatient PCIs during AMI episodes receive the PCIs between 2 and 90 days post-discharge from the anchor or chained anchor hospitalizations, and we do not propose to make a pricing adjustment for PCIs that occur later in the AMI model episodes after discharge from the anchor or chained anchor hospitalizations. Since a PCI for an AMI typically is provided during the anchor or chained anchor hospitalization and most PCIs later in an episode occur in the context of a beneficiary presenting through the emergency department, we believe that the beneficiary likely has experienced a complication of care resulting in a PCI that may potentially be avoided through care management during the AMI model episode. Given that our intention is to offer appropriate incentives for care quality and efficiency by holding AMI model participants accountable for readmissions that could be related to the quality of care provided prior to the readmission, we believe that an adjustment other than for a CABG readmission would not be appropriate.

The proposal for adjusting episodes involving CABG readmissions is included in § 512.300(c)(7)(iii). We seek comment on our proposal for adjusting episodes involving CABG readmissions.

(d) Potential Future Approaches to setting Target Prices for AMI and Hip Fracture Episodes

As previously described, our proposed approach for pricing AMI and CABG model episodes for beneficiaries with AMI sets different episode target prices depending upon whether the beneficiary is managed medically, undergoes PCI, or undergoes CABG during the acute phase of the episode, as well as whether the episode involves a chained anchor hospitalization or CABG readmission. Similarly, the target price set for beneficiaries experiencing hip fracture would depend on whether the patient undergoes hip fixation (and therefore initiates a SHFFT model episode) or hip arthroplasty (and therefore initiates a CJR model episode). We believe that this is a prudent approach that both recognizes the resource costs of services provided while encouraging care redesign during the portions of these episodes that we believe present the greatest opportunities to improve the quality and efficiency of the care delivered.

However, we note that the general principle guiding our payment reform efforts is that the payment system should hold providers accountable for the overall quality and cost of the care their beneficiaries receive rather than setting their payment based on the specific services delivered or settings in which they are delivered. We believe that this approach gives providers maximum flexibility to redesign care in ways that both produce the best outcomes for patients and controls the growth in spending for these services.

For this reason, we are interested in exploring future approaches to episode payment that would set an inclusive target price for episodes for beneficiaries with AMI that does not depend on whether the beneficiary is managed medically or receives PCI or CABG during the acute

portion of the episode and, similarly, future approaches that would set prices for episodes for beneficiaries with hip fracture that do not depend on whether the beneficiary undergoes hip fixation or hip arthroplasty. While we believe that the choice of treatment during the acute phase of these episodes may be determined predominantly by clinical factors such that financial factors may play a smaller role in shaping episode care redesign than they do following hospital discharge, we nevertheless believe it would be valuable to consider testing an inclusive episode payment model. Providers may be able to redesign and implement care pathways that we might not have otherwise anticipated, especially as the evidence-base for AMI and hip fracture treatment continues to grow and evolve.

We seek comment on this type of approach to setting an inclusive episode target price and on any episode payment model design features that would be needed to make such an approach successful. In particular, we seek comment on potential approaches to risk-adjustment aimed at ensuring that providers are appropriately paid for caring for high-complexity episode beneficiaries in the context of this alternative approach. We would seek to ensure that all providers caring for these episode beneficiaries, including those providers for which we propose additional protections and those that serve a high percentage of potentially vulnerable populations of medically and socially complex patients as discussed in section III.D.7.c. of this proposed rule, would not bear undue financial risk and to mitigate any incentives to avoid caring for high-complexity patients. In addition, we seek comment on whether and how our methodology linking quality performance to payment under the proposed EPMs and the CJR model might need to be modified in the context of this alternative approach that would set an inclusive episode target price, in order to appropriately incentivize the delivery of high-quality care and discourage stinting on appropriate care.

(e) Summary of Pricing Methodologies for AMI, CABG, and SHFFT Model Episode Scenarios

Tables 8 through 10 summarize the standard pricing methodologies and the adjustments that would occur that are proposed in sections III.D.4.b.(1) and (2) of this proposed rule for AMI, CABG, and SHFFT model episodes.

TABLE 8: AMI MODEL PRICING SCENARIOS

AMI PRICING SCENARIO	PRICE
AMI Scenarios without Chained Anchor Hospitalization	
Single hospital AMI MS-DRG or PCI MS-DRG (with AMI diagnosis)	Episode benchmark price is standard episode benchmark price based on anchor MS-DRG (which is the price MS-DRG)
AMI Scenarios with Chained Anchor Hospitalizations	
A chained anchor hospitalization where the discharge from the first hospital is an AMI MS-DRG or PCI MS-DRG (with AMI diagnosis) that results in a final discharge from an AMI, PCI, or CABG MS-DRG (transfer PCI and CABG MS-DRGs not required to have AMI ICD-CM diagnosis code)	Episode benchmark price is the standard episode benchmark price or the CABG model episode benchmark price corresponding to price MS-DRG, assigned as the AMI, PCI, or CABG MS-DRG with highest IPPS weight If the price MS-DRG is a CABG MS-DRG, the CABG model episode benchmark price is the sum of the CABG anchor hospitalization price for the MS-DRG and the CABG post-anchor hospitalization price based on with AMI ICD-CM diagnosis code and whether the CABG MS-DRG is w/MCC or not
AMI Scenarios with Readmissions	
An AMI MS-DRG or PCI MS-DRG (with AMI diagnosis) anchored episode without a chained anchor hospitalization ongoing with CABG readmission	Episode benchmark price is the sum of the standard episode benchmark price corresponding to the price MS-DRG and the CABG anchor hospitalization benchmark price corresponding to the CABG readmission MS-DRG
AMI MS-DRG or PCI MS-DRG (with AMI diagnosis) anchored AMI episode with chained anchor hospitalization (not containing a CABG MS-DRG) ongoing with CABG readmission	Episode benchmark price is the sum of the standard episode benchmark price for the price MS-DRG assigned to the chained anchor hospitalization and the CABG anchor hospitalization benchmark price corresponding to the CABG readmission MS-DRG

TABLE 9: CABG MODEL PRICING SCENARIOS

CABG Pricing Scenario	Price
Single hospital CABG MS-DRG with AMI diagnosis	Episode benchmark price is the sum of the CABG anchor hospitalization benchmark price for the MS-DRG and the CABG post-anchor hospitalization benchmark price based on the presence of an AMI ICD-CM diagnosis code and whether the anchor MS-DRG is w/MCC or w/o MCC
Single hospital CABG MS-DRG without AMI diagnosis	Episode benchmark price is the sum of the CABG anchor hospitalization benchmark price for the MS-DRG and the CABG post-anchor hospitalization benchmark price based on no AMI ICD-CM diagnosis code and whether the anchor MS-DRG is w/MCC or w/o MCC

TABLE 10: SHFFT MODEL PRICING SCENARIOS

SHFFT Pricing Scenario	Price
SHFFT MS-DRG	Episode benchmark price is standard episode benchmark price based on anchor MS-DRG (which is the price MS-DRG)

(3) Three Years of Historical Data

As was the case for the CJR model, we propose to use 3 years of historical EPM episodes for calculating EPM participants' EPM-episode benchmark prices, with each set of historical episodes updated every other year (80 FR 73340 through 73341). Under our proposal, each of the first 2 years of historical data would be trended to the most recent of the 3 years, based on national trend factors for each combination of price MS-DRGs and payments would be updated for each payment system (for example, IPPS, PFS, etc.) based on annual changes in input costs (see sections III.D.4.b (4) and III.D.4.b (5) of this proposed rule that immediately follow). Under our proposal, we would establish historical EPM-episode payments based on episodes that started between --

- January 1, 2013 and December 31, 2015 for performance years 1 and 2;
- January 1, 2015 and December 31, 2017 for performance years 3 and 4; and

- January 1, 2017 and December 31, 2019 for performance year 5.

We believe that 3 years of historical EPM-episode data should provide sufficient historical episode volume to reliably calculate EPM-episode benchmark prices, and that updating these data every other year would allow us to make the most current claims data available in a way that incorporates the effects of regular Medicare payment system updates and changes in utilization without creating uncertainty in pricing for EPM participants. We would further note that the effects of updating EPM-participant hospital-specific data on an EPM-episode's benchmark prices would diminish over time as the contribution of regional pricing on EPM benchmark prices will increase from one-third for performance years 1 and 2 to two-thirds in performance year 3, and 100 percent in performance years 4 and 5.

The proposal for 3 years of historical data updated every other year under the proposed EPMs is included in § 512.300(c)(1).

We seek comment on our proposal for 3 years of historical data updated every other year.

(4) Trending Historical Data to the Most Recent Year

We recognize that some payment variation could exist in the 3 years of historical EPM-episode data due to annual Medicare payment system updates (for example, IPPS, OPPS, IRF PPS, SNF PPS) and national changes in utilization patterns. Thus, EPM episodes in the third year of the 3 historical years might have higher average payments than those from the earlier 2 years, in part due to Medicare payment rate increases over the course of the 3-year period. Also, EPM-episode payments could change over time due to national trends reflecting changes in industry-wide practice patterns. For example, readmissions for all patients, including those in CABG model episodes, may decrease nationally due to improved industry-wide surgical protocols that reduce the chance of infections. We do not intend for the incentives under the

EPMs to be affected by Medicare payment system rate changes that are beyond EPM participants' control or to provide reconciliation payments to (or require repayments from) EPM participants for achieving lower (or higher) Medicare expenditures solely because they followed national changes in practice patterns. Instead, we aim to incentivize EPM participants to improve care quality and efficiency based on their hospital-specific inpatient and post-discharge care practices under the EPMs.

To mitigate the effects of Medicare payment system updates and changes in national utilization practice patterns on the 3 years of historical episode data, we propose to apply a national trend factor to each of the years of historical EPM-episode payments as we do with the CJR model (80 FR 73341 through 73342). Specifically, we propose to inflate the 2 oldest years of historical EPM-episode payments for EPM episodes to the most recent year of the 3 historical years using changes in the national EPM-episode payments for each different type of EPM episode. That is, we propose to apply separate national trend factors for the following pricing scenarios:

- SHFFT model episodes, separately by each price MS-DRG in 480-482.
- AMI model episodes without CABG readmissions, separately by each price MS-DRG in 280-282 and 246-251; and
- The anchor hospitalization portion of CABG model episodes, separately by each price MS-DRG in 231-236.
- The post-anchor hospitalization portion of CABG model episodes, separately for:

++ With AMI ICD-CM diagnosis code on the anchor inpatient claim and CABG price MS-DRG with major complication or comorbidity (231, 233, or 235);

++ With AMI ICD-CM diagnosis code on the anchor inpatient claim and CABG price

MS-DRG without major complication or comorbidity (232, 234, or 236);

++ Without AMI ICD-CM diagnosis code on the anchor inpatient claim and CABG price MS-DRG with major complication or comorbidity (231, 233, or 235); and

++ Without AMI ICD-CM diagnosis code on the anchor inpatient claim and CABG price MS-DRG without major complication or comorbidity (232, 234, or 236).

For example, when using Calendar Year (CY) 2013 through 2015 historical EPM-episode data to establish EPM-episode benchmark prices for performance years 1 and 2, we would calculate an aggregate national average SHFFT model episode payment in historical episodes with price MS-DRG 480 for each of the 3 historical years. To trend historical payments to the most recent year in an historical window, we would create a ratio based on national average historical EPM-episode payment for that episode type in a previous year and for the most recent year. Thus, in this example, we would create a ratio of national average SHFFT model historical episode payment with price MS-DRG 480 in CY 2015 as compared to that national average SHFFT model historical episode payment in CY 2013 in order to trend the CY 2013 historical SHFFT model episode payments to CY 2015. Similarly, we would determine the ratio of the national average SHFFT model historical episode payment for CY 2015 to national average SHFFT model historical episode payment in CY 2014 to trend 2014 SHFFT model episode payments to CY 2015. This process would be repeated for each pricing scenario previously listed.

We believe this method for trending data would capture updates in Medicare payment systems as well as national utilization pattern changes that might have occurred within that 3-year period. Moreover, as with the CJR model, we believe that adjusting for national rather than regional trends in utilization would be most appropriate as any Medicare payment system

updates and significant changes in utilization practice patterns would not be region-specific but rather be reflected nationally.

The proposal for trending historical data is included in § 512.300(c) (11). We seek comment on our proposal for trending historical data.

(5) Update Historical EPM-Episode Payments to Account for Ongoing Payment System Updates

As previously mentioned, we propose to prospectively update the historical EPM- episode payments to account for ongoing updates to Medicare payment systems (for example, IPPS, OPPS, IRF PPS, SNF, PFS, etc.) in order to ensure we incentivize EPM participants based on historical utilization and practice patterns, not Medicare payment system rate changes that are beyond hospitals' control. Under our proposal, we would apply the same methodology developed for the CJR model to incorporate Medicare payment updates (80 FR 73342 through 73446).

Because Medicare payment systems rates are not updated at the same time during the year—for example, rates under the IPPS, IRF PPS, and SNF payment systems are updated effective October 1, while the hospital OPPS and MPFS rates are updated annually effective January 1—we propose to generally update historical EPM-episode payments and calculate EPM-episode benchmark prices separately for EPM episodes initiated between January 1 and September 30 versus October 1 and December 31 of each performance year, and at other intervals if determined necessary. The EPM-episode benchmark price in effect as of the day the EPM episode is initiated would be the EPM-episode benchmark price for the whole EPM episode. Note that for performance year 5, the second set of EPM-episode benchmark prices would be for EPM episodes that start and end between and including October 1 and

December 31 because the fifth performance period of the SHFFT, CABG, and AMI models would end on December 31, 2021. Also, an EPM episode benchmark price for a given EPM performance year could be applied to EPM episodes included in another performance year. For example, an EPM episode initiated in November 2017, and ending in February 2018 would have an EPM-episode benchmark price based on the second set of 2017 EPM-episode benchmark prices (for EPM episodes initiated between October 1, 2017, and December 31, 2017), and it would be captured in the CY 2018 EPM performance year (performance year 2) because it ended between January 1, 2018, and December 31, 2018. We refer to section III.D.2.a. of this proposed rule for further discussion on the definition of EPM performance years.

We propose to update historical EPM-episode payments by applying separate Medicare payment system update factors each January 1 and October 1 to each of the following six components of each EPM participant's historical EPM-episode payments:

- Inpatient acute.
- Physician.
- IRF.
- SNF.
- HHA.
- Other services.

A different set of update factors would be calculated for January 1 through September 30 versus October 1 through December 31 EPM episodes each EPM performance year. The six update factors for each of the previously stated components would be EPM-participant hospital-specific and would be weighted by the percent of the Medicare payment for which each

of the six components accounts in the EPM participant's historical EPM episodes. The weighted update factors would be applied to historical EPM-participant hospital-specific average payments to incorporate ongoing Medicare payment system updates. A weighted update factor would be calculated by multiplying the component-specific update factor by the percent of the EPM participant's historical EPM-episode payments the component represents, and summing together the results. Each of an EPM participant's six update factors would be based on how inputs have changed in the various Medicare payment systems for the specific EPM participant.

As an example, we will assume for purposes of this example that 50 percent of an EPM participant's historical EPM-episode payments were for inpatient acute care services, 15 percent were for physician services, 35 percent were for SNF services, and 0.0 percent were for the remaining services. We will also assume for purposes of this example that the update factors for inpatient acute care services, physician services, and SNF services are 1.02, 1.03, and 1.01, respectively. The weighted update factor in this example would be the following: (0.5 * 1.02) + (0.15*1.03) + (0.35*1.01) = 1.018. The EPM participant in this example would have its historical average EPM-episode payments multiplied by 1.018 to incorporate ongoing payment system updates. The specific order of steps, and how this step fits in with others, is discussed further in sections III.D.4.c through d. of this proposed rule. Also, as discussed further in sections III.D.4.c. through d. the update factors would vary by price MS-DRG. For example, in CABG model episodes, the update factors would be calculated separately for the anchor hospitalization portion of episodes and the post-anchor hospitalization portion of episodes, as described in section III.D.4.d.

Region-specific update factors for each of the previously stated components and weighted update factors would also be calculated in the same manner as the EPM-participant

hospital-specific update factors. Instead of using historical EPM episodes attributed to a specific hospital, region-specific update factors would be based on all historical EPM episodes initiated at any IPPS hospital within the region with historical EPM episodes, regardless of whether or not the MSAs in which the hospitals are located were selected for inclusion in the models. We refer to the CJR Final Rule for further discussion of our specific methodology and considerations for adopting this methodology for updating historical EPM-episode payments for ongoing payment system updates (80 FR 73342 through 73446).

The proposal for updating episode payments for ongoing annual Medicare payment updates is included in § 512.300(c)(10). We seek comment on our proposal for updating episodes payments for ongoing annual Medicare payment updates.

(6) Blend Hospital-Specific and Regional Historical Data

We propose to calculate EPM-episode benchmark prices using a blend of EPM-participant hospital-specific and regional historical average EPM-episode payments, including historical EPM-episode payments for all IPPS hospitals that are in the same U.S. Census division, which is discussed further in section III.D.4.b.(7) of this proposed rule. Specifically, we propose to blend two-thirds of the EPM-participant hospital-specific historical EPM-episode payments and one-third of the regional historical EPM-episode payments to set an EPM participant's EPM-episode benchmark prices for the first 2 performance years of the proposed EPMs (CYs 2017 and 2018). For performance year 3 of the EPMs (CY 2019), we propose to adjust the proportion of the EPM-participant hospital-specific and regional historical EPM-episode payments used to calculate the EPM-episode benchmark prices from two-thirds EPM-participant hospital-specific and one-third regional to one- third EPM-participant hospital-specific and two-thirds regional. Finally, we propose to use only regional historical

EPM-episode payments for performance years 4 and 5 of the EPMs (CYs 2020 and 2021) to set an EPM participant's EPM episode- benchmark prices, rather than a blend between the hospital-specific and regional historical EPM episode payments.

Consistent with our methodology for the CJR model, we propose two exceptions. First, we propose to use only regional historical EPM-episode payments to calculate EPM episode- benchmark prices for EPM participants with low historic EPM-episode volume (80 FR 73544). For SHFFT model episodes, this exception applies to SHFFT model participants with fewer than 50 historical SHFFT model episodes in total across the 3 historical years. For AMI model episodes anchored by MS-DRGs 280-282, this exception applies to AMI model participants with fewer than 75 of these particular AMI model historical episodes in total across the 3 historical years. For AMI model episodes anchored by PCI MS-DRGs 246-251, this exception applies to AMI model participants with fewer than 125 of this particular AMI model historical episodes in total across the 3 historical years. For CABG model episodes, this exception applies to CABG model participants with fewer than 50 historical CABG model episodes in total across the 3 historical years. The proposed thresholds for low historic volume in this proposed rule are higher than the CJR model threshold for low historical LEJR episode volume of 20 episodes in total across the 3 historical years. The higher thresholds are based on the volume thresholds from the BPCI Model 2 Risk Track B for 90-day episodes, which increase when the ratio of within-hospital episode spending variation to between-hospital episode spending variation increases. That is, as EPM episode payment variation increases within a hospital relative to EPM-episode payment variation between hospitals, it is necessary to have more EPM episodes at that hospital to estimate a stable EPM- episode benchmark price using data from only that hospital. We propose to set higher thresholds for the SHFFT, AMI, and

CABG models based on internal analysis from BPCI episode data that shows higher within-hospital episode spending variation relative to between-hospital episode spending variation for episodes anchored by the EPM MS-DRGs, compared to episodes anchored by MS-DRGs 469 and 470 included in the CJR model.[65]

Second, in the case of an EPM participant that has undergone a merger, consolidation, spin-off, or other reorganization that results in a new hospital entity without 3 full years of historical claims data, we propose that EPM participant hospital-specific historical EPM-episode payments would be determined using the historical EPM episode payments attributed to their predecessor(s), as in the CJR model (80 FR 73544).

The aforementioned proposals align with our method for blending EPM participant hospital-specific and regional data under the CJR model. We refer to the CJR model Final Rule for further discussion on alternatives to and reasons for adopting this methodology for the CJR model, which informs our proposal with respect to the proposed EPMs (80 FR 73346 – 73349).

The proposal for blending payments when establishing participants' benchmark and quality-adjusted targets and certain exceptions is included in § 512.300(c)(2), (3), and (4). We note that the specific order of steps, and how this step fits in with others, is discussed further in section III.D.4.c. of this proposed rule. We seek comment on our proposal for blending payments when establishing participants' benchmark and quality-adjusted targets as well as the proposed exceptions.

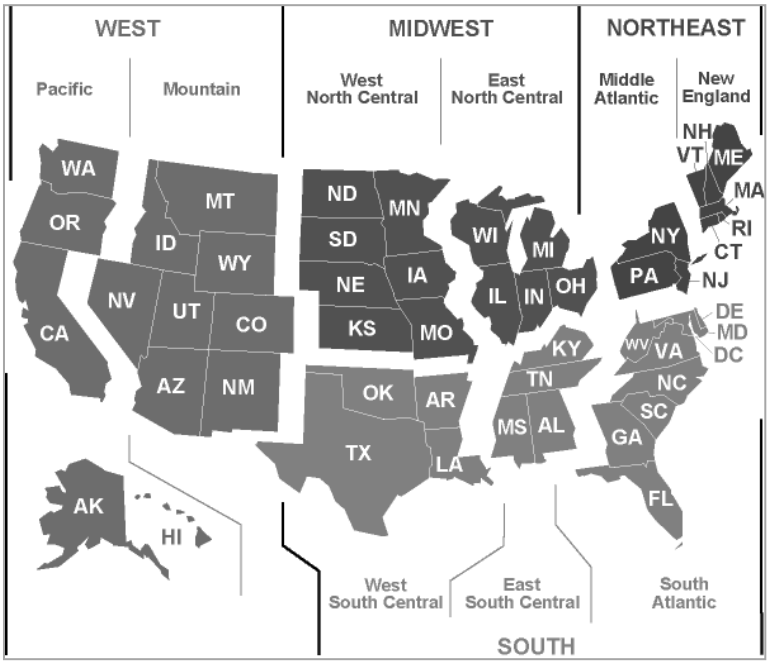
(7) Define Regions as U.S. Census Divisions

As we do for the CJR model, for all 5 performance years, we proposed to define "region"

[65] BPCI Model 2 Baseline Price Common Template calculations for 90-day episodes in Risk Track B calculates BPCI volume thresholds based on the ratio of within-hospital episode spending variation and between-hospital episode spending variation for BPCI Clinical Episodes, based on episodes that met BPCI eligibility criteria and that began in July 1, 2009 – June 30, 2012.

as one of the nine U.S. Census divisions[66] in Figure 1 (80 FR 73349 thorugh73350).

FIGURE 1: U.S. CENSUS DIVISIONS[67]



We believe U.S. Census divisions provide the most appropriate balance between very large areas with highly disparate utilization patterns and very small areas that would be subject to price distortions due to low volume or hospital-specific utilization patterns. We clarify that we would ascribe the same regional component of EPM-episode benchmark prices for EPM participants in MSAs that span U.S. Census divisions. That is, selected MSAs that span U.S. Census divisions would be attributed to one U.S. Census division for purposes of calculating the regional component of an EPM-episode benchmark price. Specifically, we will attribute an

[66] There are four census regions—Northeast, Midwest, South, and West. Each of the four census regions is divided into two or more "census divisions". Source: https://www.census.gov/geo/reference/gtc/gtc_census_divreg.html. Accessed on April 15, 2015.

[67] http://www.eia.gov/consumption/commercial/census_maps.cfm

MSA to the U.S. Census division in which the majority of people in the MSA reside.

The proposal to define a region as one of the nine U.S. Census divisions is included in § 512.300(c)(2). We seek comment on our proposal to define region in this manner.

(8) Normalize for Provider-Specific Wage Adjustment Variations

Some variation in historical EPM-episode payments across hospitals in a region may be due to wage adjustment differences in Medicare payments. In setting Medicare payment rates, Medicare typically adjusts facilities' costs attributable to wages and wage-related costs (as estimated by the Secretary from time to time) by a factor (established by the Secretary) that reflects the relative wage level in the geographic are of the facility or practitioner (or the beneficiary's residence, in the case of home health and hospice services) compared to a national average wage level. Such adjustments are essential for setting accurate payments, as wage levels vary significantly across geographic areas of the country. However, having the wage level for one hospital influence the regional-component of another hospital's EPM episode-benchmark price with a different level would introduce unintended pricing distortion not based on utilization pattern differences.

To preserve how wage levels affect provider payment amounts, while minimizing the distortions introduced when calculating the regional-component of blended EPM-episode benchmark prices, we propose to normalize for wage indices at the claim level for both historical EPM-episode payments and actual EPM-episode payments. As discussed in section III.D.3.b. of proposed rule, we propose to utilize the CMS Price (Payment) Standardization Detailed Methodology to calculate EPM-episode benchmark and quality-adjusted target prices and actual EPM-episode spending. This methodology removes wage level differences in calculating standardized payment amounts.

We believe it is important to reintroduce wage index variations near the end of the EPM-episode price-setting methodology and when calculating actual EPM-episode payments during an EPM performance year, to account for the differences in cost for care redesign across different geographic areas of the country. For example, hiring additional hospital staff to aid in patient follow-up during the post-discharge period of an AMI model episode would be significantly more costly in San Francisco than in rural Idaho. If we do not reintroduce wage index variations into EPM-episode benchmark price and actual EPM-episode payment calculations, we would calculate reconciliation and repayment amounts that would not capture labor cost variation throughout the country, and EPM participants in certain regions may see less opportunity and financial incentive to invest in care redesign. Thus, when setting EPM-episode benchmark prices and calculating actual EPM-episode payments, we propose to reintroduce the hospital-specific wage variations by multiplying EPM-episode payments by the wage normalization factor when calculating the EPM-episode benchmark prices and actual EPM -episode payments for each EPM participant, as described in section III.D.4.c. of the proposed rule.

We propose to use the following algorithm to create a wage normalization factor: 0.7 * IPPS wage index + 0.3. The 0.7 approximates the labor share in IPPS, IRF PPS, SNF, and HHA Medicare payments. The specific order of steps, and how this step fits in with others, is discussed further in section III.D.4.c. of the proposed rule. We refer to the CJR model Final Rule for more detailed information on our normalization process adopted for the CJR model (80 FR 73350 through 73352).

The proposal to normalize for provider-specific wage adjustment variations is included in § 512.300(c)(12). We seek comment on our proposal to normalize for these variations.

(9) Combining Episodes to Set Stable Benchmark and Quality-Adjusted Target Prices

For the purposes of having sufficient episode volume to set stable EPM-episode benchmark and quality-adjusted target prices, we propose generally to follow the process from the CJR model to calculate severity factors, EPM-participant hospital-specific weights, and region-specific weights that allow us to surmount issues of low volume for EPM episodes with particular characteristics by aggregating EPM episodes and portions of EPM episodes across dimensions that include anchor MS-DRGs, the presence of AMI ICD-CM diagnosis code on the anchor inpatient claim, and the presence of a major complication or comorbidity for anchor CABG MS-DRGs (80 FR 73352 through 73353). Where the CJR Final Rule refers to anchor factors, for the purposes of this proposed rule we refer to severity factors to avoid confusion when performing calculations pertaining to expenditures that occurred during the anchor hospitalization and after the anchor hospitalization in CABG model episodes.

For SHFFT model episodes, we propose to combine episodes with price MS-DRGs 480-482 to use a greater historical episode volume to set more stable SHFFT episode benchmark and quality-adjusted target prices. To do so, we propose to calculate severity factors for episodes with price MS-DRGs 480 and 481 equal to --

$$MS-DRG\ 480\ severity\ factor = \frac{Natl.avg.\ MS-DRG\ 480\ episode\ spend}{Natl.avg.\ MS-DRG\ 482\ episode\ spend}$$

$$MS-DRG\ 481\ severity\ factor = \frac{Natl.avg.\ MS-DRG\ 481\ episode\ spend}{Natl.avg.\ MS-DRG\ 482\ episode\ spend}$$

The national average would be based on SHFFT model episodes attributed to any IPPS hospital. The resulting severity factors would be the same for all SHFFT model participants. For each SHFFT model participant, a hospital weight would be calculated using the following formula, where SHFFT model episode counts are SHFFT-model-participant hospital-specific and based

on the SHFFT model episodes in the 3 historical years used in SHFFT model episode benchmark and quality-adjusted target price calculations:

$$\frac{Count\ of\ episodes\ with\ price\ MS-DRG\ 480-482}{\begin{array}{c} MS-DRG\ 480\ episode\ count * \ MS-DRG\ 480\ severity\ factor + \\ MS-DRG\ 481\ episode\ count * \ MS-DRG\ 481\ severity\ factor + \\ MS-DRG\ 482\ episode\ count * 1 \end{array}}$$

A SHFFT model participant's hospital-specific average episode payment would be calculated by multiplying such participant's hospital weight by its combined historical average episode payment (sum of historical episode payments for historical episodes with price MS-DRGs 480-482 divided by the number of historical episodes with price MS–DRGs 480-482). The calculation of the hospital weights and the hospital-specific pooled historical average episode payments would be comparable to how case-mix indices are used to generate case-mix adjusted Medicare payments. The hospital weight essentially would count each episode with price MS–DRGs 480 and 481 as more than one episode (assuming episodes with price MS– DRGs 480 and 481 have higher average payments than episodes with price MS–DRG 482) so that the pooled historical average episode payment, and subsequently the SHFFT model episode benchmark and quality-adjusted target prices, are not skewed by the SHFFT model participant's relative breakdown of historical episodes with price MS–DRGs 480 and 481 versus historical episodes with price MS-DRG 482.

We would calculate region-specific weights and region-specific pooled historical average payments following the same steps proposed for hospital-specific weights and hospital-specific pooled average payments. Instead of grouping episodes by the attributed hospital as is proposed for hospital-specific calculations, region-specific calculations would group together SHFFT model episodes that were attributed to any IPPS hospital located within the region. The

hospital-specific and region-specific pooled historical average payments would be blended together as discussed in section III.D.4.b.(6) of the proposed rule. The specific order of steps, and how this step fits in with others, is discussed further in section III.D.4.c. of the proposed rule.

Afterwards, the blended pooled calculations would be "unpooled" by setting the episode benchmark price for episodes with price MS-DRG 482 to the resulting calculation, and by multiplying the resulting calculation by the severity factors to produce the episode benchmark prices for episodes with price MS-DRGs 480 and 481. Applying the discount factor as discussed in III.D.4.b.(10) and III.D.4.c. would result in the SHFFT model quality-adjusted target prices for episodes with price MS-DRGs 480-482.

For episodes in the AMI model with price MS-DRGs in 280-282 or 246-251 and without readmissions for CABG MS-DRGs, we propose to follow an analogous procedure to the SHFFT model with the following modifications. First we propose to group episodes with price MS-DRGs 280-282 separately from episodes with price MS-DRGs 246-251 for the calculations. Second, we propose to calculate severity factors for episodes with price MS-DRGs 280-282 as --

$$MS-DRG\ 280\ severity\ factor = \frac{Natl.avg.\ MS-DRG\ 280\ episode\ spend}{Natl.avg.\ MS-DRG\ 282\ episode\ spend}$$

$$MS-DRG\ 281\ severity\ factor = \frac{Natl.avg.\ MS-DRG\ 281\ episode\ spend}{Natl.avg.\ MS-DRG\ 282\ episode\ spend}$$

Third, we propose to calculate hospital-specific weights and region-specific weights for episodes with price MS-DRGs 280-282 as --

$$\frac{Count\ of\ episodes\ with\ price\ MS-DRG\ 280-282}{\begin{gathered}MS-DRG\ 280\ episode\ count\ *\ MS-DRG\ 280\ severity\ factor\ + \\ MS-DRG\ 281\ episode\ count\ *\ MS-DRG\ 281\ severity\ factor\ + \\ MS-DRG\ 282\ episode\ count * 1\end{gathered}}$$

Fourth, we propose to calculate severity factors for episodes with price MS-DRG 246-251 as --

$$MS-DRG\ 246\ severity\ factor = \frac{Natl.avg.\ MS-DRG\ 246\ episode\ spend}{Natl.avg.\ MS-DRG\ 251\ episode\ spend}$$

$$MS-DRG\ 247\ severity\ factor = \frac{Natl.avg.\ MS-DRG\ 247\ episode\ spend}{Natl.avg.\ MS-DRG\ 251\ episode\ spend}$$

$$MS-DRG\ 248\ severity\ factor = \frac{Natl.avg.\ MS-DRG\ 248\ episode\ spend}{Natl.avg.\ MS-DRG\ 251\ episode\ spend}$$

$$MS-DRG\ 249\ severity\ factor = \frac{Natl.avg.\ MS-DRG\ 249\ episode\ spend}{Natl.avg.\ MS-DRG\ 251\ episode\ spend}$$

$$MS-DRG\ 250\ severity\ factor = \frac{Natl.avg.\ MS-DRG\ 250\ episode\ spend}{Natl.avg.\ MS-DRG\ 251\ episode\ spend}$$

Fifth, we propose to calculate hospital-specific weights and region-specific weights for episodes with price MS-DRG 246-251 as --

$$\frac{Count\ of\ episodes\ with\ price\ MS-DRG\ 246-251}{\begin{array}{c} MS-DRG\ 246\ episode\ count\ *\ MS-DRG\ 246\ severity\ factor\ + \\ MS-DRG\ 247\ episode\ count\ *\ MS-DRG\ 247\ severity\ factor\ + \\ MS-DRG\ 248\ episode\ count\ *\ MS-DRG\ 248\ severity\ factor\ + \\ MS-DRG\ 249\ episode\ count\ *\ MS-DRG\ 249\ severity\ factor\ + \\ MS-DRG\ 250\ episode\ count\ *\ MS-DRG\ 250\ severity\ factor\ + \\ MS-DRG\ 251\ episode\ count * 1 \end{array}}$$

After blending historical and regional pooled episode payments for episodes with price MS-DRGs 280-282, the blended pooled calculations would be "unpooled" by setting the episode benchmark price for price MS–DRG 282 to the resulting calculation, and by multiplying the resulting calculation by the severity factors to produce the episode benchmark prices for price MS-DRGs 280 and 281.

After blending historical and regional pooled episode payments for episodes with price MS-DRGs 246-251, the blended pooled calculations would be "unpooled" by setting the episode benchmark price for price MS–DRG to the resulting calculation, and by multiplying the resulting calculation by the severity factors to produce the episode benchmark prices for price MS-DRGs 246-251.

Applying the discount factor as discussed in III.D.4.b.(10) and III.D.4.c would result in the quality-adjusted target prices for price MS-DRGs 280-282 and 246-251.

For episodes in the CABG model with price MS-DRGs in 231-236, we propose to calculate severity factors, hospital-specific weights, and region-specific weights separately for the anchor hospitalization portion of CABG model episodes and the post-anchor hospitalization portion of CABG model episodes.

For the anchor hospitalization portion of CABG model episodes, we propose to follow an analogous procedure to the SHFFT model with the anchor hospitalization portion of CABG model episodes grouped by the price MS-DRG. Specifically, we propose to calculate anchor hospitalization severity factors for price MS-DRGs 231-235 as --

$$MS-DRG\ 231\ anchor\ hosp.severity\ factor = \frac{Natl.avg.\ MS-DRG\ 231\ anchor\ hosp.spend}{Natl.avg.\ MS-DRG\ 236\ anchor\ hosp.spend}$$

$$MS-DRG\ 232\ anchor\ hosp.severity\ factor = \frac{Natl.avg.\ MS-DRG\ 232\ anchor\ hosp.spend}{Natl.avg.\ MS-DRG\ 236\ anchor\ hosp.spend}$$

$$MS-DRG\ 233\ anchor\ hosp.severity\ factor = \frac{Natl.avg.\ MS-DRG\ 233\ anchor\ hosp.spend}{Natl.avg.\ MS-DRG\ 236\ anchor\ hosp.spend}$$

$$MS-DRG\ 234\ anchor\ hosp.severity\ factor = \frac{Natl.avg.\ MS-DRG\ 234\ anchor\ hosp.spend}{Natl.avg.\ MS-DRG\ 236\ anchor\ hosp.spend}$$

$$MS-DRG\ 235\ anchor\ hosp.severity\ factor = \frac{Natl.avg.\ MS-DRG\ 235\ anchor\ hosp.spend}{Natl.avg.\ MS-DRG\ 236\ anchor\ hosp.spend}$$

We also propose to calculate hospital-specific weights and region-specific weights for the anchor hospitalization portion of CABG model episodes as --

$$\frac{Count\ of\ episodes\ with\ price\ MS-DRG\ 231-236}{\begin{array}{c} MS-DRG\ 231\ episode\ count\ *\ MS-DRG\ 231\ anchor\ hosp.severity\ factor\ + \\ MS-DRG\ 232\ episode\ count\ *\ MS-DRG\ 232\ anchor\ hosp.severity\ factor\ + \\ MS-DRG\ 233\ episode\ count\ *\ MS-DRG\ 233\ anchor\ hosp.severity\ factor\ + \\ MS-DRG\ 234\ episode\ count\ *\ MS-DRG\ 234\ anchor\ hosp.severity\ factor\ + \\ S-DRG\ 235\ episode\ count\ *\ MS-DRG\ 235\ anchor\ hosp.severity\ factor\ + \\ MS-DRG\ 236\ episode\ count\ *\ 1 \end{array}}$$

After blending historical and regional pooled anchor hospitalization payments for the CABG model episodes, the blended pooled calculations would be "unpooled" by setting the price MS–DRG 236 anchor hospitalization benchmark price to the resulting calculation, and by multiplying the resulting calculation by the severity factors to produce the anchor hospitalization benchmark prices for price MS-DRGs 231-235.

For the post-anchor hospitalization portion of CABG model episodes, we propose to follow an analogous procedure to the SHFFT model with the post-anchor hospitalization portion of CABG model episodes grouped in the following manner --

- With AMI diagnosis on the anchor inpatient claim and price MS-DRG with major complication or comorbidity (231, 233, or 235)
- With AMI diagnosis on the anchor inpatient claim and price MS-DRG without major complication or comorbidity (232, 234, or 236)
- Without AMI diagnosis on the anchor inpatient claim and price MS-DRG with major complication or comorbidity (231, 233, or 235)
- Without AMI diagnosis on the anchor inpatient claim and price MS-DRG without major complication or comorbidity (232, 234, or 236)

Specifically, we propose to calculate post-anchor hospitalization severity factors as --

$$w/AMI\ and\ MS-DRG\ w/MCC\ post-anchor\ hosp.severity\ factor = \frac{Natl.avg.\ w/AMI\ and\ MS-DRG\ w/MCC\ post-anchor\ hosp.spend}{Natl.avg.\ w/o\ AMI\ and\ MS-DRG\ w/o\ MCC\ post-anchor\ hosp.spend}$$

$$w/AMI\ and\ MS - DRG\ w/o\ MCC\ post - anchor\ hosp.severity\ factor = \frac{Natl.avg.\ w/AMI\ and\ MS - DRG\ w/o\ MCC\ post - anchor\ hosp.spend}{Natl.avg.\ w/o\ AMI\ and\ MS - DRG\ w/o\ MCC\ post - anchor\ hosp.spend}$$

$$w/o\ AMI\ and\ MS - DRG\ w/MCC\ post - anchor\ hosp.severity\ factor = \frac{Natl.avg.\ w/o\ AMI\ and\ MS - DRG\ w/\ MCC\ post - anchor\ hosp.spend}{Natl.avg.\ w/o\ AMI\ and\ MS - DRG\ w/o\ MCC\ post - anchor\ hosp.spend}$$

We also propose to calculate hospital-specific weights and region-specific weights for the post-anchor hospitalization portion of CABG model episodes as --

$$\frac{Count\ of\ episodes\ with\ price\ \ MS - DRG\ 231 - 236}{\begin{pmatrix} w/AMI\ and\ MS - DRG\ w/MCC\ \ episode\ count\ * \\ w/AMI\ and\ MS - DRG\ w/MCC\ post - anchor\ hosp.severity\ factor \end{pmatrix} + \begin{pmatrix} w/AMI\ and\ MS - DRG\ w/o\ MCC\ \ episode\ count\ * \\ w/AMI\ and\ MS - DRG\ w/o\ MCC\ post - anchor\ hosp.severity\ factor \end{pmatrix} + \begin{pmatrix} w/o\ AMI\ and\ MS - DRG\ w/MCC\ episode\ count\ * \\ w/o\ AMI\ and\ MS - DRG\ w/MCC\ post - anchor\ hosp.severity\ factor \end{pmatrix} + (w/o\ AMI\ and\ MS - DRG\ w/o\ MCC\ episode\ count\ *\ 1)}$$

After blending historical and regional pooled post-anchor hospitalization payments for the CABG model episodes, the blended pooled calculations would be "unpooled" by setting the without AMI ICD-CM diagnosis code on the anchor inpatient claim and price MS-DRG without major complication or comorbidity (232, 234, or 236) post-anchor hospitalization benchmark price to the resulting calculation, and by multiplying the resulting calculation by the severity factors to produce the post-anchor hospitalization benchmark prices for:

- With AMI diagnosis on the anchor inpatient claim and price MS-DRG with major complication or comorbidity (231, 233, or 235)
- With AMI diagnosis on the anchor inpatient claim and price MS-DRG without major complication or comorbidity (232, 234, or 236)
- Without AMI diagnosis on the anchor inpatient claim and price MS-DRG with major complication or comorbidity (231, 233, or 235)

We propose to calculate episode benchmark prices for CABG model episodes by summing combinations of CABG anchor hospitalization benchmark prices and CABG post-anchor hospitalization benchmark prices. Applying the discount factor as discussed in III.D.4.b.(10) and III.D.4.d of this proposed rule would result in the quality-adjusted target prices for CABG model episodes.

For episodes in the AMI model with CABG readmissions, we propose to perform no additional blending of hospital-specific and regional-specific episode payments. We propose to calculate the AMI model episode benchmark and quality-adjusted target prices for such episodes as described in section III.D.4.e. of this proposed rule.

The proposals to combine episodes to set stable benchmark and quality-adjusted target prices are included in § 512.300(c)(13). We seek comment on our proposals for combining episodes for these purposes.

(10) Effective Discount Factors

As discussed in section III.D.2.c. of this proposed rule, we propose to make EPM participants partly or fully accountable for EPM-episode payments in relationship to the EPM quality-adjusted target price. As part of this, in setting an episode quality-adjusted target price for an EPM participant, we propose to apply an effective discount factor to an EPM participant's hospital-specific and regional blended historical EPM-episode payments for a performance period. We expect EPM participants to have a significant opportunity to improve the quality and efficiency of care furnished during episodes in comparison with historical practice, because the EPMs would facilitate the alignment of financial incentives among providers caring for EPM beneficiaries. Our proposed effective discount factors are intended to serve as Medicare's portion of reduced expenditures from an EPM episode with any EPM-episode expenditures

below the quality-adjusted target price potentially available as reconciliation payments to the EPM participant where the anchor hospitalization occurred.

For the EPMs, we propose to establish a 3 percent effective discount factor to calculate the quality-adjusted target prices for EPM participants in the below acceptable and acceptable quality categories, as discussed in section III.E.3.f. of this proposed rule and similar to the CJR model (80 FR 73355). The effective discount factor to calculate the quality-adjusted target price for EPM participants in the good and excellent quality categories would be 2 percent and 1.5 percent, respectively.

Because of the proposed phase-in of repayment responsibility as discussed in section III.D.2.c. of this proposed rule, with no responsibility in either performance year 1 or performance year 2 (NDR) and only partial repayment responsibility in performance year 2 (DR) and all of performance year 3, an EPM participant with actual EPM-episode payments that exceed the quality-adjusted target prices multiplied by the EPM participant's number of EPM episodes to which each quality-adjusted target price would apply in performance year 2 (DR) and performance year 3 would owe Medicare less that would otherwise result from this calculation. As discussed in section III.E.3.f of this rule, an "applicable discount factor" applies to repayment amounts in performance years 2 and 3 while this repayment responsibility is being phased –in. We refer to section III.E.1. and specifically Tables 20 through 28 in this proposed rule for further illustration of the discount percentages that would apply for reconciliation payment and Medicare repayment over the 5 EPM performance years. We believe this methodology offers EPM participants an opportunity to create savings for themselves and Medicare, while also maintaining or improving quality of care for EPM model beneficiaries.

The proposal to establish discount factors that would apply to the quality categories is included in § 512.300(d). We seek comment on our proposal to establish discount factors that apply to the quality categories.

c. Approach to Combine Pricing Features for all SHFFT Model Episodes and AMI Model Episodes without CABG readmissions

The following presents our proposed methodology for combining the pricing features presented in section III.D.4.b. of this proposed rule with respect to SHFFT model episodes and AMI model episodes without a CABG readmission.

- Step 1 - Calculate historical EPM-episode payments for episodes that were initiated during the 3-historical-years of each applicable EPM (that is, individually for each of the SHFFT and AMI models) (section III.D.4.b.(3) of this proposed rule) for all IPPS hospitals for all Medicare Part A and B services included in the EPM episodes. Limit the potential AMI model episodes to those episodes with price MS-DRGs in 280-282 or 246-251 and without readmissions for CABG MS-DRGs. We note that specific PBPM payments may be excluded from historical EPM-episode payment calculations as discussed in section III.D.6.d. of this proposed rule.

- Step 2 - Remove the effects of special payment provisions (section III.D.3.b. of this proposed rule) and normalize for wage index differences (section III.D.4.b.(8) of this proposed rule) by standardizing Medicare FFS payments at the claim-level.

- Step 3 - Prorate Medicare payments for included episode services that span a period of care that extends beyond the episode (section III.D.3.c. of this proposed rule.).

- Step 4 - Trend forward the 2 oldest historical years of data to the most recent year of historical data (section III.D.4.b.(4) of this proposed rule). Separate national trend factors would be applied for each combination of price MS–DRGs.

- Step 5 - Cap high episode payment episodes with a region- and price-MS-DRG-specific high payment ceiling (section III.D.3.d. of this proposed rule), using the episode output from the previous step.

- Step 6 - Group episodes based on price MS-DRGs (SHFFT MS-DRGs 480-482; AMI MS-DRGs 280-282; PCI MS-DRGs 246-251). Within each group of episodes, calculate severity factors and EPM-participant hospital-specific weights (section III.D.4.b.(9) of this proposed rule) using the episode output from the previous step to pool together episodes in each group of price MS-DRGs, resulting in EPM-participant hospital-specific pooled historical average episode payments for each group of price MS-DRGs. Similarly, calculate region-specific weights to calculate region-specific pooled historical average episode payments for each group of price MS-DRGs.

- Step 7 - Calculate EPM-participant hospital-specific and region-specific weighted update factors (section III.D.4.b.(5) of this proposed rule). Multiply each EPM-participant hospital-specific and region-specific pooled historical average episode payment by its corresponding EPM-participant hospital-specific and region-specific weighted update factors to calculate EPM-participant hospital-specific and region-specific updated, pooled, historical average episode payments.

- Step 8 - Blend together each EPM-participant hospital-specific updated, pooled, historical average episode payment with the corresponding region-specific updated, pooled, historical average episode payment according to the proportions for the EPM performance year (III.D.4.b.(6) of this proposed rule). EPM participants that do not have the minimum episode volume across the historical 3 years would use 0.0 percent and 100 percent as the proportions for hospital and region, respectively.

- Step 9 - Multiply the outputs of step (8) by the wage normalization factor described in section III.D.4.b.(8) of this proposed rule to reintroduce geographic variation. For purposes of this proposed rule, we will define the three outputs of this step as the standard episode benchmark price for --

++ SHFFT model episodes with price MS-DRG 482

++ AMI model episodes with price MS-DRG 282 without readmission for CABG, and

++ AMI model episodes with price MS-DRG 251 without readmission for CABG.

- Step 10 - Multiply the output of step (9) by the appropriate severity factors (step (6) of this calculation process and detailed in section III.D.4.b.(9) of this proposed rule) to calculate the standard episode benchmark prices for --

++ SHFFT model episodes with price MS-DRGs 480-481

++ AMI model episodes with price MS-DRGs 280-281 without readmission for CABG

++ AMI model episodes with price MS-DRGs 246-250 without readmission for CABG

- Step 11 - Multiply the outputs of step (9) and (10) by 1 minus the applicable effective discount factor based on the EPM participant's quality category as described in sections III.D.4.b.(10) and III.E.3.f. of this proposed rule. For purposes of this proposed rule, we will define the outputs of this step as the episode quality-adjusted target prices for:

++ SHFFT model episodes with price MS-DRGs 480-482

++ AMI model episodes with price MS-DRGs 280-282 without readmission for CABG, and

++ AMI model episodes with price MS-DRGs 246-251 without readmission for CABG

d. Approach to Combine Pricing Features for CABG Model Episodes

The following presents our proposed methodology for combining the pricing features

presented in section III.D.4.b of this proposed rule with respect to CABG model episodes.

(1) Anchor Hospitalization Portion of CABG Model Episodes

- Step 1 - Calculate historical episode payments that occurred during the anchor hospitalization of CABG model episodes that were initiated during the 3 historical years (section III.D.4.b.(2). of this proposed rule) for all IPPS hospitals for all Medicare Part A and B services included in the episodes. We note that specific PBPM payments may be excluded from historical episode payment calculations as discussed in section III.D.6. of this proposed rule.

- Step 2 - Apply steps III.D.4.c.(2) through (4) to the results of step (1) with trend factors calculated based on the anchor hospitalization portion of CABG model episodes with price MS-DRGs 231-236.

- Step 3 - Group the anchor hospitalization portion of episodes based on price MS-DRGs 231-236 and apply steps III.D.4.c.(6) through (10) to the anchor hospitalization portion of the CABG model episodes with severity factors, hospital-specific weighted update factors, and region-specific weighted update factors calculated to apply based only on the anchor hospitalization portion of CABG model episodes with price MS-DRGs 231-236. For purposes of this proposed rule, we will define the output of this step as CABG anchor hospitalization benchmark prices for CABG model episodes with price MS-DRGs 231-236.

(2) Approach to Combine Pricing Features for Post-Anchor Hospitalization Portion of CABG Model Episodes

- Step 1 - Calculate historical episode payments that occurred after the anchor hospitalization for CABG model episodes that were initiated during the 3 historical years (section III.D.4.b.(2) of this proposed rule) for all IPPS hospitals for all Medicare Parts A and B services included in the episodes. We note that specific PBPM payments may be excluded from historical

episode payment calculations as discussed in section III.D.6. of this proposed rule.

- Step 2 - Apply steps III.D.4.c.(2) through (4) to the results of step (1) with trend factors calculated based on the post-anchor hospitalization portion of CABG model episodes with price MS-DRGs 231-236, as described in section III.D.4.b.(4) of this proposed rule.

- Step 3 - Group the post-anchor hospitalization portion of episodes based on --

++ With AMI diagnosis on the anchor inpatient claim and price MS-DRG with major complication or comorbidity (231, 233, or 235)

++ With AMI diagnosis on the anchor inpatient claim and price MS-DRG without major complication or comorbidity (232, 234, or 236)

++ Without AMI diagnosis on the anchor inpatient claim and price MS-DRG with major complication or comorbidity (231, 233, or 235)

++ Without AMI diagnosis on the anchor inpatient claim and price MS-DRG without major complication or comorbidity (232, 234, or 236).

Then apply steps III.D.4.c.(6)-(10) to the post-anchor hospitalization portion of the CABG model episodes with severity factors, hospital-specific weights, and region-specific weights calculated to apply based on the groups previously described in this step. For purposes of this proposed rule, we will define the output of this step as CABG post-anchor hospitalization benchmark prices for CABG model episodes corresponding to the groups described in this step.

(3) Combine CABG Anchor Hospitalization Benchmark Price and CABG Post-Anchor Hospitalization Benchmark Price

- Step 1 - Sum the CABG anchor hospitalization benchmark price corresponding to each price CABG MS-DRG and the CABG post-anchor hospitalization price corresponding to each of the post-anchor hospitalization groupings described in III.D.4.d.(2). For purposes of

this proposed rule, we will define the outputs of those calculations to be CABG model episode benchmark prices for --

++ CABG model episodes with price MS-DRG 231 and with AMI diagnosis

++ CABG model episodes with price MS-DRG 232 and with AMI diagnosis

++ CABG model episodes with price MS-DRG 233 and with AMI diagnosis

++ CABG model episodes with price MS-DRG 234 and with AMI diagnosis

++ CABG model episodes with price MS-DRG 235 and with AMI diagnosis

++ CABG model episodes with price MS-DRG 236 and with AMI diagnosis

++ CABG model episodes with price MS-DRG 231 and without AMI diagnosis

++ CABG model episodes with price MS-DRG 232 and without AMI diagnosis

++ CABG model episodes with price MS-DRG 233 and without AMI diagnosis

++ CABG model episodes with price MS-DRG 234 and without AMI diagnosis

++ CABG model episodes with price MS-DRG 235 and without AMI diagnosis, and

++ CABG model episodes with price MS-DRG 236 and without AMI diagnosis

The CABG episode benchmark prices for each price CABG MS-DRG with AMI diagnosis would also apply as AMI model episode benchmark prices for AMI model episodes with price MS-DRGs 231-236.

● Step 2 - Multiply the results of step 1 by the appropriate effective discount factor that reflects the EPM participant's quality category as described in sections III.D.4.b.(10) and III.E.3.f. of this proposed rule. For purposes of this proposed rule, we will define the outputs of this step to be CABG model episode quality-adjusted target prices for --

++ CABG model episodes with price MS-DRG 231 and with AMI diagnosis

++ CABG model episodes with price MS-DRG 232 and with AMI diagnosis

++ CABG model episodes with price MS-DRG 233 and with AMI diagnosis

++ CABG model episodes with price MS-DRG 234 and with AMI diagnosis

++ CABG model episodes with price MS-DRG 235 and with AMI diagnosis

++ CABG model episodes with price MS-DRG 236 and with AMI diagnosis

++ CABG model episodes with price MS-DRG 231 and without AMI diagnosis

++ CABG model episodes with price MS-DRG 232 and without AMI diagnosis

++ CABG model episodes with price MS-DRG 233 and without AMI diagnosis

++ CABG model episodes with price MS-DRG 234 and without AMI diagnosis

++ CABG model episodes with price MS-DRG 235 and without AMI diagnosis, and

++ CABG model episodes with price MS-DRG 236 and without AMI diagnosis

The episode quality-adjusted target prices for each anchor CABG MS-DRG with AMI diagnosis would also apply as AMI model episode quality-adjusted target prices for AMI model episodes with price MS-DRGs 231-236. The effective discount factor applied to calculate the AMI model episode quality-adjusted target prices for AMI model episodes with price MS-DRGs 231-236 could differ from the effective discount factor applied to calculate CABG model episode quality-adjusted target prices for CABG model episodes if the participant had different levels of quality performance on the AMI and CABG model composite quality scores that determine the discount factor for the quality-adjusted target prices.

e. Approach to Combine Pricing Features for AMI Model Episodes with CABG Readmissions

The following presents our proposed methodology for combining the pricing features presented in section III.D.4.b of this proposed rule with respect to AMI model episodes with a CABG readmission.

In general, the AMI model episode benchmark price for AMI model episodes with CABG readmission is the sum of the applicable standard AMI model episode benchmark price for an AMI episode without readmission corresponding to the AMI price MS-DRG and the applicable CABG anchor hospitalization benchmark price for a CABG model episode corresponding to the CABG readmission MS-DRG in the AMI model.

- Step 1 - For each combination of AMI price MS-DRG and CABG readmission MS-DRG, sum the corresponding AMI model episode benchmark price and CABG anchor hospitalization benchmark price. This results in 54 possible CABG readmission AMI model episode benchmark prices, corresponding to --

++ Price MS-DRG 280; Readmission MS-DRG 231

++ Price MS-DRG 280; Readmission MS-DRG 232

++ Price MS-DRG 280; Readmission MS-DRG 233

++ Price MS-DRG 280; Readmission MS-DRG 234

++ Price MS-DRG 280; Readmission MS-DRG 235

++ Price MS-DRG 280; Readmission MS-DRG 236

++ Price MS-DRG 281; Readmission MS-DRG 231

++ Price MS-DRG 281; Readmission MS-DRG 232

++ Price MS-DRG 281; Readmission MS-DRG 233

++ Price MS-DRG 281; Readmission MS-DRG 234

++ Price MS-DRG 281; Readmission MS-DRG 235

++ Price MS-DRG 281; Readmission MS-DRG 236

++ Price MS-DRG 282; Readmission MS-DRG 231

++ Price MS-DRG 282; Readmission MS-DRG 232

++ Price MS-DRG 282; Readmission MS-DRG 233

++ Price MS-DRG 282; Readmission MS-DRG 234

++ Price MS-DRG 282; Readmission MS-DRG 235

++ Price MS-DRG 282; Readmission MS-DRG 236

++ Price MS-DRG 246; Readmission MS-DRG 231

++ Price MS-DRG 246; Readmission MS-DRG 232

++ Price MS-DRG 246; Readmission MS-DRG 233

++ Price MS-DRG 246; Readmission MS-DRG 234

++ Price MS-DRG 246; Readmission MS-DRG 235

++ Price MS-DRG 246; Readmission MS-DRG 236

++ Price MS-DRG 247; Readmission MS-DRG 231

++ Price MS-DRG 247; Readmission MS-DRG 232

++ Price MS-DRG 247; Readmission MS-DRG 233

++ Price MS-DRG 247; Readmission MS-DRG 234

++ Price MS-DRG 247; Readmission MS-DRG 235

++ Price MS-DRG 247; Readmission MS-DRG 236

++ Price MS-DRG 248; Readmission MS-DRG 231

++ Price MS-DRG 248; Readmission MS-DRG 232

++ Price MS-DRG 248; Readmission MS-DRG 233

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++ Price MS-DRG 251; Readmission MS-DRG 236

● Step 2 - Multiply the results of step 1 by the effective discount factor that reflects the EPM participant's quality category, as described in sections III.D.4.b.(10) and III.E.3.f. of this proposed rule. For purposes of this proposed rule, we will define the outputs of this step to be AMI model episode quality-adjusted target prices for the same combinations of AMI price MS-DRG and readmission MS-DRG in step (1).

5. Process for Reconciliation

a. Net Payment Reconciliation Amount (NPRA)

Consistent with the CJR model, we propose to conduct reconciliation for each EPM by calculating an EPM-specific NPRA for each EPM participant (80 FR 73381 through 73383). After the completion of an EPM performance year, we propose to retrospectively calculate an EPM participant's actual EPM-episode payments based on the EPM episode definitions as discussed in sections III.C.3. and III.C.4. of this proposed rule and the payment policies applicable to calculating actual EPM-episode payments as discussed in the subsections of section III.D.3 of this proposed rule.

We propose to compare each EPM participant's actual EPM episode payments to its quality-adjusted target prices. We propose, as discussed in section III.D.4. of this proposed rule, that an EPM participant would have multiple quality-adjusted target prices for EPM episodes ending in a given performance year, based on the anchor MS–DRG for the EPM episode, whether the EPM episode included a chained anchor hospitalization; whether the EPM episode included readmission for CABG MS-DRGs; whether the EPM episode included an AMI ICD-CM diagnosis code on the anchor inpatient claim; the performance year when the EPM episode was initiated; when the EPM episode was initiated within a given performance year (January 1 through September 30 of the performance year, October 1 through December 31 of the performance year, October 1 through December 31 of the prior performance year); and the potential effective discount factors. The difference between each EPM episode's actual EPM episode payment and the relevant quality-adjusted target price under the EPM (calculated as quality-adjusted target price subtracted by actual EPM episode payment) would be aggregated for all EPM episodes in each EPM for an EPM participant within the performance year, representing the NPRA. For performance year 2, we would perform two separate aggregations in

order to create two NPRAs—one reflecting episodes that ended during performance year 2 (NDR), and a second for episodes that ended during performance year 2 (DR).

We propose to not include any reconciliation payments or repayments to Medicare under the EPMs for a given performance year when calculating actual episode spending and, therefore the NPRA for a subsequent performance year. We want to incentivize providers to provide high-quality and efficient care in all years of the EPMs. If reconciliation payments for a performance year were counted as Medicare expenditures in a subsequent performance year, an EPM participant would experience higher Medicare expenditures in the subsequent performance year as a consequence of providing high-quality and efficient care in the prior performance year, negating some of the incentive to perform well in the prior year. Therefore, we propose to not have the NPRA for a given performance year be impacted by EPM repayments or reconciliation payments made in a prior performance year. For example, if an EPM participant receives a $10,000 reconciliation payment in the second quarter of 2018 for achieving episode spending below the quality-adjusted target price for performance year 1, that $10,000 reconciliation payment amount would not be included in the performance year 2 calculations of actual EPM-episode payments.

The NPRA would be subject to the stop-loss and stop-gain limits described in section III.D.7.b. of this proposed rule.

b. Payment Reconciliation

We propose to retrospectively reconcile an EPM participant's actual EPM-episode payments against the quality-adjusted target prices 2 months after the end of the performance year. Specifically, we would capture claims submitted by March 1st following the end of the performance year and carry out the NPRA calculation as described previously to make an EPM

reconciliation payment or hold hospitals responsible for repayment, as applicable, in quarter 2 of that calendar year.

We also propose that during the following performance year's reconciliation process, we would calculate the prior performance year's actual EPM episode payments a second time to account for final claims run-out and any canceled EPM episodes, due to overlap with other models or other reasons as specified in section III.C.4.b of this proposed rule. This calculation, termed the subsequent reconciliation, would occur approximately 14 months after the end of the prior performance year. As discussed later in this section, the amount from this calculation, if different from zero, would be applied to the NPRA for the subsequent performance year, as well as the post-episode spending and ACO overlap calculation in order to determine the amount of the payment Medicare would make to the EPM participant or such participant's repayment amount. We note that the subsequent reconciliation calculation would be combined with the previous calculation of NPRA for a performance year to ensure the stop-loss and stop-gain limits discussed in section III.D.7.b. of this proposed rule are not exceeded for a given performance year.

For the performance year 1 reconciliation process, we would calculate an EPM participant's NPRA as previously described, and if positive, such participant would receive the amount as a reconciliation payment from Medicare, subject to the stop-gain limit for performance year 1. If negative, the EPM participant would not be responsible for repayment to Medicare, consistent with our proposal to phase in financial responsibility beginning in the second quarter of performance year 2.

For the performance year 2 reconciliation process, we would calculate two separate NPRAs for an EPM participant—one for episodes that ended during performance year 2 (NDR)

and a second for episodes that ended during performance year 2 (DR). While these NPRAs would be separately determined for each of these two periods, whether an EPM participant receives a Medicare reconciliation payment or makes a Medicare repayment in performance year 2 would be determined based on the sum of these two separately determined NPRAs. The NPRA for both performance year 2 (NDR) and performance year 2 (DR) would be subject to the same stop-gain limit of 5 percent, but because EPM participants would only have repayment responsibility for negative NPRA in performance year 2 (DR), the stop-loss limit of 5 percent would only apply to performance year 2 (DR). Thus, if an EPM participant's NPRA for the first quarter of performance year 2 is positive, that amount would be counted toward a reconciliation payment from Medicare, subject to the stop-gain limit for performance year 2. If negative, the EPM participant would not be responsible for repayment to Medicare of the amount determined for performance year 2 (NDR). If an EPM participant's NPRA is positive for episodes ending during performance year 2 (DR), that amount would be counted toward a reconciliation payment from Medicare, subject to the stop-gain limit for performance year 2. If negative, the EPM participant would be responsible for repayment to Medicare of the amount determined for episodes ending during performance year 2 (DR), subject to the stop loss limits for performance year 2 (DR).

During the subsequent reconciliation process for performance year 2, we would also calculate the prior performance year's actual EPM episode payments a second time separately for episodes that ended during performance year 2 (NDR) and for episodes that ended during performance year 2 (DR).

Also, starting with the EPM reconciliation process for performance year 2, in order to determine the reconciliation or repayment amount, the amount from the subsequent

reconciliation calculation would be combined with the NPRA for that subsequent year. The result of the post-episode spending calculation for performance year 1, as proposed in section III.D.7.e., and the dollar amount of the EPM discount percentage that was paid out as shared savings to an ACO during the prior year as specified in section III.D.6.b. of this proposed rule, would also be added to the NPRA and subsequent reconciliation calculation in order to create the reconciliation payment or repayment amount. If the amount is positive, and if the EPM participant is in the acceptable or better quality category for the EPM (discussed further in section III.E.3.f of this proposed rule), the EPM participant would receive the amount as a reconciliation payment from Medicare. If the amount is negative, Medicare would hold the EPM participant responsible for repaying the absolute value of the repayment amount following the rules and processes for all other Medicare debts. For example, when we conduct reconciliation for performance year 2 in early 2019, we would calculate the performance year 2 NPRA and the subsequent reconciliation calculation, post-episode spending, and ACO overlap calculation for performance year 1. These amounts would be added together to create the reconciliation payment or repayment amount.

Note that given our proposal to not hold EPM participants financially responsible for repayment for the first performance year, during the reconciliation process for performance year 2, the subsequent reconciliation calculation amount (for performance year 1) would be compared against the performance year 1 NPRA to ensure that the sum of the NPRA calculated for performance year 1 and the subsequent reconciliation calculation for year 1 is not less than zero. Likewise given our proposal to not hold EPM participants financially responsible for repayment for episodes ending during performance year 2 (NDR), during the reconciliation process for performance year 3, the subsequent reconciliation calculation amount for performance year 2

(NDR) would be compared against the performance year 2 (NDR) NPRA to ensure that the sum of the NPRA calculated for performance year 2 (NDR) and the subsequent reconciliation calculation for performance year 2 (NDR) is not less than zero.

For performance year 2 (DR) and performance years 3 through 5, though, we propose that Medicare would hold the participant responsible for repaying part or all of the absolute value of the repayment amount, as proposed in section III.D.2.c. of this proposed rule, following the rules and processes for all other Medicare debts. Table 11 illustrates a simplified example of how the subsequent reconciliation calculation may affect the following year's reconciliation payment. Note that this example assumes the EPM participant is not responsible for post-episode spending or ACO overlap for performance year 1.

TABLE 11: SAMPLE RECONCILIATION RESULTS

	Performance Year 1 (2017) NPRA	**Performance Year 1 Subsequent Reconciliation Calculation**	**Difference Between PY1 Subsequent Reconciliation Calculation and NPRA**	**Performance Year 2 (2018) NPRA***	**Reconciliation Payment Made to EPM Participant in Quarter 2 2019**
Hospital A	$50,000	$40,000	($10,000)	$25,000	$15,000

*Note the calculation of NPRA for performance year 2 represents the combined amounts of the NPRA for performance year 2 (NDR) and performance year 2 (DR).

The second column represents the NPRA calculated for performance year 1, meaning that EPM participant Hospital A's aggregated episode payment was $50,000 below the sum of quality–adjusted target prices for all of Hospital A's EPM episodes. The third column represents the subsequent reconciliation calculation, indicating that when calculating actual EPM-episode payments during performance year 1 a second time, we determined that Hospital A's aggregated EPM-episode payment was $40,000 below the sum of quality-adjusted target prices for all of Hospital A's EPM episodes, due to claims run out, accounting for model overlap, or other

reasons. The fourth column represents the difference between the subsequent reconciliation calculation and the raw NPRA calculated for performance year 1. This difference is then combined with the amount in the fifth column to create the reconciliation payment amount for PY2, which is reflected in the sixth column.

This reconciliation process would account for overlap between the CJR model and other CMS models and programs as discussed in section III.D.6.b of this proposed rule, and would also involve updating performance year EPM-episode claims data. We also note that in cases where an EPM participant has appealed one or more of its EPM quality measure results through the HIQR Program appeal process (which is not part of the proposed EPM appeals process), where such HIQR Program appeal findings would result in a different effective discount factor for the EPM participant to calculate the quality-adjusted target prices from EPM-episode benchmark prices, the subsequent reconciliation calculation would account for these changes as well.

For example, for performance year 1 for these EPMs in 2017, we would capture claims submitted by March 1, 2018, and reconcile payments for EPM participants approximately 6 months after the end of the performance year 1 in quarter 2 of calendar year 2018. We would carry out the subsequent reconciliation calculation in the following year in quarter 2 of calendar 2019, simultaneously with the reconciliation process for the second performance year, 2018. Table 12 displays the reconciliation timeframes for the EPMs.

TABLE 12: PROPOSED TIMEFRAME FOR RECONCILIATION FOR EPMs

EPM Performance Year	EPM Performance Period	Reconciliation Claims Submitted By	NPRA Calculation	Second Reconciliation, ACO Overlap, and Post-Episode Spending Calculations	Calculation Amounts Included in Reconciliation Payment and Repayment Amounts
Year 1*	Episodes beginning on or after July 1, 2016 and ending through December 31, 2017	March 1, 2018	Q2 2018	March 1, 2019	Q2 2019
Year 2	Episodes ending January 1, 2018 through December 31, 2018	March 1, 2019	Q2 2019	March 1, 2020	Q2 2020
Year 3	Episodes ending January 1, 2019 through December 31, 2019	March 1, 2020	Q2 2020	March 2, 2021	Q2 2021
Year 4	Episodes ending January 1, 2020 through December 31, 2020	March 2, 2021	Q2 2021	March 1, 2021	Q2 2021
Year 5	Episodes ending January 1, 2021 through December 31, 2021	March 1, 2022	Q2 2022	March 1, 2023	Q2 2023

* Note that the reconciliation for Year 1 would not include repayment responsibility from EPM participants.

We propose this approach in order to balance our goals of providing reconciliation payments in a reasonable timeframe, while being able to account for overlap and all Medicare claims attributable to EPM episodes. We believe that beginning to pull claims 2 months after the end of the performance year would provide sufficient claims run-out to conduct the reconciliation in a timely manner, given that our performance year includes EPM episodes ending, not beginning, by December 31st. We note that in accordance with the regulations at § 424.44 and

the Medicare Claims Processing Manual (Pub. L. 100–04), Chapter 1, Section 70, Medicare claims can be submitted no later than 1 calendar year from the date-of-service. We recognize that by pulling claims 2 months after the end of the performance year to conduct reconciliation, we would not have complete claims run-out. However, we believe that the 2 months of claims run-out would be an accurate reflection of EPM-episode payments and consistent with the claims run-out timeframes used for reconciliation in other payment models, such as BPCI Models 2 and 3 and the CJR model. The alternative would be to wait to reconcile until we have full claims run out 12 months after the end of the performance year, but we are concerned that this approach would significantly delay earned reconciliation payments under the EPMs.

However, we propose to conduct a subsequent reconciliation calculation 14 months after the end of a performance year to account for canceled episodes, post-episode spending, overlap with other CMS models and programs, and any remaining claims available at that time. The proposals for the annual reconciliation and subsequent reconciliation calculation are included in § 512.305 and § 512.307. We seek comment on these proposals for an annual reconciliation and subsequent calculation.

c. Reconciliation Report

For EPM participants to receive timely and meaningful feedback on their performance under the models as well as better understand the basis of their reconciliation payment or Medicare repayment for a given performance year, if any, we propose to annually issue to EPM participants a reconciliation report, similar to the CJR Reconciliation Report we make available to CJR participants (80 FR 73408). We propose that these reports would contain the following information:

- Information on the EPM participant's composite quality score described in section

III.E.3.a. through III.E.3.e of this proposed rule.

- The total actual episode payments for the EPM participant.
- The NPRA.
- Whether the EPM participant is eligible for a reconciliation payment or must make a repayment to Medicare.
- The NPRA and subsequent reconciliation calculation amount for the previous performance year, as applicable.
- The post-episode spending amount and ACO overlap calculation for the previous performance year, as applicable.
- The reconciliation payment or repayment amount.

For performance year 2, we propose that the reconciliation report would include information separately for the performance year 2 (NDR) and performance year 2 (DR) portions of that year.

As discussed in section III.D.8 of this proposed rule, EPM participants would review their reconciliation report and would be required to provide written notice of any error, in a calculation error form that must be submitted in a form and manner specified by CMS. Unless the EPM participant provides such notice, the reconciliation report would be deemed final within 45 calendar days after it is issued, and CMS would proceed with payment or repayment. The proposal to issue a reconciliation report is included in § 512.305(f). We seek comments on our proposal to issue a reconciliation report to EPM participants and what other information, if any, would be helpful to include in this report.

6. Adjustments for Overlaps with Other Innovation Center Models and CMS Programs

a. Overview

Three issues may arise in overlap situations that must be addressed under EPM. First, we acknowledge that there may be circumstances where a hospital in a geographic area selected for the AMI, CABG or SHFFT model is also participating in BPCI for the same episode. We refer to this as "provider overlap." Second, there may be situations where a Medicare beneficiary receives care that could potentially be counted under more than one episode or total cost of care payment model. We refer to this as "beneficiary overlap." Finally, EPM reconciliation payments and Medicare repayments made under Parts A and B and attributable to a specific beneficiary's episode may be at risk of not being accounted for by other models and programs when determining the beneficiary's cost of care under Medicare. Therefore, a payment reconciliation policy is necessary in order to credit the entity that is closest to that care for the episode of care in terms of time, location, and care management responsibility.

We establish our proposal for provider overlap at § 512.100(b) and § 512.230(g). We establish our proposal for beneficiary overlap at § 512.230(f), § 512.230(h), and § 512.230(i). We establish our proposal for payment reconciliation at § 512.210 and § 512.305. We seek comment on our proposals to account for overlap between EPMs and other CMS models or programs.

b. Provider Overlap

(1) BPCI Participant Hospitals in Geographic Areas Selected for EPMs

Provider overlap exists when a hospital in a geographic area selected for the AMI, CABG or SHFFT model is also an episode initiator in BPCI for an episode anchored by that EPM's DRG. BPCI is an episode payment model testing AMI, CABG, SHFFT, and 45 other episodes in acute care, post-acute care, or both acute care and post-acute care settings.

Similar to CJR, we propose that in the geographic areas where the AMI, CABG and SHFFT models will be implemented, an acute care hospital participating in BPCI Model 2 or 4 will participate in an EPM for episodes anchored by EPM MS-DRGs that are not covered under the hospital's current BPCI agreement. If a BPCI hospital in an EPM-selected area withdraws from BPCI episodes anchored by EPM MS-DRGs, the BPCI hospital will participate in the EPMs for which it was previously excluded. This proposal promotes accountable care by ensuring beneficiary coverage by BPCI or an EPM in selected areas.

We establish the proposal for hospitals in geographic areas selected for EPMs that are also participating in BPCI episodes anchored by EPM DRGs at § 512.100(b). We seek comment on this proposal.

(2) BPCI Physician Group Practice (PGP) Episode Initiators in Hospitals Participating in EPMs

It is possible that a physician in a BPCI PGP may treat a Medicare beneficiary in a hospital participating in one or more EPM. We propose that if a beneficiary is admitted to an EPM participant for an episode anchored by EPM MS-DRGs covered under the PGP's BPCI agreement and the attending or operating physician on the admission's inpatient claim is a member of the BPCI PGP, the BPCI episode will take precedence over the EPM episode for which the hospital would otherwise be the accountable entity. In other words, if, for any portion of the EPM episode, a beneficiary would also be in a BPCI PGP episode, we will cancel or never initiate the EPM episode. For example --

- A beneficiary is admitted for a CABG to an EPM participant in the CABG model. The attending or operating physician on the inpatient claim for the admission is in a BPCI Model 2 PGP participating in CABG. The episode is initiated under BPCI; an EPM episode does not initiate.

● A beneficiary is admitted for an AMI to an EPM participant in the AMI model. The beneficiary receives a PCI while hospitalized. The attending or operating physician on the inpatient claim for the admission is in a BPCI Model 2 PGP participating in PCI episodes but not medical AMI episodes. A PCI episode is initiated under BPCI; an EPM episode does not initiate.

● A beneficiary is admitted for an AMI to an EPM participant in the AMI model. A PCI was not part of the beneficiary's treatment. The attending or operating physician on the inpatient claim for the admission is in a BPCI Model 2 PGP participating in PCI episodes only. The episode is initiated under the AMI model. A PCI episode under BPCI Model 2 would not initiate unless a PCI were performed on the beneficiary, and

● A beneficiary is admitted for an AMI to an EPM participant in the AMI model. A CABG was not part of the beneficiary's treatment. The attending or operating physician on the inpatient claim is in a BPCI Model 2 PGP participating in CABG episodes only. The episode is initiated under the AMI model. A CABG episode under BPCI Model 2 would not be initiated unless a CABG was performed on the beneficiary while hospitalized.

We establish the proposal for BPCI PGP episode initiators in hospitals participating in EPMs at § 512.230(g). We seek comment on this proposal.

(c) Beneficiary Overlap

(1) Beneficiary Overlap with BPCI

We also need to account for instances where a different model's episode could initiate during an ongoing EPM episode. We propose that any BPCI Model 2, 3 or 4 episode, regardless of its anchor DRG exclusion status from an EPM episode definition, takes precedence over an AMI,

CABG or SHFFT episode such that it would cancel or prevent the initiation of an AMI, CABG or SHFFT episode. For example --

- If a beneficiary is in an ongoing AMI model episode and is treated for SHFFT by a hospital, PGP physician, or post-acute care provider participating in a BPCI SHFFT episode, the initial AMI model episode will be canceled. The second entity will initiate a new episode under BPCI subject to the payment rules under that model, and
- If a beneficiary is in an ongoing BPCI AMI episode and is readmitted for SHFFT to an EPM participant in the SHFFT model, the BPCI episode would continue and the SHFFT model episode would not initiate.

Participants in BPCI have an expectation that eligible episodes will be part of the BPCI model test, whereas based on our proposal EPM participants would be aware that episodes may be canceled when there is overlap with BPCI episodes. We aim to preserve the integrity of ongoing model tests without introducing major modifications that could make evaluation of existing models more challenging. Given the current scheduled end date for the BPCI, we are proposing to give precedence to episodes covered under BPCI Models 2, 3 and 4 initiated on or before September 30, 2018.

We acknowledge this BPCI-EPM overlap policy differs from the CJR beneficiary overlap policy, where a beneficiary may be in a CJR LEJR episode and a non-LEJR BPCI episode concurrently. However, in CJR this overlap is rare. Within the 90-day post-hospital discharge period, included readmissions occur for less than 1 percent of LEJR beneficiaries. In contrast, included readmissions occur for approximately 25 percent of AMI and CABG beneficiaries. The high incidence of included readmissions for AMI, CABG and SHFFT episodes necessitates a different policy to avoid double-paying savings and double-counting

losses, as well as not initiating new episodes when the readmission is a complication of care during the first episode that could be managed.

We considered alternative options for dealing with situations in which a beneficiary in an EPM episode could also be in a BPCI episode, including allowing the first episode initiated to take precedence regardless of the model under which it occurred. This would encourage more accountable care, particularly with AMI, CABG, and SHFFT episodes that are more likely to involve readmissions for complications than generally occur with LEJR. However, preventing BPCI episodes from being initiated, particularly those initiated by post-acute care providers which, by definition, occur after an anchor hospitalization, could substantially reduce the number of such episodes and our ability to fully test BPCI. Moreover, operational challenges due to different timelines for payment reconciliation are of concern.

We establish the proposal for beneficiary overlap with BPCI at § 512.230(h). We seek comment on this proposal.

(2) Beneficiary Overlap with the CJR Model and other EPMs

As discussed in section III.C.4. of this proposed rule, if a beneficiary is in a SHFFT, AMI or CABG model or CJR episode and has a hospital readmission that is not excluded from the ongoing episode definition and would otherwise initiate an episode in a different EPM or the CJR model, that hospital readmission will not initiate another episode or cancel the ongoing episode. If a beneficiary is in a SHFFT, AMI or CABG model episode or CJR episode and has a hospital readmission that is excluded from the ongoing episode definition and could initiate an episode in a different EPM or the CJR model, the subsequent EPM or CJR episode will initiate, the ongoing episode would continue, and both episodes will occur concurrently. For example --

- The CJR model episode definition does not exclude the MS-DRGs that would initiate

a SHFFT model episode. If a beneficiary is in the CJR model and receives SHFFT at an EPM participant in the SHFFT model during the ongoing CJR episode, the CJR episode will continue and the SHFFT model episode will not initiate;

- SHFFT model episode definition does not exclude the MS-DRGs that would initiate a CJR LEJR episode. If a beneficiary is in the SHFFT model and receives an LEJR at a CJR hospital during the ongoing SHFFT episode, the SHFFT episode will continue and the CJR episode will not initiate;
- The SHFFT model episode definition does not exclude the MS-DRGs that would initiate an AMI model episode. If a beneficiary is in the SHFFT model and is readmitted for an AMI to an EPM participant in the AMI model during the ongoing SHFFT model episode, the SHFFT model episode will continue and the AMI model episode will not initiate;
- The AMI model episode definition does not exclude the MS-DRGs that would initiate a CABG model episode. If a beneficiary is in the AMI model and is readmitted for a CABG to the same or another EPM participant in the CABG model during the ongoing AMI model episode, the AMI model episode will continue and the CABG model episode will not initiate.

We believe that an overlap policy that gives precedence to the ongoing episode over subsequent episodes initiated during the post-hospital discharge period, except where the second admission is explicitly excluded, aligns with our stated goal of encouraging more accountable care. Moreover, this policy would establish an operationally straightforward policy for future EPMs.

We establish the proposal for beneficiary overlap with the CJR model and other EPMs at § 512.230(i). We seek comment on this proposal.

(3) Beneficiary Overlap with Shared Savings Models and Programs

We expect many beneficiaries in an AMI, CABG or SHFFT model episode will also be aligned or attributed to a Shared Savings Program participant or a participant in an ACO model initiated by the CMS Innovation Center. For the purposes of this discussion, the term ACO will be used generically to refer to either Shared Savings Program or Innovation Center ACO models. Shared savings payments to ACOs and shared savings losses repaid by ACOs to CMS have the potential to overlap with EPM reconciliation payments. As with CJR, we propose to attribute savings achieved during an EPM episode to the EPM participant, and include EPM reconciliation payments for ACO-aligned beneficiaries as ACO expenditures. In order to address comments received during rulemaking for CJR, we propose to test an alternative strategy to address ACO overlap. Specifically, we propose to exclude beneficiaries from EPMs who are aligned to ACOs in the Next Generation ACO model and End Stage Renal Disease (ESRD) Seamless Care Organizations (ESCOs) in the Comprehensive ESRD Care initiative in tracks with downside risk for financial losses. We do not propose to exclude beneficiaries aligned to Shared Savings Program ACOs in Tracks 1, 2, or 3 at this time. However, we seek comment on excluding beneficiaries from EPMs that are prospectively assigned to SSP Track 3 as well as to other financial risk tracks. The Shared Savings Program is a national program. We do not believe that testing a new approach to addressing overlap, which could potentially disrupt ACO investments, operations, and care redesign activities, would be appropriate at this time prior to a test with a smaller population. We plan to monitor and learn from the test of excluding beneficiaries prospectively assigned to an ACO from risk tracks and consider these results and comments in future rule-making.

Several strong considerations drive us to otherwise follow CJR precedent for addressing ACO overlap. First, CMS continues to avoid double payment of savings and double

recoupment of losses, which is an important principle of successful payment reform. Second, in implementing the EPMs, there would be no additional operational effort due to consistency in ACO overlap policies across models. In this respect, we anticipate little to no difficulty in replicating prior policy as new episode payment models are introduced. Third, this would have no negative financial impact on EPM participants, an important consideration for future EPMs. The payment reconciliation for EPM participants is described in section III.D.5. of this proposed rule.

Therefore, we propose to follow the policy set forth in the CJR Final Rule for accounting for overlap between EPMs and the Shared Savings Program and ACO models other than the Next Generation ACO model and CEC listed previously.

Additionally, for programmatic consistency among ACO models and programs, given that our ACO models generally are tested for the purpose of informing future potential changes to the Shared Savings Program, we believe that the ACO model overlap adjustment policy should be aligned with the Shared Savings Program policy. Thus, we propose that under EPMs, we would make an adjustment to the reconciliation amount to account for any of the applicable discount for an episode resulting in Medicare savings that is paid back through shared savings under the Shared Savings Program or any other ACO model, but only when an EPM hospital also participates in the ACO and the beneficiary in the EPM episode is also aligned to that ACO. This adjustment would be necessary to ensure that the applicable discount under the EPM is not reduced because a portion of that discount is paid out in shared savings to the ACO and thus, indirectly, back to the hospital.

However, we propose not to make an adjustment under EPMs when a beneficiary receives an AMI, SHFFT, or CABG at a hospital participating in the corresponding EPM and

is aligned to an ACO in which the hospital is not participating. While this proposal would leave overlap unaccounted for in such situations, we do not believe it would be appropriate to hold responsible for repayment the hospital that managed the beneficiary during the episode through an EPM adjustment, given that the participant may have engaged in care redesign and reduced spending during the EPM episode. The participant may be unaware that the beneficiary is also aligned to an ACO. However, we recognize that as proposed this policy would allow an unrelated ACO full credit for the Medicare savings achieved during the episode. The evaluation of each of the EPMs, as discussed in section IV. of this proposed rule, would examine overlap in such situations and the potential effect on Medicare savings.

We note that our proposed policy as outlined in this proposed rule would entail CMS reclaiming from the EPM participant any discount percentage paid out as shared savings for the Shared Savings Program or ACO models only when the hospital is an ACO participant and the beneficiary is aligned with that ACO, while other total cost of care models such as the Comprehensive Primary Care Plus initiative (CPC+) would adjust for the discount percentage in their calculations. We believe that other ACO models in testing that share operating principles with the Shared Savings Program should follow the same policies as the EPM Shared Savings Program adjustment for certain overlapping ACO beneficiaries. As the landscape of CMS models and programs changes, we may revisit this policy through future rulemaking.

However, there are circumstances when an alternative option may be appropriate to consider. Therefore, we are also considering an EPM-ACO overlap policy that would exclude from EPMs beneficiaries who are aligned to ACOs in the Next Generation ACO model and ESCOs in the Comprehensive ESRD Care Initiative in tracks with downside risk for financial

losses. Some ACOs have successfully managed acute care and post-acute care expenditures below regional or national mean costs, and expressed that the current CJR and BPCI ACO overlap policies deprives them of a key source of savings. We are aware of situations in certain markets that seem to reduce opportunities for ACOs to achieve savings given historic experience that indicates these particular ACOs are able to manage the care within episodes as successfully as EPM participants. Attributing savings to participants in episode payment models, such as CJR participants and EPM participants under this proposed rule, creates a problem where the ACO is accountable for coordinating a beneficiary's care over a performance year but is not able to benefit from savings achieved from episodes completed during the performance year. Data shows that post-acute care spending is among the most significant sources of savings for ACOs currently, and where they focus significant investments.[68,69]

Certain considerations weigh against exclusion of all ACO-aligned beneficiaries from participation in EPM episodes. Such a blanket exclusion would remove a large proportion of Medicare FFS beneficiaries from the EPMs, many of whom would inevitably receive care at EPM participants. This would dilute the power of the EPM test and generalizability of EPM findings. Additionally, differences between ACO beneficiary alignment algorithms do not support a blanket exclusion. It is more operationally feasible to identify and exclude beneficiaries who are prospectively aligned to ACOs. In retrospective alignment models, beneficiaries may be aligned to an ACO at the end of the performance year, before the

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[68] McWilliams, J. Michael, Laura A. Hatfield, Michael E. Chernew, Bruce E. Landon, and Aaron L. Schwartz. "Early Performance of Accountable Care Organizations in Medicare — NEJM." N Engl J Med. Massachusetts Medical Society, 13 Apr. 2016. Web. 02 May 2016. http://www.ncbi.nlm.nih.gov/pubmed/27075832.

[69] McWilliams, J. Michael, Michael E. Chernew, Bruce E. Landon, and Aaron L. Schwartz. "Performance Differences in Year 1 of Pioneer Accountable Care Organizations." N Engl J Med. (2015); 372(20): 1927-936. Massachusetts Medical Society, 15 Apr. 2015. Web. 02 May 2016. http://www.ncbi.nlm.nih.gov/pubmed/25875195.

performance year, or preliminarily aligned to one ACO before the performance year and subsequently aligned to a different ACO after all qualifying services are considered. In retrospective alignment, there will be significant numbers of beneficiaries aligned at final reconciliation to a given ACO who were not identified as preliminarily aligned to that ACO prior to the performance year. That is, they were identified either as unaligned to any ACO or aligned to a different ACO. In prospective alignment models and tracks, the list of aligned beneficiaries is available prior to the start of the performance year and a beneficiary's alignment does not change on the basis of his or her utilization in the performance year (subject to various exclusions made on a quarterly basis, such as a beneficiary's election into a Medicare Advantage plan).

Because ACOs in two-sided risk arrangements have stronger incentives than those in one-sided risk arrangements to reduce total cost of care, especially given the possibility of paying CMS shared losses, we believe that ACOs in two-sided risk arrangements may be best positioned to assume the risk associated with EPM episodes, while ACOs in one-sided risk arrangements may be less well-positioned to do so. ACOs in one-sided risk arrangements, such as those in the Shared Savings Program Track 1, do not bear the risk of owing losses to CMS. In contrast, ACOs in two-sided risk arrangements, such as the Next Generation ACO model, are held to as much as 80 percent to 100 percent of first dollar losses. Thus, we believe that pursuing a blanket exclusion from EPMs of aligned beneficiaries from all ACOs would inappropriately disadvantage EPM participants that carry significant financial risk under EPM.

This proposed ACO overlap policy would grant ACOs in models and tracks with the highest levels of downside risk for financial losses -- the Next Generation ACO model and tracks of the Comprehensive ESRD Care Initiative with downside risk for financial losses—

paramount financial opportunity in exchange for accepting total cost of care responsibility for their beneficiaries. EPM participants may still realize opportunities to save by partnering with ACOs, but outside of the EPM arrangement. Specifically, we refer to section IIII. I. of this proposed rule which describes opportunities for gainsharing allowed under these models.

This policy tests the effects of such an ACO-aligned beneficiary exclusion policy within a broader test of the effectiveness of EPMs. We can learn its impact on EPM participants and ACOs that have beneficiaries excluded from EPMs, as well as ACOs that do not have beneficiaries excluded from EPMs. This will improve our understanding about the appropriate entity to hold accountable for the costs within the episode. For this reason we are recommending this test be limited to the AMI, CABG, and SHFF, and CJR models, and ACO models being conducted under CMS' Innovation Center, and are not proposing to implement the policy more broadly to other ACOs, such as those in the Shared Savings Program. In proposing the exclusion of beneficiaries in only a limited number of ACO initiatives we attempt to balance the desire to build a new payment reform initiative while mitigating the potential challenges to existing shared savings models and programs. We seek comment on this proposal as well as input on extending the proposal to CJR and other ACOs accepting two-sided risk, such as those ACOs in the Shared Savings Program Track 3.

We have investigated CMS data related to the services under consideration in the AMI, CABG and SHFFT models. A small fraction of total beneficiaries aligned to ACOs qualifying for this exclusion in fact have relevant anchor hospitalizations that would initiate an EPM in a given calendar year. For instance, from 2013 through 2015, about 2.4 percent of beneficiaries aligned to Pioneer ACO model participants had an anchor hospitalization that would have initiated an AMI, CABG or SHFFT model.

We have considered several additional options to account for EPM-ACO beneficiary overlap prior to proposing the strategy outlined previously. We considered whether to split the risk, including at an equal sharing rate, at the time of financial reconciliation between EPM participants and ACOs when episodes included overlapping beneficiaries. This has the advantage of mitigating the supposed "carve out" of ACO expenditures, but requires CMS to arbitrarily declare a level of risk sharing. We are also concerned about the operational feasibility of such calculations, given that reconciliation would have to occur in tandem, resulting in long delays in payments or recoupments for both EPM participants and ACOs. We also considered whether to attribute to ACOs the more favorable of either the episode-specific target price or the actual expenditures incurred by the beneficiary during the episode time period. However, this policy would result in significant losses to the Medicare Trust Fund, as the double payment of savings/losses would be a certainty.

We establish the proposal to exclude from the EPMs beneficiaries who are aligned to an ACO in the Next Generation ACO Model or Comprehensive ESRD Care Initiative at § 512.230(f). We establish the proposal to attribute savings achieved during an EPM episode to the EPM participant, and include EPM reconciliation payments for other ACO-aligned beneficiaries as ACO expenditures at § 512.305 and § 512.307. We seek comment on our proposals to account for beneficiary overlap with shared savings models and programs.

d. Payment Reconciliation of Overlap with non-ACO CMS Models and Programs

In general, Per-Beneficiary Per-Month (PBPM) payments are for new or enhanced provider or supplier services that share the goal of improving quality of care overall and reducing Medicare expenditures for services that could be avoided through improved care coordination. Some of these PBPM payments may be made for services furnished to a

beneficiary that is in another Innovation Center model at the that same time that the beneficiary is in an EPM, but the clinical relationship between the services paid by the PBPM payments and the EPM will vary. For purposes of this proposed rule, we consider clinically related those services paid by PBPM payments that are for the purpose of care coordination and care management of any beneficiary diagnosis or hospital admission not excluded from an EPM's episode definition, as discussed in section III.C. of this proposed rule.

As with CJR, we propose to include PBPM payments for new and enhanced services in EPM reconciliation calculations if we determine, on a model by model basis, that the services paid by PBPM payments are (1) not excluded from an EPM model's episode definition; (2) rendered during the episode; and (3) paid for from the Medicare Part A or Part B Trust Funds. That is, we would include the clinically related services paid by a PBPM payment if the services would not otherwise be excluded based on the principal diagnosis code on the claim, as discussed in section III.C. of this proposed rule. The PBPM payments for clinically related services would not be excluded from the EPMs' historical episodes used to calculate target prices when the PBPM payments are made from the Part A or Part B Trust Fund, and they would not be excluded from calculation of actual episode expenditures during an EPM's performance period. PBPM model payments that we determine are clinically unrelated would be excluded, regardless of the funding mechanism or diagnosis codes on claims for those payments. We note that in the case of PBPM model payments, principal diagnosis codes on a Part B claim (which are used to identify exclusions from EPMs, as discussed in section III.C. of this proposed rule) would not be the only mechanism for exclusion of a service from an EPM. All such PBPM model payments we determine are clinically unrelated would be excluded as discussed in this proposed rule. Finally, all services paid by PBPM payments

funded through the Innovation Center's appropriation under section 1115A of the Act would be excluded from the EPMs, without a specific determination of their clinical relationship to an EPM. We believe including such PBPM payments funded under the Innovation Center's appropriation and not included on claims would be operationally burdensome and could significantly delay any reconciliation payments and repayments for the EPMs. In addition, because these services are not paid for from the Medicare Parts A or B Trust Funds, we are not confident that they would be covered by Medicare under existing law. Therefore, we believe the services paid by these PBPM payments are most appropriately excluded from the EPMs. Our proposal for the treatment of services paid by PBPM payments in the EPMs would pertain to all existing models with PBPM payments, as well as future models and programs that incorporate PBPM payments. We believe that this proposal is fully consistent with our goal of including all related Part A and Part B services in the EPMs, as discussed in section III.C. of this proposed rule.

As with CJR, the OCM and MCCM services and conditions are excluded from the AMI, CABG, and SHFFT episode definitions and thus their payments are excluded from EPM reconciliation (listed on the CMS webpage at https://innovation.cms.gov/Files/x/cjr-pbpmexclusions.xlsx). While the OCM will pay for new or enhanced services through PBPM payments funded by the Medicare Part B Trust Fund, we do not believe these services are clinically related to the EPMs. The OCM incorporates episode-based payment initiated by chemotherapy treatment, a service generally reported with ICD-9-CM and ICD-10-CM codes that will be excluded from the AMI, CABG, and SHFFT episode definition in section III.C. of this proposed rule. We believe the care coordination and management services paid by OCM PBPM payments would be focused on chemotherapy

services and their complications, so the services would be clinically unrelated to AMI, CABG and SHFFT model episodes. Therefore, we propose that services paid by PBPM payments under the OCM be excluded from the AMI, CABG and SHFFT models. Similarly, we propose to exclude services paid by PBPM payments under the MCCM. The MCCM focuses on providing care coordination and palliative care services for beneficiaries with certain conditions certified as terminally ill with a life expectancy of 6 months or less that have not elected the Medicare hospice benefit. The MCCM seeks to test whether providing palliative care services, without beneficiaries having to forgo curative care, incentivizes beneficiaries to elect hospice sooner. This is aimed at addressing the large percentage of hospice beneficiaries who elect the hospice benefit too late to fully benefit from the range of services that hospice has to offer at end of life. Since the purpose of the MCCM is to test whether providing palliative care services to beneficiaries who are otherwise eligible to elect the Medicare hospice benefit without requiring the beneficiary to forgo curative care results in beneficiaries electing the hospice benefit sooner, we will not include such payments in the AMI, CABG and SHFFT models' episode spending calculations. In addition, unlike the regular hospice benefits, which are furnished to beneficiaries in lieu of curative care and which therefore can be coordinated during an AMI, CABG or SHFFT model episode, the services furnished under the MCCM will be in addition to curative services. We note that we are including such curative services in the EPM episode, as they are consistent with our episode definition described in III.C. of this proposed rule, but not the services represented by the PBPM, which are provided in addition to curative services. Beneficiaries electing the hospice benefit could have lower episode spending because they have forgone curative care, however beneficiaries included in the MCCM may have higher episode spending because they are receiving both curative care and the services represented by

the PBPM. We do not want to create incentives that deter providers from enrolling beneficiaries in the MCCM.

We acknowledge there may be new models that could incorporate a PBPM payment for new or enhanced services. We would plan to make our determination about whether services paid by a new model PBPM payment that is funded under the Medicare Trust Funds are clinically related to EPM episodes through the same sub regulatory approach that we are proposing to use to update the episode definitions (excluded MS-DRGs and ICD-CM diagnosis codes). We would assess each model's PBPM payment to determine if it would be primarily used for care coordination or care management services for excluded clinical conditions in the EPMs based on the standards we propose to use to update EPM episode definitions that are discussed in section III.C. of this proposed rule.

If we determine that a PBPM payment would primarily be used to pay for services to manage an excluded clinical condition, we would exclude the PBPM payment from the EPM on the basis that it pays for unrelated services. If we determine that the PBPM payment could primarily be used for services to manage an included clinical condition, we would include the PBPM payment in the EPM if the diagnosis code on the claim for the PBPM payment was not excluded from the episode, following our usual process for determining excluded claims for Part B services in accordance with the EPM episode definitions discussed in section III.C. of this proposed rule. We would post our proposed determination about whether the PBPM payment would be included in the episode to the CMS website to allow for public input on our planned application of these standards, and then adopt changes to the overlap list with posting to the CMS website of the final updated list after our consideration of the public input.

The payment reconciliation is described in section III.D.5. of this proposed rule. As with CJR, it is important that other models and programs in which providers are accountable for the total cost of care be able to account for the full Medicare payment, including EPM-related reconciliation payments and repayments as described in section III.D.5. of this proposed rule, for beneficiaries who are also in EPM episodes.

We establish the proposal for accounting for non-ACO services and payments in the EPM reconciliation process at § 512.210. We seek comment on this proposal.

7. Limits or Adjustments to EPM Participants' Financial Responsibility

a. Overview

We recognize that hospitals that would be designated for participation in the proposed EPMs currently vary with respect to their readiness to function under an EPM with regard to their organizational and systems capacity and structure, as well as their beneficiary population served. Some EPM participants may be more quickly able to demonstrate high quality performance and savings than others, even though we proposed that the EPM-episode benchmark prices be based predominantly on the hospital's own historical EPM-episode utilization in the early years of the EPMs. We also note that providers may be incentivized to excessively reduce or shift utilization outside of an EPM's episode by the proposed payment policies of the EPMs. In order to mitigate any excessive repayment responsibility for EPM participants or reduction or shifting of care outside an EPM episode, especially beginning in performance year 2 of the EPMs when we propose to begin to phase in responsibility for repaying Medicare for excess EPM-episode payments, we propose several specific policies as follows.

b. Limit on Actual EPM-Episode Payment Contribution to Repayment Amounts and

Reconciliation Payments

(1) Limit on Actual EPM-Episode Payment Contribution to Repayment Amounts

As discussed in section III.D.3.d. of this proposed rule regarding our proposed pricing adjustment for high payment EPM episodes, EPM participants would not bear financial responsibility for actual EPM-episode payments greater than a ceiling set at 2 standard deviations above the mean regional EPM-episode payment. Nevertheless, EPM participants would begin to bear repayment responsibility beginning performance year 2 (DR) for those EPM episodes where actual EPM-episode payments are greater than the EPM quality-adjusted target prices up to the level of the regional EPM-episode ceiling. When aggregated across all EPM episodes in a model, the total money owed to Medicare by an EPM participant for actual EPM-episode payments above the applicable EPM quality-adjusted target price could be substantial if a hospital's EPM episodes generally had high payments. As an extreme example, if a hospital had all of its EPM episodes paid at 2 standard deviations above the mean regional EPM-episode payment, the EPM participant would need to repay Medicare a large amount of money, especially if the number of EPM episodes was large.

To limit a hospital's overall repayment responsibility for actual EPM-episode payments under the EPMs, (hereafter called a "stop-loss limit"), we propose to establish the same stop-loss limits that were adopted for the CJR model (80 FR 73401); except, that they would apply beginning in the second rather than first quarter of performance year 2. Specifically, we propose a 5 percent stop-loss limit in performance year 2 (DR), a 10 percent stop-loss limit in performance year 3, and a 20 percent stop-loss limit for performance years 4 and 5 for each EPM. That is, beginning in the second quarter of performance year 2 as we phase in repayment responsibility, the EPM participant would owe Medicare under each proposed EPM no more

than 5 percent of the sum of the EPM quality-adjusted target prices for all of the EPM participant's EPM episodes during performance year 2 (DR). This responsibility gradually phases up to 20 percent by performance year 4.

For performance year 2, the comparison against the stop loss limit would only apply for NPRA attributable to episodes ending in performance year 2 (DR). When we calculate the NPRA for performance year 2 as described in section III.D.5. of this proposed rule, we would ensure the NPRA attributable to episodes ending during performance year 2 (NDR) is not less than zero and that NPRA attributable to episodes ending during performance year 2 (DR) does not exceed the stop-loss limit of 5 percent of the sum of quality-adjusted target prices for episodes that ended during performance year 2 (DR).

Similarly, when we conduct the subsequent reconciliation calculation to reassess actual EPM-episode payments for performance year 2 (which will occur concurrently with the reconciliation for performance year 3), we would combine the performance year 2 (NDR) NPRA and the result of the subsequent reconciliation calculation for performance year 2 (NDR) to ensure the result is not less than zero. Also, we would combine the performance year 2 (DR) NPRA and the result of the subsequent reconciliation calculation for performance year 2 (DR) to ensure the stop-loss limit is not exceeded.

For performance years 3 through 5, it would not be necessary to split the performance years to ensure that the stop-loss limit is not exceeded as a single stop-loss limit would apply in each year. For example, when we calculate the NPRA for performance year 3, as described in section III.D.5. of this proposed rule, we would ensure the NPRA does not exceed the stop-loss limit of 10 percent of the sum of quality-adjusted target prices. Similarly when we conduct the subsequent reconciliation calculation to reassess actual EPM-episode payments for performance

year 3 (which will occur concurrently with the reconciliation for performance year 4), we would combine the performance year 3 NPRA and the result of the subsequent reconciliation calculation for performance year 3 to ensure the stop-loss limit is not exceeded.

Note that, as described in sections III.D.5.b. and III.D.7.e., the result of the post-episode spending calculation and ACO overlap calculation that would occur concurrently with the subsequent reconciliation calculation for a given performance year would not be subject to the stop-loss limit. The result of these calculations will be added to the NPRA and subsequent reconciliation calculation to create the repayment amount or reconciliation payment. We believe that these limits both offer EPM participants reasonable protections while maintaining incentives to improve care quality and efficiency. We would note that in addition to the CJR model, we apply a similar ultimate 20 percent stop-loss limit to payments under the BPCI initiative.

The proposal to limit hospitals' overall payment responsibility under the models is included in § 512.305(c)(2)(iii)(A). We seek comment on our proposal to limit hospitals' overall payment responsibility.

(2) Limitation on Reconciliation Payments

We believe limits on reconciliation payments made under the proposed EPMs would also be appropriate for several reasons. Under our proposal, in performance year 1, EPM participants have no repayment responsibility for excess EPM episode spending above the EPM quality-adjusted target price. CMS bears full financial responsibility for Medicare actual EPM-episode payments for an EPM episode that exceeds the EPM quality-adjusted target price, and we believe our responsibility should have judicious limits. Therefore, we believe it would be reasonable to cap an EPM participant's reconciliation payment due to actual EPM-episode

payments for a given performance year as a percentage of EPM-episode payment on the basis of responsible stewardship of CMS resources. In addition, we note that beginning in performance year 1, EPM participants would be eligible for reconciliation payments due to the NPRA if actual EPM-episode payments are less than the quality-adjusted target prices. This proposal for reconciliation payments due to the NPRA provides a financial incentive to EPM participants from the beginning of the model to manage and coordinate care throughout the EPM episode with a focus on ensuring that EPM beneficiaries receive the lowest intensity, medically appropriate care throughout the EPM episode that results in high quality outcomes. Therefore, we also believe it would be reasonable to cap an EPM participant's reconciliation payment resulting from actual EPM-episode payments based on concerns about potential excessive reductions in utilization under the proposed EPMs that could lead to beneficiary harm.

In determining what would constitute an appropriate reconciliation payment limit due to actual episode spending (hereafter called a "stop-gain limit"), we believe it should provide significant opportunity for EPM participants to receive reconciliation payments for greater episode efficiency that includes achievement of quality care and actual EPM-episode payment reductions below the quality-adjusted target price, while avoiding the creation of significant incentives to sharply reduce utilization that could be harmful to EPM beneficiaries. We also believe that establishing parallel stop-gain and stop-loss limits is important to provide proportionately similar protections to CMS and EPM participants for their financial responsibilities under the EPMs as well as to protect the health of beneficiaries. Accordingly, we propose to establish symmetrical stop-gain limits. Specifically, we propose a 5 percent stop-gain limit in performance years 1 and 2, a 10 percent stop-gain limit in performance year 3, and a 20 percent stop-gain limit for performance years 4 and 5 for each EPM. That is, in performance

year 1 as we phase in the stop-gain limits, the reconciliation payment that the EPM participant would be eligible to receive under each proposed EPM would be no more than 5 percent of the sum of the EPM quality-adjusted target prices for all of the EPM participant's EPM episodes during the performance year. This limit gradually phases up to 20 percent by performance year 4. As indicated in the CJR Final Rule, we want to ensure that any savings achieved by EPM participants in the early years of the EPM are not due to random variation, and that changes undertaken to improve efficiency include achievement in care quality and not sharp decreases in utilization that could be harmful to beneficiaries (80 FR 73402).

We clarify that, as with the stop-loss limit as discussed in this section, we propose that we would determine whether an EPM participant has met the stop-gain limit by assessing the NPRA and subsequent reconciliation for a given performance year, if any. We believe this approach aligns with our goal to place limits on the amount a participant may earn as a reconciliation payment due to reduced actual EPM-episode payments.

We would also note that we plan to monitor beneficiary access and utilization of services and the potential contribution of the stop-gain limit to any inappropriate reduction in EPM- episode services. We refer to section III.G. of this proposed rule for our proposals on monitoring and addressing hospital performance under the proposed EPMs.

The proposal to establish a cap on an EPM participant's reconciliation payment due to actual EPM-episode payments for a given performance year as a percentage of EPM-episode payment is included in § 512.305(c)(2)(iii)(B). We seek comment on this proposed cap.

c. Additional Protections for Certain EPM Participants

(1) Proposed Policies for Certain EPM Participants to Further Limit Repayment Responsibility

While the aforementioned proposals generally provide additional safeguards to ensure

that EPM participants would have limited repayment responsibility due to the raw NPRA, we are proposing additional protections for certain groups of EPM participants that may have a lower risk tolerance and less infrastructure and support to achieve efficiencies for high-payment EPM episodes. Specifically, we are proposing additional protections for rural hospitals, SCHs, Medicare Dependent Hospitals, and Rural Referral Centers (RRCs). We note that these categories of hospitals often have special payment protections or additional payment benefits under Medicare because we recognize the importance of preserving Medicare beneficiaries' access to care from these hospitals.

For the purpose of these models, we propose to define a Rural Hospital as an IPPS hospital that is either located in a rural area in accordance with § 412.64(b) or in a rural census tract within an MSA defined at § 412.103(a)(1) or has reclassified to rural in accordance with § 412.103.

We propose to define a Sole Community Hospital as it is defined in § 412.92. That is, hospitals paid under the IPPS can qualify for SCH status if they meet one of the following criteria:

- Located at least 35 miles from other like hospitals.
- Located in a rural area, located between 25 and 35 miles from other like hospitals, and no more than 25 percent of residents or Medicare beneficiaries who become hospital inpatients in the hospital's service area are admitted to other like hospitals located within a 35-mile radius of the hospital or the hospital has fewer than 50 beds and would meet the 25 percent criterion if not for the fact that some beneficiaries or residents were forced to seek specialized care outside of the service area due to the unavailability of necessary specialty services at the hospital.

- Hospital is rural and located between 15 and 25 miles from other like hospitals but because of local topography or periods of prolonged severe weather conditions, the other like hospitals are inaccessible for at least 30 days in each of 2 out of 3 years.
- Hospital is rural and the travel time between the hospital and the nearest like hospital is at least 45 minutes.

We propose to define a Medicare Dependent Hospital (MDH) as it is defined in § 412.108. That is, an MDH is a hospital that meets the following criteria:

- Located in a rural area.
- Has 100 beds or less.
- Is not a SCH.
- Sixty percent of the hospital's inpatient days or discharges were attributable to individuals entitled to Medicare Part A benefits during specified time periods as provided in § 412.108.

We propose to define a Rural Referral Center as it is defined in § 412.96. Specifically, RRCs are defined as IPPS hospitals with at least 275 beds that meet the following criteria:

- Fifty percent of the hospital's Medicare patients are referred from other hospitals or from physicians who are not on the staff of the hospital.
- At least 60 percent of the hospital's Medicare patients live more than 25 miles from the hospital.
- At least 60 percent of all services the hospital furnishes to Medicare patients are furnished to patients who live more than 25 miles from the hospital.

If a hospital does not meet these criteria, a hospital can also qualify for RRC status if a hospital meets the following criteria:

- For specified period of time, the hospital has a case-mix that equals at least the lower of the median case mix index (CMI) value for all urban hospitals nationally; or the median CMI value for urban hospitals located in its region, excluding those hospitals receiving indirect medical education payments.
- Its number of discharges is at least—

++ 5,000 (or 3,000 for an osteopathic hospital); or

++ The median number of discharges for urban hospitals in the census region in which it is located, set by the CMS through IPPS rulemaking.

- Additionally, a hospital must meet one of the following criteria:

++ More than 50 percent of its active medical staff are specialists who meet the conditions specified at§ 412.96(c)(3).

++ At least 60 percent of all discharges are for inpatients who reside more than 25 miles from the hospital.

++ At least 40 percent of all inpatients treated are referred from other hospitals or from physicians who are not on the hospital's staff.

Additional information on these hospitals can be found in the CJR Final Rule at 80 FR 73403 through 73405.

In the CJR Final Rule, we established the same stop-gain limits for these hospitals as for hospitals in general (that is, 5 percent in performance years 1 and 2, 10 percent in performance year 3, and 20 percent in performance years 4 and 5); however, we limited losses for rural hospitals, SCHs, Medicare Dependent Hospitals and RRCs to 3 percent in performance year 2, and 5 percent in performance years 3 through 5 (80 FR 73406). In that Final Rule, we noted that these hospitals can face unique challenges that do not exist for most other hospitals. For

example, these hospitals may be the only source of healthcare services for beneficiaries or certain beneficiaries living in rural areas, and may be in areas with fewer providers including fewer physicians and post-acute care facilities. Further, these hospitals may have more limited options in coordinating care and reducing spending while maintaining quality of care. We continue to believe that urban hospitals may not have similar concerns as they are often in areas with many other providers and have a greater opportunity to develop efficiencies under the EPMs. Given these circumstances, for the CJR model we determined that we should have a more protective stop-loss limit policy for these hospitals. Given the similarity between the CJR model and the proposed EPMs, we have similar concerns, which we believe should be addressed by establishing greater protections for these hospitals when they are EPM participants. Accordingly, we are proposing the same stop-loss thresholds for these hospitals participating in the proposed EPMs as were adopted for the CJR model except that the thresholds would begin in performance year 2 (DR)—specifically, 3 percent in performance year 2 (DR), and 5 percent for performance years 3 through 5 for each EPM.

The proposal to establish separate financial loss limits for certain hospitals that could be less able to tolerate risk is included in § 512.305(c)(2)(iii)(C). We seek comment on our proposed limit on financial loss for these hospitals.

(2) Considerations for Hospitals Serving a High Percentage of Potentially Vulnerable Populations

In addition to the aforementioned hospitals, we recognize that other EPM participants, for which we do not propose additional protections, could also face factors affecting their ability to achieve savings under the proposed EPMs, and that these factors could be unrelated to their practice patterns but instead could reflect the EPM participants' responsibilities for a relatively

high percentage of potentially vulnerable populations with higher than average historical spending and/or less opportunities for efficiencies. For example, this could include hospitals that serve a relatively high percentage of beneficiaries that are dually eligible for both Medicare and Medicaid or whose total Medicare payments include a relatively high proportion of disproportionate share hospital payments under 1886(d) (5) (F) of the Act. Some of these hospitals are located in rural areas and would thus likely be classified as a type of hospital for which we propose additional protections. However, most hospitals that serve a relatively high percentage of beneficiaries that are dually eligible for both Medicare and Medicaid or whose total Medicare payments include a relatively high proportion of disproportionate share hospital payments are located in urban areas, and very few are classified as a rural hospital, RRC, MDH, or SCH that would be subject to the additional protections we propose. For the first 2 performance years of the EPMs, where quality-adjusted target prices are set predominantly based on EPM-participant hospital-specific data, factors affecting these hospitals may be of less concern than in the final 3 performance years of the EPMs where pricing is either predominantly or totally based on regional data.

The potential challenges posed by these kinds of factors is highlighted in Section 2(d) of the Improving Medicare Post-Acute Care Transformation "IMPACT" Act of 2014 (P.L. 113-183). Specifically, Section 2(d) requires the Secretary to conduct a study that examines the effect of individuals' socioeconomic status, including their Medicaid eligibility, on quality measures and resource use and other measures for individuals under the Medicare program, in recognition that less healthy individuals may require more intensive interventions. The Secretary is required to submit a report on the results of this study within 2 years of enactment of the IMPACT Act. The IMPACT Act also requires the Secretary to conduct a second study that

examines the impact of various risk factors, as well as race, health literacy, limited English proficiency (LEP), and Medicare beneficiary activation, on quality measures and resource use and other measures under the Medicare program in order to recognize that less healthy individuals may require more intensive interventions. The Secretary must submit a report on the results of this study within 5 years of enactment of the IMPACT Act.

If these studies find a relationship between the factors examined in the studies and quality measures and resource use and other measures, then the Secretary shall provide recommendations for, among other things, how CMS should account for such factors in quality measures, resource use measures, and other measures under Medicare; and in determining payment adjustments based on such measures in other applicable provisions related to the program. Likewise, taking into account these studies and their recommendations as well as other relevant information, the Secretary is required to routinely, as determined appropriate and based on an individual's health status and other factors, assess appropriate adjustments to quality measures, resource use measures, and other measures under the Medicare program; and assess and implement appropriate adjustments to Medicare payments based on these measures. The Assistant Secretary for Planning and Evaluation is responsible for these studies and a report on the results of the first one is forthcoming. Upon issuance of these studies' reports, we plan to consider their results as we implement the proposed EPMs. We also plan to monitor the influence of beneficiary characteristics such as socioeconomic status on EPM participants' performance during our implementation and evaluation of the EPMs. Given that the performance of EPM participants would be compared largely against their own historical episode cost performance data for the first 2 years of the models, we do not anticipate that the aforementioned factors should materially affect participants' ability to achieve savings.

However, as we increasingly begin to rely more on regional cost performance data to determine episode benchmarks and quality-adjusted target prices in performance year 3, these factors could become more germane. Thus, in the event we identify the need for adjustments, we could consider proposing additional policies through subsequent rulemaking. Additionally, we plan to use information collected as part of our efforts to monitor beneficiary access to care and quality of care as discussed in sections III.G.4. and III.G.5. of this proposed rule to inform if potential adjustments would be needed in future years of the model.

Protections for EPM participants are discussed in section III.D.7.b.(1) of this proposed rule. We seek comment about all issues specific to hospitals serving a high percentage of potentially vulnerable populations and their opportunities to advance the goals of the EPMs. In particular, we seek comment, including data analysis, about approaches to identifying these hospitals; their opportunities to achieve high quality episode performance; specific considerations about their opportunities to achieve efficient care for the clinical conditions included in the AMI, CABG, and SHFFT models; potential approaches to risk adjustment as elaborated upon in section III.D.4.b.(2)(d) of this proposed rule; potential approaches to additional protections that could be considered for the future modeled after our proposals in section III.D.7.b.(1) of this proposed rule for certain other EPM participants or other alternatives; and evaluation methodologies to ensure that we include appropriate comparison groups and monitor and evaluate the most relevant outcomes.

d. Application of Stop-Gain and Stop-Loss Limits

Because hospitals could be participating in the proposed AMI, CABG, and SHFFT models concurrently with the CJR model, an additional consideration concerns the level at which the stop-loss and stop-gain thresholds would be applied, for example, at the hospital level, as is

currently the case for the CJR model, or at some other level, for example, at the model level. Our intention is to establish appropriate incentives and protections for hospitals under the proposed EPMs and the CJR model without creating unnecessary administrative complexity. This issue becomes especially relevant to the proposed EPMs and CJR model given that the CJR model and proposed EPMs would be operating at different points within their performance periods. That is, episodes under the proposed EPMs would always lag 1 performance year behind those in the CJR model. Thus, SHFFT model participants that would begin the first SHFFT model performance year in 2017 would already be participating in their second performance year under the CJR model. Consequently, in this example, a stop-loss limit could apply to the performance year 2 episodes under the CJR model but not to the performance year 1 SHFFT model episodes under the SHFFT model as SHFFT model participants would not have repayment responsibility in SHFFT model performance year 1 under our proposal. In contrast, for this example, the stop-gain limits would be the same for both the SHFFT and CJR model since the limit for both performance year 1 and 2 would be 5 percent.

Continuing with this example for a later performance year (performance year 4 for the CJR model and performance year 3 for the SHFFT model), any stop-loss limits that applied would be different. That is, the stop-loss limits for the CJR model episodes in performance year 4 would be 20 percent in contrast to the 10 percent stop-loss limit that would apply to the SHFFT model episodes in performance year 3. The proposed stop-gain limits would likewise diverge in this example as they are proposed to be symmetrical with the stop-loss limits.

Given these differences, we considered two options for setting stop-gain and stop-loss limits for hospitals participating in more than one of the AMI, CABG, SHFFT, and CJR models. Under the first option, we would determine stop-loss and stop-gain limits, in total, at the

participant level based on weighted thresholds. Specifically, CMS would calculate a single weighted stop-loss/gain threshold based on the total spending under each model. Thus, using the aforementioned example where CJR model episodes would be in performance year 4 of their model and SHFFT model episodes would be in performance year 3, assuming 50 percent of total spending under the CJR and SHFFT models is for CJR model episodes and the remaining 50 percent is for SHFFT model episodes, the weighted stop-loss limit for the two models at the hospital level would be 15 percent: (0.50 X 0.20 for CJR model episodes) + (0.5 X 0.10 for SHFFT model episodes) = 0.15. Although this option would allow the application of a single stop-loss threshold to a hospital's total repayment under the models, we are concerned that computing a single limit such as this could either dilute or magnify the intended protections of the stop-loss limit under each model. As such, a hospital that would have been protected from repayment exceeding 10 percent of its SHFFT model quality-adjusted target prices multiplied by the number of SHFFT model episodes for performance year 3 would only be protected for costs above the higher 15 percent level. Conversely, a hospital that would have been protected only for repayment above 20 percent of its CJR model quality-adjusted target prices multiple by the number of CJR model episodes for performance year 3 would be protected against repayment above the lower 15 percent threshold.

Alternatively, we considered establishing stop-loss and stop-gain thresholds at the model level; that is, separately for each of the AMI, CABG, and SHFFT models, in addition to the limits that already exist for the CJR model. Under this option, we would separately apply the CJR-applicable stop-loss and stop-gain limits to CJR model episodes, the AMI-applicable limits to AMI model episodes, and so forth. Thus, considering the aforementioned example, the stop-loss limit for CJR model episodes in performance year 4 would be 20 percent for the

hospital's CJR model episodes, while the stop-loss limit for SHFFT model episodes for performance year 3 would be 10 percent. While we might choose to aggregate these amounts to conduct a single financial transaction with a hospital participating in more than one model, we believe this option that would apply stop-loss and stop-gain limits at the model level for hospitals participating in more than one model is superior to first option in that it better maintains appropriate incentives and protections under each of the models.

The proposal to establish stop-gain and stop-loss limits at the model level is included in § 512.305(c)(2)(iii)(D). We seek comment on our proposal to establish stop-gain and stop-loss limits at the model level.

e. EPM Participant Responsibility for Increased Post-Episode Payments

We note that while episodes under the proposed EPMs would extend 90 days post-discharge from the anchor or chained anchor hospitalization, some EPM participants may have an incentive to withhold or delay medically-necessary care until after an EPM episode ends to reduce its actual EPM-episode payments. This inappropriate shifting could include both those services that are related to the episode (for which the hospital would bear financial responsibility as such services would be included in the actual EPM-episode payment calculation) and those that are unrelated (which would not be included in the actual EPM-episode payment calculation), because an EPM participant engaged in shifting of medically-necessary services outside the EPM episode for potential financial reward may be unlikely to clearly distinguish whether the services were related to the EPM episode or not in the hospital's decisions.

We believe that this inappropriate shifting would not be typical, especially given the relatively long EPM episode duration. However, in order to identify and address inappropriate shifting of care, we propose to calculate for each EPM performance year the total Medicare Parts

A and B expenditures in the 30-day period following completion of each EPM episode for all services covered under Medicare Parts A and B, regardless of whether the services are included in the proposed EPM episode definition (sections III.C.3. and III.C.4 of this proposed rule). This proposal is consistent with our processes for BPCI Model 2 and the CJR model (80 FR 73407 through 73408).

We propose that the post-episode spending calculation for a performance year would occur at the same time we perform the subsequent reconciliation calculation for that same year. We believe this timeframe will allow sufficient time for claims run out in order to set a reliable regional threshold for determining the post-episode spending. For example, we would conduct reconciliation for performance year 1 in the spring of 2018. The post-episode spending calculation for performance year 1 would occur during the next reconciliation process (spring 2019), when we conduct the subsequent reconciliation calculation for performance year 1 and account for overlap with other models and programs.

Our proposed calculation would include prorated payments for services that extend beyond the EPM episode as discussed in section III.D.3.c. of this proposed rule. Specifically, we would identify whether the average 30-day post-episode spending for an EPM participant in any given EPM performance year is greater than 3 standard deviations above the regional average 30-day post-episode spending, based on the 30-day post-episode spending for episodes attributed to all regional hospitals participating in the EPM in the same region as the EPM participant. We propose that if the EPM participant's average post-episode spending exceeds this threshold, the EPM participant would repay Medicare for the amount that exceeds such threshold. We note that an EPM participant's responsibility for post-episode spending would not be subject to the stop-loss and stop-gain limits proposed in section III.D.7.b. of this proposed rule. Although we

believe cases in which an EPM participant would be responsible for repayment of post-episode spending that exceed the threshold would be rare, our intention is to identify and hold EPM participants responsible for situations in which those participants have significantly increased spending on services in the 30 days following the end of an EPM episode in order to inappropriately shift services out of EPM episodes. We do not believe such behavior should be subject to stop-loss limits. This policy is consistent with our proposal for the CJR model in section V.D.1. of this proposed rule.

Based on our experience with BPCI, we have not found that this proposal, including our proposal to include all Medicare Parts A and B expenditures to measure 30-day post-episode spending, would inappropriately penalize EPM participants. To that end, however, we believe our proposed threshold of 3 standard deviations above the regional average is a high threshold, and we only propose that an EPM participant would repay Medicare for the amount that exceeds such threshold. We further note that those EPM participants that are eligible for reconciliation payments in an EPM performance year and also have average 30-day post-episode spending that is higher than 3 standard deviations above the regional average 30-day post-episode spending would have their reconciliation payments reduced by the amount by which spending exceeds 3 standard deviations.

The proposals to determine if a participant's post-episode spending 30 days after the end of an episode exceeds 3 standard deviations of average spending in their region for that period, and require those participants exceeding that threshold to repay Medicare for the amounts in excess of 3 standard deviations are included in § 512.307(c). We seek comment on our proposals to determine if a participant exceeds this threshold and to repay amounts in excess of the threshold.

8. Appeals Process

a. Overview

Consistent with the BPCI initiative and CJR model, we propose to institute appeals processes for the EPMs that would allow EPM participants to appeal matters related to payment, CR incentive payments, reconciliation amounts, repayment amounts, determinations associated with quality measures affecting payment, as well as non-payment related issues, such as enforcement matters. These matters are discussed throughout section III.D. and III.F. respectively.

We seek comment on the proposal to institute appeals processes, in the following discussion, for the EPMs.

b. Notice of Calculation Error (first level appeal).

We propose the following calculation error process for EPM participants to contest matters related to payment or reconciliation, of which the following is a non-exhaustive list: the calculation of the EPM participant's reconciliation amount or repayment amount as reflected in the reconciliation report; the calculation of the EPM participant's CR incentive payment as reflected in the CR incentive payment report; the calculation of NPRA; the calculation of the percentiles of quality measure performance to determine eligibility to receive a reconciliation payment; and the successful reporting of the voluntary PRO THA/TKA data to adjust the reconciliation payment. EPM participants would review their reconciliation report and CR incentive payment report and be required to provide written notice of any error, in a calculation error form that must be submitted in a form and manner specified by CMS. Unless the EPM participant provides such notice, the reconciliation report and CR incentive report would be deemed final within 45 calendar days after it is issued, and CMS would proceed with payment or

repayment. If CMS receives a timely notice of an error in the calculation, CMS would respond in writing within 30 calendar days to either confirm or refute the calculation error, although CMS would reserve the right to an extension upon written notice to the participant. We propose that if an EPM participant does not submit timely notice of a calculation error, that is notice within 45 calendar days of the issuance of the reconciliation report and CR incentive payment report the EPM participant would be precluded from later contesting any of the following matters contained in the reconciliation report or CR incentive payment report for that performance year; any matter involving the calculation of the EPM participant's reconciliation amount or repayment amount as reflected in the reconciliation report; any matter involving the calculation of the EPM participant's CR incentive payment as reflected in the CR incentive payment report; any matter involving the calculation of NPRA; the calculation of the percentiles of quality measure performance to determine eligibility to receive a reconciliation payment; and the successful reporting of the voluntary PRO THA/TKA data to adjust the reconciliation payment. Given that EPM participants bear the financial risk in the EPM model, only EPM participants may use the dispute resolution process described in this section.

In summary, we propose the following requirements in § 512.310 (a) for notice of calculation error:

- Subject to the limitations on review in subpart D of this part, if an EPM participant wishes to dispute the calculation that involves a matter related to payment, a CR incentive payment, reconciliation amounts, repayment amounts, or determinations associated with quality measures affecting payment, the EPM participant is required to provide timely written notice of the error, in a form and manner specified by CMS.
- Unless the EPM participant provides such notice, CMS deems final the reconciliation

report and CR incentive payment report 45 calendar days after the reconciliation report or CR incentive payment report is issued and proceeds with the payment or repayment processes as applicable.

- If CMS receives a notice of a calculation error within 45 calendar days of the issuance of the reconciliation report or CR incentive payment report, CMS responds in writing within 30 calendar days to either confirm that there was an error in the calculation or verify that the calculation is correct, although CMS reserves the right to an extension upon written notice to the EPM participant.
- Only EPM participants may use the notice of calculation error process described in this part.

We seek comment on the proposed notice of calculation error requirements.

c. Dispute Resolution Process (second level of appeal)

We propose the following dispute resolution process. First, we propose that only an EPM participant may utilize the dispute resolution process. Second, in order to access the dispute resolution process a participant must have timely submitted a calculation error form, as previously discussed, for any matters related to payment. We propose these matters would include any amount or calculation indicated on a reconciliation report or CR incentive payment report, including calculations not specifically reflected on a reconciliation report or CR incentive payment report but which generated figures or amounts reflected on a reconciliation report or a CR incentive payment report. The following is a non-exhaustive list of the matters we propose would need to be first adjudicated by the calculation error process as previously detailed: calculations of reconciliation or repayment amounts; calculation of CR incentive payment amounts; calculations of NPRA; and any calculations or percentile distribution involving quality measures that we propose could affect reconciliation or repayment amounts. If an EPM

participant wants to engage in the dispute resolution process with regard to one of these matters, we propose it would first need to submit a calculation error form. Where the EPM participant does not timely submit a calculation error form, we propose the dispute resolution process would not be available to the EPM participant with regard to those matters for the reconciliation report or CR incentive payment report for that performance year.

If the EPM participant did timely submit a calculation error form and the EPM participant is dissatisfied with CMS's response to the EPM participant's notice of calculation error, the EPM participant would be permitted to request reconsideration review by a CMS reconsideration official. The reconsideration review request would be submitted in a form and manner and to an individual or office specified by CMS. The reconsideration review request would provide a detailed explanation of the basis for the dispute and include supporting documentation for the EPM participant's assertion that CMS or its representatives did not accurately calculate the NPRA, the CR incentive payment, or post-episode spending amount in accordance with EPM rules. The following is a non-exhaustive list of representative payment matters:

- Calculations of NPRA, calculations of the CR incentive payment, post-episode spending amount, target prices or any items listed on a reconciliation report or CR incentive payment report.

- The application of quality measures to a reconciliation payment, including the calculation of the percentiles thresholds of quality measure performance to determine eligibility to receive reconciliation payments, or the successful reporting of the voluntary PRO THA/TKA data to adjust the reconciliation payment● Any contestation based on the grounds that CMS or its representative made an error in calculating or recording such amounts.

Where the matter is unrelated to payment, such as termination from the model, the EPM

participant need not submit a calculation error form. We propose to require the EPM participant to timely submit a request for reconsideration review, in a form and manner to be determined by CMS. Where such request is timely received, we propose CMS would process the request as discussed later in this section.

We propose that the reconsideration review would be an on-the-record review (a review of briefs and evidence only). The CMS reconsideration official would make reasonable efforts to notify the EPM participant in writing within 15 calendar days of receiving the EPM participant's reconsideration review request of the date and time of the review, the issues in dispute, the review procedures, and the procedures (including format and deadlines) for submission of evidence (the "Scheduling Notice"). The CMS reconsideration official would make reasonable efforts to schedule the review to occur no later than 30 days after the date of the Scheduling Notice. The provisions at § 425.804(b), (c), and (e) (as in effect on the publication date of this proposed rule) would apply to reviews conducted pursuant to the reconsideration review process for EPM. The CMS reconsideration official would make reasonable efforts to issue a written determination within 30 days of the review. The determination would be final and binding.

We solicit comment on our proposals related to appeals rights under this model. The two-step appeal process for payment matters — (1) calculation error form, and (2) reconsideration review—is used broadly in other CMS models. We seek comment on whether we should develop an alternative appeal process. We are also interested in whether there should be appeal rights for reductions or eliminations of NPRA as a result of enforcement actions, as discussed in section III.F. of this proposed rule, and if so, whether the process for such appeals should differ from the processes proposed here.

In summary, we propose the following requirements in § 512.310 (b) for the reconsideration process:

- If the EPM participant is dissatisfied with CMS's response to the notice of a calculation error, the EPM participant may request a reconsideration review in a form and manner as specified by CMS.
- The reconsideration request must provide a detailed explanation of the basis for the dispute and include supporting documentation for the EPM participant's assertion that CMS or its representatives did not accurately calculate the NPRA, the reconciliation payment, the CR incentive payment or the repayment amount in accordance with subpart d of this part.
- If CMS does not receive a request for reconsideration from the EPM participant within 10 calendar days of the issue date of CMS's response to the EPM participant's notice of calculation error, then CMS's response to the calculation error is deemed final and CMS proceeds with reconciliation payment or repayment processes, as applicable, as described in § 512.305.
- The CMS reconsideration official notifies the EPM participant in writing within 15 calendar days of receiving the EPM participant's review request of the following:

++ The date, time, and location of the review.

++ The issues in dispute.

++ The review procedures.

++ The procedures (including format and deadlines) for submission of evidence.

- The CMS reconsideration official takes all reasonable efforts to schedule the review to occur no later than 30 days after the date of receipt of notification.
- The provisions at § 425.804 (b), (c), and (e) of this chapter are applicable to reviews

conducted in accordance with the reconsideration review process for the EPM.

● The CMS reconsideration official issues a written determination within 30 days of the review. The determination is final and binding.

Only EPM participants may utilize the dispute resolution process described in this subpart. We seek comment on the proposed reconsideration process for the EPMs.

d. Exception to the Notice of Calculation Error Process and Notice of Termination.

Similar to the CJR model and BPCI initiative, if the EPM participant contests a matter that does not involve an issue contained in, or a calculation which contributes to, an EPM reconciliation report or a CR incentive report, a notice of calculation error is not required. Consistent with III.D.8(c) in this proposed rule, in instances where a notice of calculation error is not required, for example an EPM participant's termination from the EPM, we propose the EPM participant provide a written notice to CMS requesting review within 10 calendar days of the notice. CMS has 30 days to respond to the EPM participant's request for review. If the EPM participant fails to notify CMS, the decision is deemed final.

In summary, we propose the following requirements in § 512.310 (c) for an exception to the notice of calculation error process● If the EPM participant contests a matter that does not involve an issue contained in, or a calculation which contributes to, a reconciliation report or CR incentive payment report, a notice of calculation error is not required. In these instances, if CMS does not receive a request for reconsideration from the EPM participant within 10 calendar days of the notice of the initial determination, the initial determination is deemed final and CMS proceeds with the action indicated in the initial determination.

In summary, we propose the following requirements in § 512.310 (d) for notice of termination:● If an EPM participant receives notification that it has been terminated from the

EPM and wishes to appeal such termination, it must provide a written notice to CMS requesting review of the termination within 10 calendar days of the notice. CMS has 30 days to respond to the EPM participant's request for review. If the participant fails to notify CMS, the termination is deemed final.

We seek comment on the proposed exception to the notice of calculation error process and notice of termination.

e. Limitations on review.

In summary, we propose the following requirements in § 512.310 (e) for limitations on review:

- In accordance with section 1115A (d) (2) of the Act, there is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

++ The selection of models for testing or expansion under section 1115A of the Act.

++ The selection of organizations, sites, or participants to test those models selected.

++ The elements, parameters, scope, and duration of such models for testing or dissemination.

++ Determinations regarding budget neutrality under section 1115A (b) (3) of Act.

++ The termination or modification of the design and implementation of a model under section 1115A (b) (3)(B) of Act.

++ Decisions to expand the duration and scope of a model under section 1115A(c) of the Act, including the determination that a model is not expected to meet criteria described in paragraph (e)(1) or (2) of this section.

We seek comment on the proposed limitations on review.

III. Provisions of the Proposed Regulations

E. EPM Quality Measures, Public Display, and Use of Quality Measures in the EPM Payment Methodology

1. Background

As discussed in the CJR model final rule, Medicare payment policy has moved away from FFS payments unlinked to quality and towards payments that are linked to quality of care (80 FR 73358). Through the Medicare Modernization Act and the Affordable Care Act, we have implemented specific IPPS programs like the HIQR Program (section 1886(b)(3)(B) of the Act), the HVBP Program (subsection (o) of section 1886), the Hospital Acquired Condition Reduction Program (HACRP) (subsection (q) of section 1886), and the Hospital Readmissions Reduction Program (HRRP) (subsection (p) of section 1886), where quality of care is linked to payment. We have also implemented the Shared Savings Program, an ACO program that links shared savings payment to quality performance. The CJR model similarly incorporates pay-for-performance through the potential for financial reward to participants based on the hospital's level of quality performance, while also including an incentive for quality improvement if the hospital's current level of quality is relatively low (80 FR 73374).

We propose pay-for-performance methodologies similar to the CJR model for the proposed EPMs. Specifically, we propose to financially reward higher quality in an EPM episode by reducing the effective discount factor used to calculate EPM quality-adjusted target prices at reconciliation. We would establish the effective discount factor based on the EPM participant's overall quality performance and improvement on the EPM's quality measures as reflected in the EPM participant's EPM composite quality score. We would calculate the EPM participant's composite quality score for each EPM performance year at the time of

reconciliation. The EPM composite quality score would also determine whether an EPM participant is eligible for a reconciliation payment if savings are achieved beyond the EPM quality-adjusted target price by setting a minimum EPM composite quality score for reconciliation payment eligibility.

We note that we continue to believe that EPMs should include pay-for-performance methodologies that incentivize improvements in patient outcomes while simultaneously lowering health care spending (80 FR 73465). We believe that improved quality of care, specifically achieved through coordination and communication among providers in conjunction with patients and their caregivers, can favorably influence performance on patient outcomes. Like the CJR model, we also believe that the proposed three new EPMs would provide the opportunity for EPM participants to improve the quality of care based on timely reported patient experience, including communications with doctors and nurses, and responsiveness of hospital staff (80 FR 73465). Finally, we strive to align as many measures as possible in CMS's proposed new EPMs with those in ongoing models and programs. Our goal is to focus provider improvement efforts and minimize burden on EPM participants in needing to become familiar with and report new measures, while still allowing us to appropriately capture meaningful quality data and use it in the EPMs' pay-for-performance methodologies.

More specifically, similar to our final decision for the CJR model, we are not proposing to use any readmissions measures that could apply to clinical conditions in these EPMs but that are already in place or have been finalized for the HRRP, specifically the Hospital 30-day all-cause risk-standardized readmission rate (RSRR) following AMI hospitalization (NQF #0505) and the Hospital 30-day all-cause, unplanned, RSRR following CABG surgery (NQF #2515), due to the incentives, already in place by the HRRP, for hospitals to lower excess readmission rates (80 FR

73479). While we consider these readmissions measure rates to be important metrics for providing information about AMI and CABG hospital performance in the HRRP and HIQR Program for payment and public reporting, respectively, other proposed measures for the AMI and CABG models support the intent of these models to reduce actual payments in an EPM episode while ensuring that quality of care for AMI and CABG model beneficiaries is improved.

Furthermore, while we recognize the lack of complete alignment between EPM beneficiaries and the proposed cohorts for the EPM quality measures, we believe the proposed measures provide meaningful information about EPM participant quality performance and improvement that are relevant to EPM beneficiaries. For the AMI and CABG models in particular, beneficiaries included in the proposed episode-specific measures would significantly overlap with beneficiaries in AMI and CABG model episodes. We note that for purposes of the EPMs where we need to identify episodes that are included in the EPMs, we use the terms anchor and chained anchor hospitalization to identify hospitalizations that initiate EPM episodes for beneficiaries whose care is included in the EPMs. In describing the quality measures in detail in section III.E.4. of this proposed rule, we use the term index hospitalization to identify hospitalizations of beneficiaries whose outcomes are included in the measures. Thus, anchor hospitalizations and index hospitalizations would have varying degrees of overlap depending on the specific quality measure.

Moreover, we note that hospitals are the unit of analysis for the EPMs and that the proposed measures are hospital-centric measures, both because these are currently available measures that are aligned with those in other CMS programs and because one of the major goals of the EPMs is to encourage collaboration among different types of providers in order to achieve better care and reduced expenditures, while holding acute care hospitals financially responsible.

For further discussion of our proposal that hospitals be accountable for EPM episodes, we refer to section III.B.3. of this proposed rule.

We recognize that there are also some gaps in the current proposed measures relative to other settings in which patients receive care post-hospital discharge during EPM episodes, as well as around important complications of care for clinical conditions included in the three models. However, we believe that these hospital-level measures reasonably assess how well EPM participants provide care for EPM beneficiaries since the measures, depending on the EPM, assess -- (1) important patient outcomes, including mortality as well as complications and days of acute care following discharge from the index hospitalization which can be costly; and (2) patients' perspectives on their hospital experience, which include patient feedback on communication with doctors, communication with nurses, responsiveness of hospital staff, communication about medicines, discharge information, cleanliness of the hospital environment, quietness of the hospital environment, and transition to post-hospital care. As we gain more experience with the EPMs, as well as the CJR model currently in testing, and future EPMs, we plan to work to create a more robust set of episode quality measures for these and future models. We will continue to assess the evolving inventory of measures and will continue to refine quality measures for potential future rulemaking based on public comments, changes to the EPMs' payment methodologies, recommendations from EPM participants and their collaborators, and new CMS episode measure development activities as we learn more about the impact of EPMs on quality improvement and episode efficiency. We refer to section III.E.4.e. of this proposed rule for a discussion of potential future EPM episode measures.

2. Selection of Proposed Quality Measures for the EPMs

a. Overview of Quality Measure Selection

The outcome and patient experience measures proposed for the EPMs were selected in order to: (1) promote alignment with the financial and quality goals of the EPMs; (2) leverage hospitals' familiarity with the measures due to their use in other CMS hospital quality programs, including programs that tie payment to performance such as the HVBP Program; (3) streamline EPM measures for EPM participants testing more than one EPM; and (4) ensure consistency with CMS's priorities to reduce AMI and CABG mortality and complications while improving patient experience, as well as with CMS's priorities to reduce major LEJR surgery complications while improving patient experience for SHFFT model beneficiaries, like those in the CJR model.

b. AMI Model Quality Measures

In order to encourage care collaboration among multiple providers of AMI model beneficiaries, we propose three required measures and one measure that relies on voluntary data submission, in order to determine AMI model participant episode quality performance and improvement that would be linked to the AMI model payment methodology as discussed in section III.E.3.f.(2) of this proposed rule. We propose the following measures for the AMI model:

- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (NQF #0230) (MORT-30-AMI).
- Excess Days in Acute Care after Hospitalization for AMI (AMI Excess Days).
- HCAHPS Survey (NQF #0166).
- Voluntary Hybrid Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #2473) (Hybrid AMI Mortality) data submission.

We refer to sections III.E.4.a. and d. of this proposed rule for a detailed discussion of our proposals regarding these measures for the AMI model, including their importance as measures of the quality-of-care for beneficiaries treated for AMI. The proposals for the AMI model measures are included in § 512.411, and the proposals for reporting the measures are included in § 512.400. We seek comment on our proposals for AMI model quality measures.

c. CABG Model Quality Measures

In order to encourage care collaboration among multiple providers of CABG model beneficiaries, we propose two required measures, in order to determine CABG model participant episode quality performance and improvement that would be linked to the CABG model payment methodology as discussed in section III.E.3.f.(3) of this proposed rule. We propose the following measures for the CABG model:

- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF# 2558) (MORT-30-CABG).
- HCAHPS Survey (NQF #0166).

We refer to sections III.E.4.b. and d. of this proposed rule for a detailed discussion of our proposals regarding these measures for the CABG model, including their importance as measures of the quality-of-care for beneficiaries treated with CABG.

The proposals for the CABG model measures are included in § 512.412., and the proposals for reporting the measures are included in § 512.400. We seek comment on our proposals for CABG model quality measures.

d. SHFFT Model Quality Measures

In order to encourage care collaboration among multiple providers of SHFFT model beneficiaries, we propose two required measures and one measure that relies on voluntary data

submission, in order to determine SHFFT model participant episode quality performance and improvement that would be linked to the SHFFT model payment methodology as discussed in section III.E.3.f.(4) of this proposed rule. While we recognize that none of the proposed measures specifically target the care of SHFFT model beneficiaries, these measures are the same as those used for the CJR model because SHFFT model episodes will be tested along with the LEJR episodes in the CJR model (80 FR 73501 and 73507) at mostly the same hospitals. In addition, as discussed further in section III.E.3.e.(3) of this proposed rule, we propose to calculate a hospital-level composite quality score that would apply to episode payment for both the CJR and SHFFT models, consistent with our proposal of the same measures for the two models. We believe that due to the inclusion of beneficiaries with hip fracture in both the CJR and SHFFT models and our desire to streamline EPM participant measure reporting, as well as the focus of both models on major lower extremity orthopedic surgery, the same set of quality measures can be used for both models to incentivize quality improvement in lower extremity orthopedic surgery care and episode efficiency. We are also considering future measure development focused specifically on hip and femur fracture patients. We expect that many of the physicians and other providers collaborating with participant hospitals in the SHFFT and CJR models will be the same, such that certain care pathways and episode efficiencies may be coordinated for SHFFT and CJR model beneficiaries regardless of the model, potentially resulting in quality improvement for beneficiaries in both models. We propose the following measures for the SHFFT model:

- Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550) (Hip/Knee Complications).
- HCAHPS Survey (NQF #0166).

- Total Hip Arthroplasty (THA)/Total Knee Arthroplasty (TKA) voluntary patient-reported outcome (PRO) and limited risk variable data submission (Patient-reported outcomes and limited risk variable data following elective primary THA/TKA).

We considered an alternative approach to the required quality measures for the SHFFT model given that the proposed measures do not specifically target the SHFFT model beneficiaries. This alternative approach would not account for any hip-specific measures (such as, Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550) (Hip/Knee Complications)) and would instead only measure patient experience through the HCAHPS Survey (NQF #0166). Although there may be some rationale for excluding measures that do not specifically target SHFFT model beneficiaries, we do not propose this approach to SHFFT model quality measures because we believe that it is critical to include a measure of both clinical and patient experience outcomes in the setting of lower extremity orthopedic surgery episodes. Additionally, we believe that using quality measures for SHFFT model episodes that do not align with those in the CJR model could generate confusion at CJR model participant hospitals where we propose that the SHFFT model be tested as discussed in section III.B.4. of this proposed rule.

We refer to sections III.E.4.c. and d. of this proposed rule for a detailed discussion of our proposals regarding these measures for the SHFFT model, including their importance as measures of the quality-of-care for beneficiaries undergoing major lower extremity joint replacement surgery.

The proposals for the SHFFT model measures are included in § 512.413, and the proposals for reporting the measures are included in § 512.400. We seek comment on our proposals for SHFFT model quality measures.

3. Proposed Use of Quality Measures in the EPM Payment Methodologies

a. Overview of EPM Composite Quality Score Methodology

We believe that the proposed EPMs provide another mechanism for hospitals to improve quality of care, while also achieving cost efficiency. Incentivizing high-value care through episode payments for AMI, CABG, and hip fracture care is a primary objective of these proposed EPMs. Therefore, incorporating quality performance into the episode payment structure is an essential component of the proposed EPMs, just as it is for the CJR model (80 FR 73370). For the reasons stated previously, we believe it is important for the AMI, CABG, and SHFFT models to link the financial reward opportunity with performance and improvement in the quality of care for Medicare beneficiaries treated for AMI, CABG, and hip fracture.

As discussed in section III.D.4.a. of this proposed rule, which outlines the pricing methodologies for EPM episodes, for each EPM participant we propose to set an EPM-episode benchmark price for each EPM episode. We would apply the EPM participant's effective discount factor based on the participant's quality performance and improvement for the EPM performance year to the EPM-episode benchmark episode price to calculate the quality-adjusted target price for each EPM episode. We refer to section III.E.3.f. of this proposed rule for further discussion of the relationship between an EPM participant's quality performance and improvement and the effective discount factor. Each EPM episode includes an anchor hospitalization for either AMI (AMI MS-DRG or PCI MS-DRG with AMI ICD-10-CM diagnosis code in the principal or secondary diagnosis code position), CABG (CABG MS-DRG), or SHFFT (SHFFT MS-DRG) and a 90-day period after discharge from the anchor or chained anchor hospitalization. As discussed in section III.C.4.a.(5) of this proposed rule, a chained anchor hospitalization is an anchor hospitalization that initiates an AMI model episode and has at least one subsequent inpatient-to-inpatient transfer. An EPM quality-adjusted target price would

represent expected spending on all related Part A and Part B items and services furnished during EPM episodes based on historical EPM episodes, and would incorporate the EPM participant's effective discount factor for the EPM performance year. Participants that achieve actual EPM-episode payments below the quality-adjusted target price for a given performance year may be eligible for a reconciliation payment from CMS, subject to the proposed stop-gain limit policy as discussed in section III.D.7.b. of this proposed rule. Participants that achieve actual EPM-episode payments that exceed the quality-adjusted target price for a given performance year may be required to repay Medicare a portion or all of the excess EPM-episode spending.

We propose an EPM composite quality score methodology for linking quality and payment in the EPMs that is similar to that methodology finalized for the CJR model (80 FR 73363 to 73381). Similar to the CJR model, the EPM-specific composite quality score methodology would allow both performance and improvement on each EPM's required quality measure to be meaningfully valued in the EPMs' pay-for-performance methodology, incentivizing and rewarding cost savings in relation to the quality of episode care provided by the EPM participant (80 FR 73374 and 73370). Specifically, the EPM composite quality score is made up of the composite performance score (which includes both patient experience and outcome measures, including points for voluntarily reported measures) and an improvement score.

We believe the actual level of quality performance achieved should be most highly valued in the EPM composite quality score to reward those EPM participants furnishing high quality care to EPM beneficiaries, with a smaller contribution to the EPM composite quality score made by improvement points if measure result improvement is achieved. We acknowledge that substantial improvement on a quality measure result is not the sole indicator that an EPM

episode-of-care is high quality; yet, the improvement spurred by the hospital's participation in the EPM deserves to be valued as the EPM participant's performance is moving in a direction that is good for the health of beneficiaries. Like the CJR model, the EPMs involve a wide range of participants that must participate if they are located in the selected MSAs, and the participants would be starting from many different current levels of quality performance. We note that the Shared Savings Program utilizes a similar scoring and weighting methodology, which is described in detail in the CY 2011 Shared Savings Program Final Rule (see § 425.502). The HVBP Program and the HACRP also utilize a similar scoring methodology, which applies weights to various measures and assigns an overall score to a hospital (79 FR 50049 and 50102). Despite the small number of quality measures proposed for the EPMs, the measures represent both clinical outcomes and patient experience, and each carries substantial value in the EPM composite quality score.

Although performance and improvement on each measure would be valued in the EPM composite quality score methodology, it is the EPM participant's overall quality performance under the EPM that would be considered in the pay-for-performance approach, rather than performance on each quality measure individually determining the financial opportunity under the EPM. The EPM composite score methodology also provides a framework for incorporating additional measures of meaningful outcomes for EPM episodes in the future. Finally, while we believe that high performance on all of the quality measures represents goals of clinical care that should be achievable by all EPM participants that heighten their focus on these measures, we appreciate that many participants have room for significant improvement in their current measure performance. The EPM composite score methodology would provide the potential for financial

reward for more EPM participants that reach overall acceptable or better quality performance, thus incentivizing their continued efforts to improve the quality and efficiency of EPM episodes.

We seek comment on our proposal to use an EPM-specific composite quality score in the pay-for-performance methodologies of the AMI, CABG, and SHFFT models.

b. Determining Quality Measure Performance

Similar to our reasoning in the CJR model, we believe that relative measure performance for the EPM measures would be the most appropriate way to incorporate quality performance into the EPMs because we do not have sufficient information about participant performance to set and use an absolute performance result on each measure (80 FR 73371). Moreover, we believe that participants nationally are currently working to improve their performance on the quality measures proposed for the EPMs on an ongoing basis as these are included in other CMS programs such as the HIQR and HVBP Programs. Therefore, while we expect that EPM participants would have a heightened focus on performance on these measures as a result of the financial incentives resulting from the EPM payment methodology, we are not yet certain what performance outcomes can be achieved under best practices.

Thus, at the time of reconciliation for an EPM performance year, we propose to assign each EPM participant's measure point estimate from the most recent year as discussed in section III.E.5. of this proposed rule to a performance percentile based on the national distribution of measure results for subsection (d) hospitals that are eligible for payment under the IPPS reporting the measure that meet the minimum patient case or survey count. This proposal applies to the MORT-30-AMI (NQF #0230) and AMI Excess Days measure results for the AMI model; the MORT-30-CABG (NQF #2558) measure result for the CABG model; the Hip/Knee

Complications (NQF #1550) measure result for the SHFFT model; and the HCAHPS Survey (NQF #0166) measure result for all of the EPMs.

The measure-specific parameters that would apply to developing the national distributions are displayed in Table 13.

Table 13: REQUIREMENTS FOR USE OF SUBSECTION (d) HOSPITALS THAT ARE ELIGIBLE FOR PAYMENT UNDER THE IPPS MEASURE RESULTS IN DEVELOPING NATIONAL DISTRIBUTION OF REQUIRED MEASURES FOR EPMS

Measure	Requirements for Use in National Distribution
MORT-30-AMI (NQF #0230)	At least 25 patient cases in the 3-year measure performance period
AMI Excess Days	At least 25 patient cases in the 3-year measure performance period
MORT-30-CABG (NQF #2558)	At least 25 patient cases in the 3-year measure performance period
Hip/Knee Complications (NQF #1550)	At least 25 patient cases in the 3-year measure performance period
HCAHPS Survey (#0166)	At least 100 completed surveys in the 4-quarter reporting period

We would assign any low volume EPM participant without a reportable value for the measure, new hospitals that are identified as EPM participants, or EPM participants where CMS has suppressed the measure value due to an error in the data used to calculate the measure to the 50th performance percentile of the measure result, so as not to disadvantage an EPM participant based on its low volume or lack of applicable cases because that participant may in actuality provide high quality care. We believe that relative measures of quality performance are most appropriate for the EPMs as participants continue to make progress nationally on improving patient outcomes and experience. Proposed measure-specific assignment of points in the EPMs' composite quality scores based on relative quality measure performance are discussed in sections III.E.3.e.(1), (2), and (3) of this proposed rule.

We seek comment on our proposed overall approach to determining quality measure performance based on assigning the EPM participant's measure point estimate to a measure performance percentile based on the national distribution of measure results from subsection (d) hospitals eligible for payment under the IPPS.

c. Determining Quality Measure Improvement

Consistent with our reasoning for the CJR model, we believe it would be important in the EPMs to directly reward EPM participants for quality improvement, similar to the pay-for-performance policies under other programs such as the HVBP Program and the Shared Savings Program, in order to provide a significant incentive for quality improvement for EPM participants at all current levels of quality performance (70 FR 73379). For the CJR model, we adopted a refinement to the composite quality score methodology that would supplement the composite quality score's valuing of quality performance in the pay-for-performance methodology of the CJR model (80 FR 73379). As in the CJR model, we believe the heightened focus on EPM episode cost and quality performance by participants in the EPMs may lead to substantial year-over-year quality measure improvement over the EPM performance years. Nevertheless, we believe that the actual level of quality performance achieved in the EPMs should be most highly valued in the EPM composite quality score to reward those participants furnishing high-quality care to EPM beneficiaries, with a small contribution to the composite quality score made by improvement points if measure result improvement is achieved. Thus, we propose adding into the EPM-specific composite quality score up to10 percent of the maximum value for each EPM quality measure to which improvement could apply (excluding the voluntary data submission measures) for those EPM participants that demonstrate substantial improvement from the prior year's measure performance on that measure (80 FR 73379 through 73380). The

maximum EPM composite quality score would be capped at 20 points under this proposal. Proposed measure-specific assignment of points for improvement in the EPMs' composite quality scores are discussed in sections III.E.3.e.(1), (2), and (3).

For the AMI and CABG models, we propose to define measure improvement differently than in the CJR model, using an approach that is more similar to the methodologies of other CMS programs such as the HVBP Program. The CJR model defined measure improvement for model participants relative to a national performance distribution (80 FR 73380). In contrast, we propose to define measure improvement as any improvement in an AMI or CABG model participant's own measure point estimate from the previous year, regardless of the participant's measure point estimate starting and ending values, if the AMI or CABG model participant falls into the top 10 percent of participants based on the national distribution of measure improvement over the 2 years for subsection (d) hospitals that are eligible for payment under the IPPS reporting the measure that meet the minimum patient case or survey count. We propose this approach because it represents the greatest confidence that we are capturing meaningful improvement on a measure by an AMI or CABG model participant in comparison with performance changes of other hospitals yet, unlike the CJR and proposed SHFFT model methodologies, is founded on an AMI or CABG model participant's own measure performance change from year-to-year. We believe that moving toward incorporating a model participant's own measure performance improvement in the pay-for-performance methodologies for EPMs strengthens the incentives in the models for quality improvement, especially for EPM participants at the lower end of current measure performance.

For the SHFFT model, we propose to modify the definition of improvement used in the CJR model in two ways (80 FR 73379 through 73380). First, we propose to define measure

improvement as improving 2 deciles or more in comparison to the national distribution of measure results from the prior year, based on a comparison of relative quality measure performance over the most recent 2 years of available quality measure result data. This is the same methodology as finalized for the CJR model, except that it reduces the threshold for improvement from 3 deciles to 2 deciles in order to reward a broader range of improvement. Second, we propose to award up to 10 percent of the maximum measure performance score on the outcome and patient experience measures described in III.E.3.e.(3) of this proposed rule, with a cap of the SHFFT model composite quality score at 20 points. This alters the CJR model methodology, which calculates the measure performance score, voluntary reporting points, and measure improvement score separately for a total potential maximum score of 22. Taken together, these two changes bring calculation of the SHFFT model composite quality score into greater alignment with existing CMS programs, such as the HVBP Program, by expanding the number of SHFFT model participants eligible for quality improvement points but reducing the number of participants who receive both the highest quality performance score on a measure and points for measure improvement simultaneously.

In section V.E. of this proposed rule, we propose changes to the CJR model composite quality score calculation consistent with the SHFFT model methodology described here, allowing use of the same definition of quality improvement for the SHFFT and CJR models, because these models would be tested in mostly the same hospitals. We believe this approach would provide SHFFT model participants at all current levels of quality performance, including those historically lagging, with significant incentives to achieve improvement quality of care under the SHFFT model. Using a common approach to measuring quality improvement for the SHFFT and CJR models would provide a single participant-level composite quality score that

can be applied at reconciliation for each model to determine the payment policies that would apply to the participant for the CJR and SHFFT model episodes, taking into consideration the different model performance years.

The proposals to determine quality measure improvement for the AMI, CABG, and SHFFT models are included in § 512.315(b)(3), (c)(3), and (d)(3), respectively. We seek comment on our proposals to determine quality measure improvement for the AMI, CABG, and SHFFT models.

d. Determining Successful Submission of Voluntary Data for AMI and SHFFT Models

(1) Hybrid AMI Mortality (NQF #2473) Voluntary Data

Similar to the CJR model, we propose that AMI model participants that successfully submit the Hybrid AMI Mortality (NQF #2473) measure voluntary data would be eligible for points in the AMI model composite quality score (80 FR 73375, 73381). Encouraging collection and submission of the Hybrid AMI Mortality (NQF #2473) measure voluntary data through the AMI model would increase hospital familiarity with submitting hybrid quality measures based on claims data and data submitted from electronic health records; further develop an outcome measure that provides meaningful information on outcomes for AMI hospitalizations that are commonly experienced by Medicare beneficiaries; provide another quality measure that may be incorporated into the AMI model pay-for-performance methodology in future years, pending successful implementation testing of the measure; and inform the quality strategy of future payment models.

The proposed requirements for determining successful submission of Hybrid AMI Mortality (NQF #2473) measure voluntary data are included in § 512.411(b)(2) and discussed in

detail in section III.E.4.a.(3)(vii) of this proposed rule. We seek comment on our proposals for determining successful submission of voluntary data for each AMI model performance year.

(2) Patient-Reported Outcomes and Limited Risk Variable Voluntary Data Following Elective Primary THA/TKA

Like the CJR model, we propose that SHFFT model participants that successfully submit Patient-reported outcomes and limited risk variable voluntary data following elective primary THA/TKA be eligible for points in the SHFFT model composite quality score (80 FR 73375, 73381). We note that SHFFT model participants that are also participating in the CJR model would not need to submit data twice to satisfy the successful submission requirements of both models. If those hospitals successfully submit voluntary data for the CJR model they would be credited with successful submission under the SHFFT model.

The proposed requirements for determining successful submission of Patient-reported outcomes and limited risk variable voluntary data following elective primary THA/TKA are included in § 512.13(b)(2) and discussed in detail in section III.E.4.c.(2)(viii) of this proposed rule. We seek comment on our proposals for determining successful submission of voluntary data for each SHFFT model performance year.

e. Calculation of the EPM-Specific Composite Quality Score

(1) AMI Model Composite Quality Score

We propose to assign each participant an AMI model composite quality score, calculated as the sum of the individual quality measure performance scores (including successful submission of Hybrid AMI Mortality (NQF #2473) measure voluntary data if applicable) and improvement scores. The quality measure performance scores would be set to reflect the intended weights for each of the quality measures and the successful submission of the Hybrid

AMI Mortality (NQF #2473) voluntary data in the AMI model composite quality score. Each quality measure performance would be assigned a weight in the AMI model composite quality score, and possible scores for the measures would be set to reflect those weights. We would weight AMI model participant performance on each of the three required measures and successful submission of Hybrid AMI Mortality (NQF #2473) voluntary data according to the measure weights displayed in Table 14.

TABLE 14: MEASURES AND ASSOCIATED PERFORMANCE WEIGHTS IN AMI MODEL COMPOSITE QUALITY SCORE

Quality Measure	Weight in Composite Quality Score	Quality Domain/Weight
MORT-30-AMI (NQF #0230)	50%	Outcome/80%
AMI Excess Days	20%	
Hybrid AMI Mortality (NQF #2473) Voluntary Data	10%	
HCAHPS Survey (NQF #0166)	20%	Patient Experience/20%

We would assign the lowest weight of 10 percent to the submission of Hybrid AMI Mortality (NQF #2473) measure voluntary data because these data represent an AMI model participant's meaningful participation in advancing the quality measurement of AMI outcomes in keeping with our goal to move toward the use of electronic health records (EHRs) for measures, and in response to stakeholder feedback to include clinical data in outcome measures. Given the importance of AMI mortality as an extremely serious AMI outcome, we propose to assign the highest individual measure weight of 50 percent to the MORT-30-AMI (NQF #0230) measure. We propose to assign another 20 percent of the weight to the AMI Excess Days measure that is also included in the outcome quality domain. The remaining 20 percent of the AMI model composite quality score weight would be assigned to the HCAHPS Survey (NQF #0166) measure because we believe that incorporating this quality measure, which reflects performance

regarding patients' perspectives on care, including communication, care transitions, and discharge information, is a meaningful patient experience measure of AMI model episode quality. This proposal of weights for the outcome and patient experience quality domains for the AMI model composite quality score is similar to the proposal of weights for the CABG model composite quality score described later in this section. We would assign the highest overall weight to the outcome quality domain (consisting of two measures and voluntary data submission) because the measures in this quality domain are specific to meaningful outcomes for AMI model beneficiaries. We do not propose to assign the HCAHPS survey (NQF #0166) measure the highest weight of the quality and patient experience domains, as the measure is not specific to AMI model episodes, but rather to all clinical conditions treated by AMI model participants. Unlike the CJR model where the quality measure weights in the CJR model composite quality score relatively evenly balance the outcome and patient experience quality domains, we would assign the highest weight in the AMI model to the outcome quality domain (consisting of two measures and voluntary data submission) because the measures in this quality domain are specific to meaningful, serious outcomes for AMI model beneficiaries, especially mortality which is not an outcome measure used in the CJR model composite quality score (80 FR 73375).

Under such an approach, we would first score individually each AMI model participant on the MORT-30-AMI (NQF #0230) measure; AMI Excess Days measure; and HCAHPS Survey (NQF #0166) measure based on the AMI model participant's performance percentile as compared to the national distribution of subsection (d) hospitals that are eligible for payment under the IPPS measure performance, assigning scores according to the point values displayed in Table 15. These individual measure scores have been set to reflect the measure weights included in Table

14 so they can ultimately be summed without adjustment in calculating the AMI model composite quality score. We note that in a chained anchor hospitalization where we propose in section III.C.4.a.(5) of this proposed rule that once an AMI model episode is initiated at a participant hospital, the AMI model episode would continue under the responsibility of that participant hospital, the transfer hospital's quality measure performance would not be included in assessing the AMI model participant's measure performance for the AMI model composite quality score. However, because the MORT-30-AMI (NQF #0230) measure attributes deaths to the initial hospital that admitted the beneficiary as an inpatient for AMI treatment in a transfer scenario, AMI model beneficiaries who die following treatment at a transfer hospital would be included in the AMI model participant's measure result and, therefore, their care represented in this quality measure.

TABLE 15: INDIVIDUAL MEASURE PERFORMANCE SCORING FOR THREE REQUIRED AMI QUALITY MEASURES

Performance Percentile	MORT-30-AMI (Points)	AMI Excess Days (Points)	HCAHPS Survey (Points)
$\geq 90^{th}$	10.00	4.00	4.00
$\geq 80^{th}$ and $<90^{th}$	9.25	3.70	3.70
$\geq 70^{th}$ and $<80^{th}$	8.50	3.40	3.40
$\geq 60^{th}$ and $<70^{th}$	7.75	3.10	3.10
$\geq 50^{th}$ and $<60^{th}$	7.00	2.80	2.80
$\geq 40^{th}$ and $<50^{th}$	6.25	2.50	2.50
$\geq 30^{th}$ and $<40^{th}$	5.50	2.20	2.20
$<30^{th}$	0.00	0.00	0.00

Given the current national distribution of subsection (d) hospitals eligible for payment under the IPPS performance on these measures, we believe that small point increments related to higher measure performance deciles would be the most appropriate way to assign more points to

reflect meaningfully higher quality performance on the measures. The absolute differences for each decile among the three measures reflect the intended weight of the measure in the AMI model composite quality score. These three measures are well-established measures in use under CMS hospital programs, so we do not believe that scores below the 30th percentile reflect quality performance such that they should be assigned any individual quality measure score points under the AMI model.

Additionally, we would assign a measure quality score of 2 points for AMI model participants that successfully submit Hybrid AMI Mortality (NQF #2473) measure voluntary data and 0 points for participants that do not successfully submit these data. Because we would not use the actual Hybrid AMI Mortality (NQF #2473) measure result as an outcome measure in assessing AMI episode quality performance under the AMI model, we propose this straightforward binary approach to scoring the submission of Hybrid AMI Mortality (NQF #2473) measure voluntary data for hybrid outcome measure testing.

CMS may, in future regulations, require hospitals to report additional data elements from EHRs and propose additional hybrid measures in this and other models and programs, such as the HIQR Program. If, in future regulations, hospitals are required to report these same five data elements (age; heart rate; systolic blood pressure; troponin, creatinine) and six linking variables (CMS Certification Number (CCN), Medicare Health Insurance Claim (HIC) Number, date of birth, sex, admission date, and discharge date) that are included in the Hybrid AMI Mortality (NQF #2473) measure to support measurement through another CMS program, such as the HIQR Program, CMS may propose changes to the AMI model measures and the methodology for assigning the AMI model composite quality score.

Finally, we would award improvement scores on a measure-by-measure basis to those AMI model participants that demonstrate improvement on the measure; improvement points would be awarded for up to 10 percent of the maximum measure performance points available, with the total AMI model composite quality score capped at 20. Thus, improvement scores would be up to 1.0 points for the MORT-30-AMI (NQF #0230) measure; up to 0.4 points for the AMI Excess Days measure; and up to 0.4 points for the HCAHPS Survey (NQF #0166) measure.

We would sum the performance and improvement scores on the three quality measures and the score on successful submission of Hybrid AMI Mortality (NQF #2473) measure voluntary data to calculate an AMI composite quality score for each AMI model participant.

The proposal for the methodology to calculate the AMI model composite quality score is included in § 512.315(b)(1)-(4). We seek comment on our proposed methodology to calculate the AMI model composite quality score.

(2) CABG Model Composite Quality Score

We propose to assign each participant a CABG model composite quality score, calculated as the sum of the individual quality measure performance and improvement scores. The quality measure performance scores would be set to reflect the intended weights for each of the quality measures. Each quality measure performance would be assigned a weight in the CABG model composite quality score and possible scores for the measures would be set to reflect those weights. We would weight CABG model participant performance on each of the two required measures according to the measure weights displayed in Table 16.

TABLE 16: MEASURES AND ASSOCIATED PERFORMANCE WEIGHTS IN CABG MODEL COMPOSITE QUALITY SCORE

Quality Measure	Weight in Composite Quality Score	Quality Domain/Weight
MORT-30-CABG (NQF #2558)	75%	Outcome/75%
HCAHPS Survey (NQF #0166)	25%	Patient Experience/25%

We propose to assign 75 percent of the weight in the CABG model composite quality score to the outcome quality domain, assigning all weight to the MORT-30-CABG (NQF #2558) measure, and the remaining 25 percent of the CABG model composite quality score weight to the HCAHPS Survey (NQF #0166) measure representing the patient experience quality domain. This proposal of weights for the outcome and patient experience quality domains for the CABG model composite quality score is similar to the proposal of weights for the AMI model composite quality score described previously in this section. CABG mortality is an extremely serious outcome and, like our proposal for the Mort-30-AMI (NQF #230) measure in the AMI model composite quality score, we propose that the MORT-30-CABG (NQF #2558) measure would have the highest individual measure weight in the CABG model composite quality score. We would assign 25 percent of the weight to the HCAHPS survey measure (NQF #0166) because we believe that incorporating this quality measure, which reflects performance regarding patients' perspectives on care, including communication, care transitions, and discharge information, is a meaningful patient experience measure of CABG model episode quality. We would assign the highest overall weight to the outcome quality domain (consisting of one measure) because it is specific to meaningful outcomes for CABG surgery for CABG model beneficiaries. We do not propose to assign the HCAHPS survey (NQF #0166) measure the highest weight of the quality and patient experience quality domains, as the measure is not specific to CABG model episodes, but rather to all clinical conditions treated by CABG model

participants. Unlike the CJR model where the measure weights in the CJR model composite quality score relatively evenly balance the outcome and patient experience quality domains, CABG mortality representing the outcome quality domain is a serious outcome specific to CABG model beneficiaries such that we believe it deserves a high weight in the proposed CABG model composite quality score (80 FR 73375).

Under such an approach, we would first score individually each CABG model participant on the MORT-30-CABG (NQF #2558) measure; and HCAHPS Survey (NQF #0166) measure based on the participant's performance percentile as compared to the national distribution of subsection (d) hospitals that are eligible for payment under the IPPS measure performance, assigning scores according to the point values displayed in Table 17. These individual measure scores have been set to reflect the measure weights included in Table 16 so they can ultimately be summed without adjustment in calculating the CABG model composite quality score.

TABLE 17: INDIVIDUAL SCORING FOR TWO REQUIRED CABG QUALITY MEASURES

Performance Percentile	MORT-30-CABG (Points)	HCAHPS Survey (Points)
$\geq 90^{th}$	15.00	5.00
$\geq 80^{th}$ and $<90^{th}$	13.88	4.63
$\geq 70^{th}$ and $<80^{th}$	12.75	4.25
$\geq 60^{th}$ and $<70^{th}$	11.63	3.88
$\geq 50^{th}$ and $<60^{th}$	10.50	3.50
$\geq 40^{th}$ and $<50^{th}$	9.38	3.13
$\geq 30^{th}$ and $<40^{th}$	8.25	2.75
$<30^{th}$	0.00	0.00

Given the current national distribution of subsection (d) hospitals that are eligible for payment under the IPPS performance on these measures, we believe that small point increments related to higher measure performance deciles would be the most appropriate way to assign more

points to reflect meaningfully higher quality performance on the measures. The absolute differences for each decile among the two measures reflect the intended weight of the measure in the CABG model composite quality score. These two measures are well-established measures in use under CMS hospital programs, so we do not believe that scores below the 30th percentile reflect quality performance such that they should be assigned any individual quality measure score points under the CABG model.

Finally, we would award improvement scores on a measure-by-measure basis to those CABG model participants that demonstrate improvement on the measure; improvement points would be awarded for up to 10 percent of the maximum measure performance points available, with the total CABG model composite quality score capped at 20. Thus, improvement scores would be up to 1.5 points for the MORT-30-CABG (NQF #2558) measure; and up to 0.5 points for the HCAHPS Survey (NQF #0166) measure.

We would sum the performance and improvement scores on the two quality measures to calculate a CABG model composite quality score for each CABG model participant.

The proposal for the methodology to calculate the CABG model composite quality score is included in § 512.315(c)(1) through (4). We seek comment on our proposed methodology to calculate the CABG model composite quality score.

(3) SHFFT Model Composite Quality Score

We propose to adopt the same calculation of the SHFFT model composite quality score as the CJR model, including the proposed changes to the CJR model composite quality score methodology described in section V.E. of this proposed rule. For those participants in both SHFFT and CJR models, the SHFFT model composite quality score calculated each year would be the same as the CJR model composite quality score (80 73370 through 73381). We propose

to assign each SHFFT model participant a SHFFT model composite quality score, capped at 20 points and calculated as the sum of the individual quality measure and improvement scores as well as successful submission of THA/TKA voluntary PRO and limited risk variable data if applicable. The quality measure performance scores would be set to reflect the intended weights for each of the quality measures. Each quality measure performance would be assigned a weight in the SHFFT model composite quality score and possible scores for the measures would be set to reflect those weights. We would weight SHFFT model participant performance on each of the two required measures and successful submission of THA/TKA voluntary PRO and limited risk variable data according to the measure weights displayed in Table30.

TABLE 18: MEASURES AND ASSOCIATED PERFORMANCE WEIGHTS IN SHFFT MODEL COMPOSITE QUALITY SCORE

Quality Measure	Weight in Composite Quality Score	Quality Domain/Weight
Hip/Knee Complications (NQF #1550	50%	Outcome/50%
THA/TKA voluntary PRO and limited risk variable submission	10%	Patient Experience/50%
HCAHPS Survey (NQF #0166)	40%	

Consistent with the CJR model, we propose to assign 50 percent of the weight in the SHFFT model composite quality score to the outcome quality domain, assigning 50 percent of the weight to the Hip/Knee Complications (NQF #1550) measure. We propose to assign 50 percent of the weight to the patient experience quality domain, specifically 10 percent of the weight in that quality domain to the THA/TKA voluntary PRO and limited risk variable submission. We would assign 40 percent of the weight to the HCAHPS survey measure (NQF #0166) representing the patient experience (80 FR 73375). We would assign 40 percent to the HCAHPS survey measure (NQF #0166) because we believe that incorporating this quality

measure, which reflects performance regarding patients' perspectives on care, including communication, care transitions, and discharge information, is a highly meaningful outcome measure of SHFFT episode quality under the SHFFT model, and because doing so ensures that there is a consistent methodology for linking quality performance and improvement to payment for SHFFT model participants that are also participating in the CJR model. As in the CJR model, we believe this weighting appropriately balances patient experience with meaningful health outcomes for beneficiaries (80 FR 73375).

Under such an approach, we would first score individually each SHFFT model participant on the Hip/Knee Complications (NQF #1550) measure; and HCAHPS Survey (NQF #0166) measure based on the participant's performance percentile as compared to the national distribution of subsection (d) hospitals that are eligible for payment under the IPPS measure performance, assigning scores according to the point values displayed in Table 19. These individual measure scores have been set to reflect the measure weights included in Table D6 so they can ultimately be summed without adjustment in calculating the SHFFT model composite quality score. We note that the point score for each decile for the two measures for the SHFFT model is the same as that used for other CJR model.

TABLE 19: INDIVIDUAL SCORING FOR TWO REQUIRED SHFFT QUALITY MEASURES

Performance Percentile	Hip/Knee Complications (Points)	HCAHPS Survey Quality Score (Points)
$\geq 90^{th}$	10.00	8.00
$\geq 80^{th}$ and $<90^{th}$	9.25	7.40
$\geq 70^{th}$ and $<80^{th}$	8.50	6.80
$\geq 60^{th}$ and $<70^{th}$	7.75	6.20
$\geq 50^{th}$ and $<60^{th}$	7.00	5.60
$\geq 40^{th}$ and $<50^{th}$	6.25	5.00

Performance Percentile	Hip/Knee Complications (Points)	HCAHPS Survey Quality Score (Points)
$\geq 30^{th}$ and $<40^{th}$	5.50	4.40
$<30^{th}$	0.00	0.00

Given the current national distribution of subsection (d) hospitals that are eligible for payment under the IPPS performance on these measures, we believe that small point increments related to higher measure performance deciles would be the most appropriate way to assign more points to reflect meaningfully higher quality performance on the measures. The absolute differences for each decile among the three measures reflect the intended weight of the measure in the SHFFT model composite quality score. These two measures are well-established measures in use under CMS hospital programs, so we do not believe that scores below the 30th percentile reflect quality performance such that they should be assigned any individual quality measure score points under the SHFFT model.

As in the CJR model, we propose to assign a measure quality score of 2 points for SHFFT model participants that successfully submit THA/TKA voluntary PRO and limited risk variable data and 0 points for participants that do not successfully submit these data (80 FR 73376).

Finally, we would award improvement scores on a measure-by-measure basis to those SHFFT model participants that demonstrate improvement on the measure (defined as year-over-year improvement of 2 or more deciles in the performance distribution); improvement points would be awarded for up to 10 percent of the maximum measure performance points available, with the total SHFFT model composite quality score capped at 20. Thus, improvement scores would be up to 1.0 points for the Hip/Knee Complications (NQF #1550) measure; and up to 0.8 points for the HCAHPS Survey (NQF #0166) measure.

We would sum the performance and improvement scores on the two required quality measures and the score on successful submission of THA/TKA voluntary PRO and limited risk variable data to calculate a SHFFT model composite quality score for each SHFFT model participant. For those CJR model participants (the majority of SHFFT model participants), the SHFFT model composite quality score would be the same as the participant's score for the CJR model.

The proposal for the methodology to calculate the SHFFT model composite quality score is included in § 512.315(d)(1) through (4). We seek comment on our proposed methodology to calculate the SHFFT model composite quality score.

f. EPM Pay-for-Performance Methodologies to Link Quality and Payment

(1) Overview of Pay-for-Performance Proposals Applicable to the EPMs

As in the CJR model, we propose that the maximum effective discount factor for all EPM participants that could be incorporated in quality-adjusted target prices would be 3.0 percent (80 FR 733760). We refer to section III.D.4.b.(10) of this proposed rule for further discussion of the application of the effective discount factor to EPM-episode benchmark prices in calculating quality-adjusted target prices. EPM participants that provide high-quality episode care would have the opportunity to reduce the effective discount factor used to calculate their quality-adjusted prices at reconciliation. The effective discount factors are displayed in tables in the following EPM-specific sections, based on the EPM-specific composite quality score that would place each EPM participant into one of four quality categories, specifically "Below Acceptable," "Acceptable," "Good," and "Excellent," for each EPM performance year. Three tables are required to display the proposed effective discount factor and applicable discount factor (the discount factor that represents the phase-in of repayment responsibility in

performance years 2 (DR) and 3) for each quality category due to the phase-in of EPM participant repayment responsibility from no responsibility in performance year 1 and performance year 2 (NDR), to partial responsibility in performance years 2 (DR) and 3, and finally full responsibility in performance years 4 and 5 as discussed in section III.D.2.c. Note that the applicable discount factor only applies to EPM performance years 2 (DR) and 3.

(2) AMI and CABG Model Pay-for-Performance Methodologies

(a) AMI Model Pay-for-Performance Methodology

We propose to incorporate the AMI model composite quality score in the AMI model payment methodology by (1) requiring a minimum AMI model composite quality score for reconciliation payment eligibility if the AMI model participant's actual episode payments are less than the quality-adjusted target price and (2) determining the effective discount factor included in the quality-adjusted target price experienced by the AMI model participant in the reconciliation process. The payment policies we would apply are displayed in Tables 20, 21, and 22 for the performance years of the AMI model. Under the AMI model as proposed, there is no AMI model participant repayment responsibility in performance year 1 and performance year 2 (NDR) and this responsibility begins to be phased-in in performance year 2 (DR), with full implementation in performance year 4. Because repayment responsibility is phased-in, in performance years 2 (DR) and 3, repayment responsibility only applies to a portion of the amount of excess AMI model episode spending that results from the quality-adjusted target prices that include the AMI model participant's effective discount factor. We, therefore, refer in the repayment column to the applicable discount factor for repayment amount in performance years 2 (DR) and 3. The effective discount factor applies to both the reconciliation payment and

the repayment amount in performance years 4 and 5. We note that the average Medicare payment for historical AMI episodes beginning in CYs 2012 to 2014 was $24,200.[70]

TABLE 20: PERFORMANCE YEAR 1 AND PERFORMANCE YEAR 2 (NDR): RELATIONSHIP OF AMI MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

AMI Model Composite Quality Score	Eligible for Reconciliation Payment	Effective Discount Factor for Reconciliation Payment	Effective Discount Factor for Repayment Amount
<3.6	No	3.0%	Not applicable
>=3.6 and <6.9	Yes	3.0%	Not applicable
>=6.9 and <=14.8	Yes	2.0%	Not applicable
>14.8	Yes	1.5%	Not applicable

TABLE 21: PERFORMANCE YEARS 2 (DR) AND 3: RELATIONSHIP OF AMI MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

AMI Model Composite Quality Score	Eligible for Reconciliation Payment	Effective Discount Factor for Reconciliation Payment	Applicable Discount Factor for Repayment Amount*
<3.6	No	3.0%	2.0%
>=3.6 and <6.9	Yes	3.0%	2.0%
>=6.9 and <=14.8	Yes	2.0%	1.0%
>14.8	Yes	1.5%	0.5%

*The applicable discount factor for the repayment amount only applies in performance years 2 (DR) and 3 when repayment responsibility is being phased-in.

[70] Episodes for AMI beneficiaries initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that began in CYs 2012-2014.

TABLE 22: PERFORMANCE YEARS 4 AND 5: RELATIONSHIP OF AMI MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

AMI Model Composite Quality Score	Eligible for Reconciliation Payment	Effective Discount Factor for Reconciliation Payment	Effective Discount Factor for Repayment Amount
<3.6	No	3.0%	3.0%
>=3.6 and <6.9	Yes	3.0%	3.0%
>=6.9 and <=14.8	Yes	2.0%	2.0%
>14.8	Yes	1.5%	1.5%

Under this approach, the maximum AMI model effective discount factor included in the quality-adjusted target price would be 3.0 percent, consistent with the CJR model (80 FR 73365). We believe that a maximum effective discount factor of 3.0 percent is reasonable as it is within the range of discount percentages included in the ACE demonstration and it is the Model 2 BPCI discount factor for 30- and 60-day episodes, where BPCI participants are testing AMI episodes subject to the 3.0 percent discount factor. AMI model participants that provide high quality episode care would have the opportunity for a lower effective discount factor to be included in their quality-adjusted target prices at reconciliation as displayed in Tables 20, 21, and 22.

Under this methodology, we would require AMI model participants to achieve a minimum AMI model composite quality score of >=3.6 to be eligible for a reconciliation payment if actual episode payments were less than the quality-adjusted target price based on the 3.0 percent maximum effective discount factor. Participants with below acceptable quality performance reflected in an AMI model composite quality score <3.6 would not be eligible for a reconciliation payment if actual AMI model episode payments were less than the quality-adjusted target price. A level of quality performance that is below acceptable would not affect AMI model participants' repayment responsibility if actual AMI model episode payments

exceed the quality-adjusted target price. We believe that excessive reductions in utilization that lead to low actual AMI model episode payments and that could result from the financial incentives of an EPM would be limited by a requirement that this minimum level of AMI model episode quality be achieved for reconciliation payments to be made. This policy would encourage AMI model participants to focus on appropriate reductions or changes in utilization to achieve high quality care in a more efficient manner. Therefore, these participants would be ineligible to receive a reconciliation payment if actual AMI model episode payments were less than the quality-adjusted target price.

AMI model participants with an acceptable AMI model composite quality score of >=3.6 and <6.9 would be eligible for a reconciliation payment if actual AMI model episode payments were less than the quality-adjusted target price based on a 3.0 percent effective discount factor because their quality performance was at the acceptable level established for the AMI model. Therefore, these AMI model participants would be eligible to receive a reconciliation payment if actual AMI model episode payments were less than the quality-adjusted target price.

AMI model participants with a good AMI model composite quality score of >=6.9 and <=14.8 would be eligible for a reconciliation payment if actual AMI model episode payments were less than the quality-adjusted target price based on a 2.0 percent effective discount factor that reflects their good quality performance. Thus, participants achieving this level of quality for AMI episodes under the AMI model would either have less repayment responsibility (that is, the reduced effective discount factor would offset a portion of their repayment responsibility) or receive a higher reconciliation payment (that is, the reduced effective discount factor would increase the reconciliation payment) at reconciliation than they would have otherwise based on a

comparison of actual AMI model episode payments to quality-adjusted target prices that include the maximum 3.0 percent effective discount factor.

Finally, AMI model participants with an excellent AMI model composite score quality score of >14.8 would be eligible to receive a reconciliation payment if actual AMI model episode payments were less than the quality-adjusted target price based on a 1.5 percent effective discount factor that reflects their excellent performance. Thus, participants achieving this level of quality for AMI episodes under the AMI model would either have less repayment responsibility (that is, the reduced effective discount factor would offset a portion of their repayment responsibility) or receive a higher reconciliation payment (that is, the reduced effective discount factor would increase the reconciliation payment) at reconciliation than they would have otherwise based on a comparison of actual AMI model episode payments to quality-adjusted target prices that include the maximum 3.0 percent effective discount factor.

Under this methodology, the proposed stop-loss and stop-gain limits discussed in section III.D.7.b. of this proposed rule would not change. We believe this approach to quality incentive payments based on the AMI model composite quality score could have the effect of increasing the alignment of the financial and quality performance incentives under the AMI model to the potential benefit of AMI model participants and their collaborators as well as CMS, and would be consistent with the CJR model methodology linking quality and payment.

The proposal to link quality to payment in the AMI model pay-for-performance methodology is included in § 512.315(b)(5). We seek comment on our proposal to link quality to payment in the AMI model pay-for-performance methodology.

(b) CABG Model Pay-for-Performance Methodology

We propose to incorporate the CABG model composite quality score in the CABG model payment methodology by -- (1) requiring a minimum CABG model composite quality score for reconciliation payment eligibility if the CABG model participant's actual episode payments are less than the quality-adjusted target price; and (2) determining the effective discount factor included in the quality-adjusted target price experienced by the CABG model participant in the reconciliation process. The payment policies we would apply are displayed in Tables 23, 24, and 25 for the performance years of the CABG model. Under the CABG model as proposed, there is no CABG model participant repayment responsibility in performance year 1 and performance year 2 (NDR) and this responsibility begins to be phased-in in performance year 2 (DR), with full implementation in performance year 4. Because repayment responsibility is phased-in, in performance years 2 (DR) and 3, repayment responsibility only applies to a portion of the amount of excess CABG model episode spending that results from the quality-adjusted target prices that include the CABG model participant's effective discount factor. We, therefore, refer in the repayment column to the applicable discount factor for repayment amount in performance years 2 (DR) and 3. The effective discount factor applies to both the reconciliation payment and the repayment amount in performance years 4 and 5. We note that the average Medicare payment for historical CABG episodes beginning in CYs 2012 to 2014 was $47,000.[71]

[71] Episodes for CABG beneficiaries initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that began in CYs 2012-2014.

TABLE 23: PERFORMANCE YEAR 1 AND PERFORMANCE YEAR 2 (NDR): RELATIONSHIP OF CABG MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

CABG Model Composite Quality Score	Eligible for Reconciliation Payment	Effective Discount Factor for Reconciliation Payment	Effective Discount Factor for Repayment Amount
<2.8	No	3.0%	Not applicable
>=2.8 and <4.8	Yes	3.0%	Not applicable
>=4.8 and <=17.5	Yes	2.0%	Not applicable
>17.5	Yes	1.5%	Not applicable

TABLE 24: PERFORMANCE YEARS 2 (DR) AND 3: RELATIONSHIP OF CABG MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

CABG Model Composite Quality Score	Eligible for Reconciliation Payment	Effective Discount Factor for Reconciliation Payment	Applicable Discount Factor for Repayment Amount*
<2.8	No	3.0%	2.0%
>=2.8 and <4.8	Yes	3.0%	2.0%
>=4.8 and <=17.5	Yes	2.0%	1.0%
>17.5	Yes	1.5%	0.5%

*The applicable discount factor for the repayment amount only applies in performance years (DR) and 3 when repayment responsibility is being phased-in.

TABLE 25: PERFORMANCE YEARS 4 AND 5: RELATIONSHIP OF CABG MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

CABG Model Composite Quality Score	Eligible for Reconciliation Payment	Effective Discount Factor for Reconciliation Payment	Effective Discount Factor for Repayment Amount
<2.8	No	3.0%	3.0%
>=2.8 and <4.8	Yes	3.0%	3.0%
>=4.8 and <=17.5	Yes	2.0%	2.0%
>17.5	Yes	1.5%	1.5%

Under this approach, the maximum CABG model effective discount factor included in the quality-adjusted target price would be 3.0 percent, consistent with the CJR model (80 FR 73365). We believe that a maximum effective discount factor of 3.0 percent is reasonable as it is within the range of discount percentages included in the Medicare Acute Care Episode (ACE) demonstration and it is the Model 2 BPCI discount factor for 30 and 60 day episodes, where BPCI participants are testing CABG episodes subject to the 3.0 percent discount factor. CABG model participants that provide high quality episode care would have the opportunity for a lower effective discount factor to be included in their quality-adjusted target prices at reconciliation as displayed in Tables 23, 24, and 25.

Under this methodology, we would require CABG model participants to achieve a minimum CABG model composite quality score of >=2.8 to be eligible for a reconciliation payment if actual episode payments were less than the quality-adjusted target price based on the 3.0 percent maximum effective discount factor. Participants with below acceptable quality performance reflected in an CABG model composite quality score <2.8 would not be eligible for a reconciliation payment if actual CABG model episode payments were less than the quality-adjusted target price. A level of quality performance that is below acceptable would not

affect participants' repayment responsibility if actual CABG model episode payments exceed the quality-adjusted target price. We believe that excessive reductions in utilization that lead to low actual CABG model episode payments and that could result from the financial incentives of an EPM would be limited by a requirement that this minimum level of CABG model episode quality be achieved for reconciliation payments to be made. This policy would encourage CABG model participants to focus on appropriate reductions or changes in utilization to achieve high quality care in a more efficient manner. Therefore, these participants would be ineligible to receive a reconciliation payment if actual CABG model episode payments were less than the quality-adjusted target price.

CABG model participants with an acceptable CABG model composite quality score of >=2.8 and <4.8 would be eligible for a reconciliation payment if actual CABG model episode payments were less than the quality-adjusted target price based on a 3.0 percent effective discount factor because their quality performance was at the acceptable level established for the CABG model. Therefore, these CABG model participants would be eligible to receive a reconciliation payment if actual CABG model episode payments were less than the quality-adjusted target price.

CABG model participants with a good CABG model composite quality score >=4.8 and <=17.5 would be eligible for a reconciliation payment if actual CABG model episode payments were less than the quality-adjusted target price based on a 2.0 percent effective discount factor that reflects their good quality performance. Thus, participants achieving this level of quality for CABG episodes under the CABG model would either have less repayment responsibility (that is, the reduced effective discount factor would offset a portion of their repayment responsibility) or receive a higher reconciliation payment (that is, the reduced effective discount factor would

increase the reconciliation payment) at reconciliation than they would have otherwise based on a comparison of actual CABG model episode payments to quality-adjusted target prices that include the maximum 3.0 percent effective discount factor.

Finally, CABG model participants with an excellent CABG model composite score quality score of >17.5 would be eligible to receive a reconciliation payment if actual CABG model episode payments were less than the quality-adjusted target price based on a 1.5 percent effective discount factor that reflects their excellent performance. Thus, participants achieving this level of quality for CABG model episodes would either have less repayment responsibility (that is, the reduced effective discount factor would offset a portion of their repayment responsibility) or receive a higher reconciliation payment (that is, the reduced effective discount factor would increase the reconciliation payment) at reconciliation than they would have otherwise based on a comparison of actual CABG model episode payments to quality-adjusted target prices that include the maximum 3.0 percent effective discount factor.

Under this methodology, the proposed stop-loss and stop-gain limits discussed in section III.D.7.b. of this proposed rule would not change. We believe this approach to quality incentive payments based on the CABG model composite quality score could have the effect of increasing the alignment of the financial and quality performance incentives under the CABG model to the potential benefit of CABG model participants and their collaborators as well as CMS, and would be consistent with the CJR model methodology linking quality and payment.

The proposal to link quality to payment in the CABG model pay-for-performance methodology is included in § 512.315(c)(5). We seek comment on our proposal to link quality to payment in the CABG model pay-for-performance methodology.

(c) Alignment Between the AMI and CABG Model Methodologies

The AMI and CABG models are closely related, given that they both are based on a significant event or procedure for a beneficiary with CAD. As discussed in sections III.D.2.b. and c. of this proposed rule, we propose the use of a 30-day mortality measure in both models, specifically MORT-30-AMI (NQF #0230) with a weight of 50 percent in the AMI model composite quality score and MORT-30-CABG (NQF #2558) with a weight of 75 percent in the CABG model quality score. The beneficiaries included in the measure have some overlap, because some beneficiaries with AMI will have a CABG during their hospitalization that begins an episode. Analysis of both the MORT-30-AMI (NQF #0230) and MORT-30-CABG (NQF #2558) measure national distributions suggests that improving from the 25th percentile to 75th percentile represents roughly a 1 percentage point decrease in mortality rates for both measures.

In addition, we note that for historical episodes beginning in 2012 to 2014, the average Medicare spending for an AMI episode that extends 90 days post-hospital discharge was approximately $24,200 and for a CABG episode was approximately $47,000.[72] However, because we propose the same 1.5 percent to 3.0 percent effective discount factor range based on quality performance and improvement for the AMI and CABG models (and, to a lesser degree, because of the modestly lower weight assigned to the mortality measure under the AMI model), the absolute dollar amounts tied to changes in AMI or CABG mortality rates are different in the two models. A larger absolute financial incentive is associated with improvement in CABG mortality than AMI mortality under our proposal. We recognize that mortality is a serious outcome for beneficiaries with CAD who have a significant event or procedure, and we considered setting a wider effective discount factor range based on quality in the AMI model than the CABG model to align the absolute financial incentives to improve mortality under both

[72] Episodes for AMI and CABG beneficiaries initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that began in CYs 2012-2014.

models. For example, to create a more similar absolute financial incentive between the lowest and highest effective discount percentages in the AMI and CABG models, we could set the effective discount factor range for the AMI model at 0.75 percent to 3.75 percent and the CABG model range at 1.5 percent to 3 percent. Alternatively, we could set the AMI model effective discount factor range at 1.5 percent to 3 percent and compress the CABG effective discount factor range. While we do not propose different effective discount factor ranges for the AMI and CABG models in order to retain consistency with the CJR model and the BPCI initiative, we seek comments about the potential benefits and drawbacks of establishing the same absolute dollar incentive for similar improvements in quality across different models that have similar measures but vary in average episode cost. This feedback will be useful as we consider future episode payment models and candidate quality measures for potential new and existing models, as well as consider future refinements to the pay-for-performance methodologies under the models. Our goal in all of our episode payment models is to create strong financial incentives for quality performance and improvement for participants at all level of current quality performance and to rationalize the strength of the financial incentives in the context of the specificity and importance of the quality measures used under the models.

(3) SHFFT Model Pay-for-Performance Methodology

We propose to incorporate the SHFFT model composite quality score in the SHFFT model payment methodology by (1) requiring a minimum SHFFT model composite quality score for reconciliation payment eligibility if the SHFFT model participant's actual episode payments are less than the quality-adjusted target price and (2) determining the effective discount factor included in the quality-adjusted target price experienced by the SHFFT model participant in the reconciliation process. The payment policies we would apply are displayed in Tables 26, 27, and

28 for the performance years of the SHFFT model. Under the SHFFT model as proposed, there is no SHFFT model participant repayment responsibility in performance year 1 and performance year 2 (NDR) and this responsibility begins to be phased-in in performance year 2 (DR), with full implementation in performance year 4. Because repayment responsibility is phased-in, in performance years 2 (DR) and 3, repayment responsibility only applies to a portion of the amount of excess SHFFT model episode spending that results from the quality-adjusted target prices that include the SHFFT model participant's effective discount factor. We, therefore, refer in the repayment column to the applicable discount factor for repayment amount in performance years 2 (DR) and 3. The effective discount factor applies to both the reconciliation payment and the repayment amount in performance years 4 and 5. We note that the average Medicare payment for historical SHFFT episodes beginning in CYs 2012 to 2014 was $43,000.[73]

We refer to section V.E. of this proposed rule for discussion of the correction to the composite quality score ranges for the four quality categories from what was presented in the CJR final rule (80 FR 73378). The SHFFT model composite quality score ranges displayed in Tables 26 through 28 are the corrected ranges that also apply to the CJR model.

[73] Episodes for SHFFT beneficiaries initiated by all U.S. IPPS hospitals and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that began in CYs 2012-2014.

TABLE 26: PERFORMANCE YEAR 1 AND PERFORMANCE YEAR 2 (NDR): RELATIONSHIP OF SHFFT MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

SHFFT Model Composite Quality Score	Eligible for Reconciliation Payment	Effective Discount Factor for Reconciliation Payment	Effective Discount Factor for Repayment Amount
<5.0	No	3.0%	Not applicable
>=5.0 and <6.9	Yes	3.0%	Not applicable
>=6.9 and <=15.0	Yes	2.0%	Not applicable
>15.0	Yes	1.5%	Not applicable

TABLE 27: PERFORMANCE YEARS 2 (DR) AND 3: RELATIONSHIP OF SHFFT MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

SHFFT Model Composite Quality Score	Eligible for Reconciliation Payment	Effective Discount Factor for Reconciliation Payment	Applicable Discount Factor for Repayment Amount*
<5.0	No	3.0%	2.0%
>=5.0 and <6.9	Yes	3.0%	2.0%
>=6.9 and <=15.0	Yes	2.0%	1.0%
>15.0	Yes	1.5%	0.5%

*The applicable discount factor for the repayment amount only applies in performance years 2 (DR) and 3 when repayment responsibility is being phased-in.

TABLE 28: PERFORMANCE YEARS 4 AND 5: RELATIONSHIP OF SHFFT MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

SHFFT Model Composite Quality Score	Eligible for Reconciliation Payment	Effective Discount Factor for Reconciliation Payment	Effective Discount Factor for Repayment Amount
<5.0	No	3.0%	3.0%
>=5.0 and <6.9	Yes	3.0%	3.0%
>=6.9 and <=15.0	Yes	2.0%	2.0%
>15.0	Yes	1.5%	1.5%

Under this methodology, we would require SHFFT model participants to achieve a minimum SHFFT model composite quality score of >=5.0 to be eligible for a reconciliation payment if actual episode payments were less than the quality-adjusted target price based on the 3.0 percent maximum effective discount factor. Participants with below acceptable quality performance reflected in a SHFFT model composite quality score <5.0 would not be eligible for a reconciliation payment if actual SHFFT model episode payments were less than the quality-adjusted target price. A level of quality performance that is below acceptable would not affect participants' repayment responsibility if actual SHFFT model episode payments exceed the quality-adjusted target price. We believe that excessive reductions in utilization that lead to low actual SHFFT model episode payments and that could result from the financial incentives of an EPM would be limited by a requirement that this minimum level of SHFFT model episode quality be achieved for reconciliation payments to be made. This policy would encourage SHFFT model participants to focus on appropriate reductions or changes in utilization to achieve high quality care in a more efficient manner. Therefore, these participants would be ineligible to receive a reconciliation payment if actual SHFFT model episode payments were less than the quality-adjusted target price.

SHFFT model participants with an acceptable SHFFT model composite quality score of >=5.0 and <6.9 would be eligible for a reconciliation payment if actual SHFFT model episode payments were less than the quality-adjusted target price based on a 3.0 percent effective discount factor because their quality performance was at the acceptable level established for the SHFFT model. Therefore, these SHFFT model participants would be eligible to receive a reconciliation payment if actual SHFFT model episode payments were less than the quality-adjusted target price.

SHFFT model participants with a good SHFFT model composite quality score of >=6.9 and <=15.0 would be eligible for a reconciliation payment if actual SHFFT model episode payments were less than the quality-adjusted target price based on a 2.0 percent effective discount factor that reflects their good quality performance. Thus, participants achieving this level of quality for SHFFT model episodes under the SHFFT model would either have less repayment responsibility (that is, the reduced effective discount factor would offset a portion of their repayment responsibility) or receive a higher reconciliation payment (that is, the reduced effective discount factor would increase the reconciliation payment) at reconciliation than they would have otherwise based on a comparison of actual SHFFT model episode payments to quality-adjusted target prices that include the maximum 3.0 percent effective discount factor.

Finally, SHFFT model participants with an excellent SHFFT model composite score quality score of >15.0 would be eligible to receive a reconciliation payment if actual SHFFT model episode spending was less than the quality-adjusted target price based on a 1.5 percent effective discount factor that reflects their excellent performance. Thus, participants achieving this level of quality for SHFFT model episodes would either have less repayment responsibility (that is, the reduced effective discount factor would offset a portion of their repayment

responsibility) or receive a higher reconciliation payment (that is, the reduced effective discount factor would increase the reconciliation payment) at reconciliation than they would have otherwise based on a comparison of actual SHFFT model episode payments to quality-adjusted target prices that include the maximum 3.0 percent effective discount factor.

Under this methodology, the proposed stop-loss and stop-gain limits discussed in section III.D.7.b. of this proposed rule would not change. We believe this approach to quality incentive payments based on the SHFFT model composite quality score could have the effect of increasing the alignment of the financial and quality performance incentives under the SHFFT model to the potential benefit of SHFFT model participants and their collaborators as well as CMS, and would be consistent with the CJR model methodology linking quality and payment.

The proposal to link quality to payment in the SHFFT model pay-for-performance methodology is included in § 512.315(d)(5). We seek comment on our proposal to link quality to payment in the SHFFT model pay-for-performance methodology.

4. Details on Quality Measures for the EPMs

a. AMI Model-Specific Measures

(1) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0230)(MORT-30-AMI)

(a) Background

AMI is one of the most common principal hospital discharge diagnoses among older adults and is associated with high mortality. AMI was the tenth most common principal discharge diagnosis among patients with Medicare in 2012.[74] Each year, over 600,000 Americans will experience an AMI. Despite improvements in treatments, 30-day mortality rates

[74] Agency for Healthcare Research and Quality (AHRQ). Healthcare Cost and Utilization Project (HCUP) http://hcupnet.ahrq.gov/.

following AMI exceed 7 percent. CMS pays approximately $11.7 billion annually for in-hospital costs for Medicare beneficiaries with coronary heart disease, of which AMI is a major contributor. The high prevalence and considerable morbidity and mortality associated with AMI create an economic burden on the healthcare system.[75]

Hospital mortality is an outcome that is likely attributable to care processes and is an important outcome for patients. Complex and critical aspects of care, such as communication between providers, prevention of and response to complications, patient safety, and coordinated transitions to the outpatient environment, all contribute to patient outcomes. Many current hospital interventions are known to decrease the risk of death within 30 days of hospital admission.[76,77] We believe it is important to assess the quality of care provided to Medicare beneficiaries who are hospitalized for AMI.

The measure developed by CMS, and currently implemented in the HIQR and HVBP Programs, assesses a hospital's risk-standardized mortality rate, which is the rate of death after admission to a hospital with a principal diagnosis of AMI. The measure outcome is the rate of mortality occurring after admission with a principal diagnosis of AMI for patients 65 and older during a 30-day period that begins with the date of the index admission for the specific hospital. An index admission is the hospitalization which is included in the measure cohort because it meets all inclusion criteria and does not meet any exclusion criteria. The index admission is the hospitalization to which the mortality outcome is attributed. The median hospital-level

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[75] American Heart Association. Heart Disease and Stroke Statistics – 2010 Update. Dallas, Texas: American Heart Association; 2010. c2010, American Heart Association.

[76] Jha AK, Orav EJ, Li Z, Epstein AM. The inverse relationship between mortality rates and performance in the Hospital Quality Alliance measures. Health Aff (Millwood). 2007 Jul-Aug; 26(4):1104-10.

[77] Rathore SS, Curtis JP, Chen J, Wang Y, Nallamothu BK, Epstein AJ, Krumholz HM; National Cardiovascular Data Registry. Association of door-to-balloon time and mortality in patients admitted to hospital with ST elevation myocardial infarction: national cohort study. BMJ. 2009 May 19; 338:b1807.

risk-standardized mortality rate for 2016 public reporting on Hospital Compare was 14.2 percent, with a interquartile range from 13.7 percent to 14.6 percent in hospitals. The variation in mortality rates suggests that important differences in the quality of care delivered across hospitals exist, and there is room for quality improvement.

We developed the measure of hospital-level risk-standardized mortality rate (RSMR) following AMI hospitalization, which was later endorsed by the NQF (NQF #0230). The measure has been publicly reported on Hospital Compare since FY 2007, and was incorporated into what is now the HIQR Program since FY 2008 (FY 2008 IPPS/LTCH final rule 71 FR 67960), and the HVBP Program since FY 2014 (FY 2011 IPPS/LTCH final rule 76 FR 26510).

(b) Data Sources

We propose to use Medicare Part A and Part B FFS claims submitted by the AMI model participant as the data source for calculation of the MORT-30-AMI (NQF #0230) measure. Index admission diagnoses and in-hospital comorbidities are assessed using Medicare Part A claims. Additional comorbidities prior to the index admission are assessed as Part A inpatient, outpatient, and Part B office visit Medicare claims in the 12 months prior to the index (initial) admission. Enrollment and post-discharge mortality status are obtained from Medicare's enrollment database which contains beneficiary demographics, benefits/coverage, and vital status information.

(c) Cohort

The MORT-30-AMI (NQF #0230) measure includes Medicare FFS beneficiaries, aged 65 years or older, discharged from non-federal acute care hospitals with a principal discharge diagnosis of AMI and with a complete claims history for the 12 months prior to admission.

Eligible hospitalizations are defined using the following ICD-10-CM codes: I2109, I2119, I2111, I2119, I2129, I214, and I213.

We propose that the measure will include index admissions to all non-federal acute care hospitals, which includes all AMI model participants. Hospital performance will only be publically reported for hospitals with 25 or more index admissions in the 3-year measurement period. The AMI model cohort would differ from the hospital cohort that is currently captured in the measure through the HIQR Program. Although performance on the measure will not be publically reported for hospitals with fewer than 25 cases, they will receive information about their performance. We refer readers to section III.B.5. of this proposed rule for participant selection for the AMI model. For eligible hospitalizations defined using ICD-9-CM codes, we refer readers to the CMS Web site at: http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

(d) Inclusion and Exclusion Criteria

We propose that an index admission is the hospitalization to which the mortality outcome is attributed. We note that for purposes of the EPMs where we need to identify episodes that are included in the EPMs, we use the terms anchor and chained anchor hospitalization to identify hospitalizations that initiate EPM episodes for beneficiaries whose care is included in the EPMs. In describing the quality measures themselves in detail in section III.E.4. of this proposed rule, we use the term index hospitalization to identify hospitalizations of beneficiaries whose outcomes are included in the measures. Thus, anchor hospitalizations and index hospitalizations would have varying degrees of overlap depending on the specific quality measure. The measure includes the following index admissions for patients:

- Having a principal discharge diagnosis of AMI.
- Enrolled in Medicare FFS.
- Aged 65 or over.
- Not transferred from another acute care facility.
- Enrolled in Medicare Part A and Part B for the 12 months prior to the date of index admission, and enrolled in Part A during the index admission.

This measure excludes the following index admissions for patients:

- Discharged alive on the day of admission or the following day who were not transferred to another acute care facility.
- With inconsistent or unknown vital status or other unreliable demographic (age and gender) data;
- Enrolled in the Medicare hospice program any time in the 12 months prior to the index admission, including the first day of the index admission;
- Discharged against medical advice American Medical Association (AMA); or
- Without at least 30 days of post-discharge enrollment in FFS Medicare as the 30-day mortality outcome cannot be assessed for these patients.

Finally, for the purpose of this measure, admissions within 30 days of discharge from an index admission are not eligible to also be index admissions. Thus, only one index admission for AMI per beneficiary is randomly selected for inclusion in the cohort.

(e) Risk-Adjustment

We note that this measure is aligned with the risk-adjustment methodologies adopted for the MORT-30-AMI (NQF #0230) measure under the HIQR Program in accordance with section 1886(b)(3)(B)(viii)(VIII) of the Act, as finalized in FY 2008 IPPS/LTCH final rule (2008

IPPS/LTCH final rule 71 FR 67960). We also note that the measure risk adjustment takes into account patient age, sex, and comorbidities to allow a fair assessment of hospital performance. The measure defines the patient risk factors for mortality using diagnosis codes collected from all patient claims 1 year prior to patient index hospitalization for AMI. As previously noted in the MORT-30-AMI measure (NQF #0230), ICD-10-CM codes on Medicare Parts A and B administrative claims are used to inform the risk prediction for each patient; diagnostic codes from post-acute care settings are included in the measure, but this information is only used to identify a hospital's patient case mix in order to adequately adjust for differences in case mix across hospitals. Use of Parts A and B data does not mean the measure is applicable to post-acute care settings, only that it uses comprehensive data to predict the risk of the outcome and adjust for hospital patient case mix. We note that the patient diagnosis codes are grouped using Hierarchical Condition Categories (HCCs), which are clinically relevant diagnostic groups of codes. The CCs used in the risk-adjustment model for this measure are provided on the CMS QualityNet Web site at: https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069856694.

In summary, age, sex, and comorbidities present at the time of admission are adjusted for differences in hospital case mix (patient risk factors). The measure uses the hierarchical logistic regression model (HLM) statistical methodology for risk adjustment.

(f) Calculating the Risk-Standardized Mortality Ratio (RSMR) and Performance Period

We propose to calculate hospital 30-day, all-cause, risk-standardized mortality rates consistent with the methodology used to risk standardize all readmission and mortality measures used in CMS hospital quality programs. Using HLM, we calculate the hospital-level

risk-standardized mortality rate following AMI hospitalization by producing a ratio of the number of "predicted" deaths (that is, the adjusted number of deaths at a specific hospital) to the number of "expected" deaths (that is, the number of deaths if an average quality hospital treated the same patients) for each hospital and then multiplying the ratio by the national raw mortality rate.

A 3-year rolling period for calculating measure results would be consistent with the time frame used for the HIQR Program (FY 2008 IPPS/LTCH final rule 71 FR 67960). Section III.E.5. of this proposed rule, Form, Manner, and Timing of Quality Measure Submission, summarizes the proposed measure performance periods for AMI model performance years 1 through 5. We note that, for each performance year, improvement on the MORT-30-AMI (NQF #0230) measure would be determined by comparing measure results from that performance year to results in the 3-year rolling measurement period immediately preceding each AMI model performance year to results from the 3-year period from July 1, 2014 through June 30, 2017, for performance year 2 by comparing measure results in this year to results from the 3-year period from July 1, 2015 through June 30, 2018, in performance year 3 by comparing measure results in this year to results from the 3-year period from July 1, 2016 and June 30, 2019, in performance year 4 by comparing measure results in this year to results from the 3-year period from July 1, 2017 and June 30, 2020, and in performance year 5 by comparing measure results in this year to results from the 3-year period from July 1, 2018 and June 30 2021.

The proposal to include Hospital-level 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) following AMI hospitalization (NQF #0230) measure in the AMI model is included in § 512.411(a)(1). We seek comment on this proposal to include Hospital-level

30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) following AMI hospitalization (NQF #0230) measure in the AMI model to assess quality performance.

(2) Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction (AMI Excess Days)

(a) Background

The Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction (AMI) measure (AMI Excess Days) is a risk-standardized outcome measure that compares the number of days that patients are predicted to spend in acute care across the full spectrum of possible acute care events (hospital readmissions, observation stays, and ED visits) after discharge from a hospital for AMI, to the days patients are expected to spend in acute care based on their degree of illness.

Some of the costs for AMI can be attributed to high acute care utilization for post-discharge AMI patients in the form of readmissions, observation stays, and emergency department (ED) visits. We note that patients admitted for AMI have disproportionately high readmission rates, and that readmission rates following discharge for AMI are highly variable across hospitals in the United States.[78,79]

For the previously adopted HIQR Program measure, Hospital 30-Day, All-Cause Risk- Standardized Readmission Rate (RSRR) following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0505) (CY 2009 OPPS/ASC final rule with comment period; 73 FR

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[78] Krumholz HM, Merrill AR, Schone EM, et al.: Patterns of hospital performance in acute myocardial infarction and heart failure 30-day mortality and readmission. Circulation. Cardiovascular Quality & Outcomes. Sep 2009;2(5):407-413.

[79] Bernheim SM, Grady JN, Lin Z, et al.: National patterns of risk-standardized mortality and readmission for acute myocardial infarction and heart failure. Update on publicly reported outcomes measures based on the 2010 release. Circulation. Cardiovascular Quality & Outcomes. Sep 2010;3(5):459-467.[80] Centers for Medicare and Medicaid Services. Medicare Hospital Quality Chartbook Performance

68780 through 68781), publicly reported 30-day risk-standardized readmission rates for AMI ranged from 17.5 percent to 30.3 percent for the time period between July 2011 and June 2012.[80] However, in addition to an increased risk of requiring readmission in the post-discharge period, patients are also at risk of returning to the hospital for both observation stays and ED visits which also characterize potentially preventable acute care. ED visits represent a significant proportion of post-discharge acute care utilization for all conditions, including patients with AMI. Two recent studies conducted in patients of all ages showed that 9.5 percent of patients return to the ED within 30 days of hospital discharge; additionally, about 12 percent of these patients are initially discharged from the ED and are not captured by the previously adopted HIQR Program readmission measures.[8,9]The rising use of observation stays among Medicare beneficiaries between 2001 and 2008 sparked concern among patients, providers, and policymakers that the AMI 30-day Readmission (NQF #0505) measure does not capture the full range of unplanned acute care events that occur in the post-discharge period. In order to address the rising use of observation stays amongst Medicare beneficiaries CMS is proposing the Excess Days in Acute Care after Hospitalization for AMI (AMI Excess Days) measure for use in the AMI model. The AMI Excess Days measure comprehensively captures all post-discharge, unplanned acute care events as a count of the excess days a hospital's patients spent as inpatients, in observation, or in the ED over a 3-year measurement period.

In 2014, we developed the proposed measure of excess days in acute care following AMI hospitalization, supported for use in the Hospital Quality Reporting Program by the MAP and

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[80] Centers for Medicare and Medicaid Services. Medicare Hospital Quality Chartbook Performance Report on Outcome Measures September 2013. September 2013; Available at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/-Medicare-Hospital-Quality-Chartbook-2013.pdf.

submitted to the NQF for endorsement. We note that this measure was submitted for endorsement to the NQF All-Cause Admissions and Readmissions Committee in January 2016 with appropriate consideration for sociodemographic status. The measure was finalized for the HIQR Program FY 2018 payment determination (FY 2016 IPPS/LTCH final rule 80 FR 49690).

(b) Data Sources

We propose to use Medicare Part A and Part B FFS claims submitted by the AMI model participant as the data source for calculation of the AMI Excess Days measure as harmonized with the MORT-30-AMI(NQF #0230) and READM-30-AMI(NQF #0505) measures. Index admission diagnoses and in-hospital comorbidities are assessed using Medicare Part A claims. Additional comorbidities prior to the index admission are assessed as Part A inpatient, outpatient, and Part B office visit Medicare claims in the 12 months prior to the index (initial) admission. Enrollment and post-discharge mortality status are obtained from Medicare's enrollment database which contains beneficiary demographic, benefits/coverage, and vital status information.

(c) Cohort

The AMI Excess Days measure includes Medicare FFS beneficiaries, aged 65 years or older, discharged from non-federal acute care hospitals with a principal discharge diagnosis of AMI and with a complete claims history for the 12 months prior to index admission. Eligible hospitalizations are defined using the following ICD-10-CM codes: I2109, I2111, I2119, I2129, I214, and I213.

We propose that the measure will include index admissions to all non-federal acute care hospitals, which includes all participants in the AMI model. Hospital performance will only be publically reported for hospitals with 25 or more index admissions in the 3-year measurement

period. The AMI model cohort would differ from the hospital cohort that is currently captured in the measure through the HIQR Program. Although performance on the measure will not be publically reported for hospitals with fewer than 25 cases, such hospitals will receive information about their performance on the measure. We refer readers to section III.B.5. of this proposed rule for a discussion of AMI model participant selection.

(d) Inclusion and Exclusion Criteria

We propose that an index admission is the hospitalization to which the excess days in acute care outcome is attributed. We note that for purposes of the EPMs where we need to identify episodes that are included in the EPMs, we use the terms anchor and chained anchor hospitalization to identify hospitalizations that initiate EPM episodes for beneficiaries whose care is included in the EPMs. In describing the quality measures themselves in detail in section III.E.4. of this proposed rule, we use the term index hospitalization to identify hospitalizations of beneficiaries whose outcomes are included in the measures. Thus, anchor hospitalizations and index hospitalizations would have varying degrees of overlap depending on the specific quality measure. The measure includes the following index admissions for patients:

- Having a principal discharge diagnosis of AMI.
- Enrolled in Medicare FFS.
- Aged 65 or over.
- Not transferred from another acute care facility.
- Enrolled in Medicare Part A and Part B for the 12 months prior to the date of index admission, and enrolled in Part A during the index admission.

The measure excludes the following index admissions for patients:

- Discharged alive on the day of index admission or the following day who were not transferred to another acute care facility.
- With inconsistent or unknown vital status or other unreliable demographic (age & gender) data.
- Enrolled in the Medicare hospice program any time in the 12 months prior to the index admission, including the first day of the index admission.
- Discharged AMA.
- Without at least 30 days of post-discharge enrollment in FFS Medicare as the 30-day excess days outcome cannot be assessed for these patients.

Finally, for the purpose of this measure, hospitalizations that occur within 30 days of discharge from an index admission are not eligible to also be index admission. Thus, only one index admission for AMI per beneficiary is randomly selected for inclusion in the cohort.

(e) Risk-Adjustment

We propose for the AMI model to align this measure with the risk-adjustment methodologies adopted for the AMI Excess Days measure under the HIQR Program in accordance with section 1886(b)(3)(B)(viii)(VIII) of the Act, as finalized in the FY 2016 IPPS/LTCH final rule (80 FR 49682). We also note that the measure risk adjustment takes into account patient age, sex, and comorbidities to allow a fair assessment of hospital performance. The measure defines the patient risk factors for excess days using diagnosis codes collected from all patient claims 1 year prior to a patient's index hospitalization for AMI. Accordingly, only comorbidities that convey information about the patient at the time of index admission or in the 12 months prior, and not complications that arise during the course of the index hospitalization, are included in the risk-adjustment model. The measure does not adjust for patients' index

admission source or their discharge disposition (for example, SNF) because these factors are associated with the structure of the healthcare system, not solely patients' clinical comorbidities. Regional differences in the availability of post-acute care providers and practice patterns might also exert undue influence on measure results. In addition, data fields that capture discharge disposition, for example to post-acute care settings, on inpatient claims are not audited and are not as reliable as diagnosis codes.

As previously noted in the AMI Excess Days measure, ICD-10-CM diagnosis codes present on Parts A and B administrative claims are used to inform the risk prediction for each patient. Diagnostic codes from post-acute care settings are utilized in the measure calculation, but this information is only used to identify a hospital's patient case mix in order to adequately adjust for differences in case mix across hospitals. We note that the patient diagnosis codes are grouped using HCCs, which are clinically relevant diagnostic groups of codes. The CCs used in the risk-adjustment model for this measure are provided on the CMS QualityNet website: https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069856694.

In summary, age, sex, and comorbidities present at the time of index admission are adjusted for differences in hospital case mix (patient risk factors). The measure uses the HLM statistical methodology for risk adjustment.

(f) Calculating the Rate and Performance Period

We propose to calculate hospital 30-day excess days in acute care with the methodology used to risk standardize all excess days measures used in CMS hospital quality programs. The outcome of the measure is a count of the number of days the patient spends in acute care within 30 days of discharge. We define days in acute care as days spent in an ED, admitted to an

observation unit, or admitted as an unplanned readmission for any cause within 30 days from the date of discharge from the index AMI hospitalization. Each ED treat-and-release visit is counted as 1 half-day (0.5 days). Observation stays are recorded in terms of hours and are rounded up to the nearest half-day. Each readmission day is counted as 1 full day (1 day). We count all eligible outcomes occurring in the 30-day period, even if they are repeat occurrences. The measure incorporates "exposure time" (the number of days each patient survives after discharge, up to 30). This exposure time is included to account for differential risk for excess days in acute care after discharge among those patients who do not survive the full post-discharge period. If a readmission or observation stay extends beyond the 30-day window, only those days within the 30-day window are counted.

Using a two-part random effects model, or "hurdle" model, we account for the structure of the data (patients clustered within hospitals) and the observed distribution of the outcome. Specifically, we model the number of acute care days for each patient as: a) the probability that the patient will have a non-zero number of days in post-discharge acute care; and b) the number of days the patient is predicted to spend given that this number is non-zero. The first part is specified as a legit model, and the second part is specified as a Poisson model, with both parts having the same risk-adjustment variables and each part having a random effect. This model is used to calculate the predicted (including random effects) and expected (assuming random effects are zero) number of days in post-discharge acute care for each patient. The average difference between patients' predicted and expected estimates for each hospital is used to construct the risk-standardized excess days outcome. The excess days outcome is reported at the hospital-level per 100 discharges.

We define the time period for the measure as within 30 days of the date of discharge of the index AMI hospitalization. The 30-day post-discharge window for assessing the outcome is consistent with the claims-based MORT-30-AMI (NQF #0230) and Hybrid AMI Mortality (NQF #2473) measures as noted in this proposed rule.

A 3-year rolling performance period would be consistent with that used for the HIQR Program (FY 2016 IPPS/LTCH final rule 80 FR 49681). Section III.E.5., Form, Manner, and Timing of Quality Measure Data Submission, of this proposed rule summarizes the proposed measure performance periods for AMI model performance years 1 through 5. We note that improvement on the AMI Excess Days measure would be determined from the immediate 3-year rolling performance period available for the year preceding the AMI model performance year as explained in Table 30.

The proposal to include the Excess Days in Acute Care after Hospitalization for AMI measure in the AMI model is included in § 512.411(a)(2). We seek comment on this proposal to include the Excess Days in Acute Care after Hospitalization for AMI measure in the AMI model to assess quality performance.

(3) Hybrid Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF# 2473)(Hybrid AMI Mortality)

(a) Background

In keeping with our goal to move toward the use of EHRs, and in response to stakeholder feedback to include clinical data in outcome measures, we have developed the hospital 30-day risk-standardized acute myocardial infarction (AMI) mortality eMeasure (NQF #2473) (herein after referred to as Hybrid AMI Mortality measure). This measure will incorporate a combination of claims data and EHR data submitted by hospitals, and because of these combined

data sources, it is referred to as a hybrid measure. The Hybrid AMI Mortality (NQF #2473) measure cohort and outcome are identical to those in the hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following acute myocardial infarction (AMI) (NQF #0230), measure which is also being proposed in the AMI model.

In contrast to the claims-only MORT-30-AMI (NQF #0230) measure, the proposed Hybrid AMI Mortality (NQF #2473) measure utilizes five core clinical data elements (age; heart rate; systolic blood pressure; troponin; creatinine) in the risk-adjustment methodology that are obtainable through EHR data. These five core clinical data elements are intended to reflect patients' clinical status when they first present to an acute care hospital for treatment of AMI. The clinical data elements include age at the time of admission, first-captured vital signs (heart rate, systolic blood pressure) collected within 2 hours of the patient first presenting to the hospital, and the first captured laboratory values (troponin, creatinine) collected within 24 hours of the patient first presenting to the hospital to which they are subsequently admitted. We note that these five data elements are routinely collected on hospitalized adults with AMI upon presentation to the hospital, consistently captured in medical records under current clinical practice, and can be feasibly electronically extracted from hospital EHRs.

In order to prepare for future reporting of the Hybrid AMI Mortality (NQF #2473) measure, we are proposing to seek and reward voluntary data submission of the five core clinical data elements included in the risk model for the Hybrid AMI mortality (NQF #2473) measure. We are also proposing to require submission of six additional linking variables (CCN, HIC Number, date of birth, sex, admission date, and discharge date) to ensure that the datasets containing administrative claims data are correctly linked with EHR datasets containing the core clinical data elements for proper risk adjustment. The voluntary data submission initiative will

allow AMI model participants to build processes to extract and report the EHR data elements, as well as support CMS testing of systems required for Hybrid AMI Mortality measure (NQF #2473) production including data receiving and auditing, the merging EHR and claims data, calculation and production of measure results.

Finally, we are considering using the Hybrid AMI Mortality (NQF #2473) measure as a replacement for the current publicly reported MORT-30-AMI (NQF #0230) measure in CMS models or programs when appropriate. In future years CMS may implement the Hybrid AMI Mortality (NQF #2473) measure in models and/or programs, such as in the AMI model or HIQR Program. In that event, we would propose to adopt the measure through notice and comment rulemaking. We refer readers to more detailed information on the measure specifications in this proposed rule and to the CMS Web site at: http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

(b) Data Sources

We propose to use two sources of data submitted by AMI model participants to calculate the Hybrid AMI Mortality (NQF #2473) measure: Medicare Part A and Part B (FFS claims to identify index admission diagnoses; and EHR-captured clinical information collected at presentation for risk-adjustment of patients' severity of illness. Deaths are identified using the Medicare Enrollment Database which contains beneficiary demographic, benefits/coverage, and vital status information.

For the voluntary data submission initiative, EHR data submission will align with existing Electronic Clinical Quality Measure (eCQM) standards and data reporting procedures for hospitals. In alignment with these standards, we are posting the electronic specifications for

the Hybrid AMI Mortality (NQF #2473) measure, which include the Measure Authoring Tool (MAT) output and value sets for all included data elements, on the CMS Web site at: http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

The Office of the National Coordinator for Health Information Technology (ONC) adopted quality reporting document architecture (QRDA) as the standard to support both QRDA Category I (individual patient) and QRDA Category III (aggregate) data submission approaches for Meaningful Use Stage 2 in the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology rule (77 FR 54163 through 54292). We intend to provide AMI model participants with information about how many qualifying admissions are submitted successfully. We refer readers to the definition of "successful data submission" in section III. E.4.a.(3)(vii) of this proposed rule.

We seek comment on our proposal to use the following reporting mechanisms in performance year 1: QRDA, a simpler mechanism such as a spreadsheet, or both. We propose using QRDA in AMI model performance years 2 through 5. The purpose of the use of a simpler reporting format in the first performance year reporting format in the first performance year would be to allow hospitals to perfect data extraction with the 2017 data and postpone mastery of reporting in the QRDA format to the following year.

(c) Cohort

The Hybrid AMI Mortality (NQF #2473) measure includes Medicare FFS beneficiaries, aged 65 years or older, discharged from non-federal acute care hospitals with a principal

discharge diagnosis of AMI. Eligible hospitalizations are defined using the following ICD-10-CM codes: I2109, I2111, I2119, I2129, I214, and I213.

Hospital performance for the Hybrid AMI Mortality (NQF #2473) measure will not be publicly reported. However, AMI model participants will receive hospital-specific reports for each performance year with information about the success of their voluntary submission of EHR data.

(d) Inclusion and Exclusion Criteria

We propose that an index admission is the hospitalization to which the mortality outcome is attributed. The Hybrid AMI mortality (NQF #2473) measure includes the following index admissions for patients:

- Having a principal discharge diagnosis of AMI.
- Enrolled in Medicare FFS.
- Aged 65 or over.
- Not transferred from another acute care facility.
- Enrolled in Medicare Part A and Part B for the 12 months prior to the date of index admission, and enrolled in Part A during the index admission.

This measure excludes the following index admissions for patients:

- Discharged alive on the day of admission or the following day who were not transferred to another acute care facility.
- With inconsistent or unknown vital status or other unreliable demographic (age & gender) data.
- Enrolled in the Medicare hospice program any time in the 12 months prior to the index admission, including the first day of the index admission.

- Discharged AMA.
- Without at least 30 days of post-discharge enrollment in FFS Medicare as the 30-day mortality outcome cannot be assessed for these patients.

Finally, for the purpose of this measure, only one index admission per patient for AMI is randomly selected for inclusion in the cohort.

(e) Risk-Adjustment

We note that this measure is aligned with the methodology approach adopted for the MORT-30-AMI (NQF #0230) measure under the HIQR Program in accordance with section 1886(b)(3)(B)(viii)(VIII) of the Act, as finalized in FY 2008 IPPS/LTCH final rule (2008 IPPS/LTCH final rule 71 FR 67960). The Hybrid AMI Mortality (NQF #2473) measure uses EHR data and not administrative claims data to adjust for differences across hospitals in how at-risk their patients are for death, relative to patients cared for by other hospitals. The risk model was developed with input from the literature, clinical and EHR experts, and Health Information Technology vendors. In order to be included as risk variables, clinical data elements had to be -- (1) consistently obtained in the target population (Medicare FFS AMI patients) based on current clinical practice; (2) captured with a standard definition and recorded in a standard format within the EHR; and (3) entered in structured fields that are feasibly retrieved from current EHR systems. The final measure includes five variables that meet these feasibility criteria, are present for most patients at the time of clinical presentation to the hospital, are clinically relevant to patients with AMI, and demonstrate a strong statistical association with 30-day mortality. Hospitals will submit the first-captured data values of each of the five core clinical data elements upon patient presentation to the hospital. They are: age; the first-captured heart rate and systolic blood pressure measured within 2 hours of a patient presenting to the

hospital; and the first captured troponin and creatinine values within 24 hours of a patient presenting to the hospital. Although EHRs likely will ultimately link across clinical episodes of care and contain historical patient data, given the EHR environment at the time of measure development and inability to reliably obtain data from the outpatient setting prior to admission, we only considered for inclusion those measure variables that would be available and consistently collected at first presentation to the hospital.

The overall performance of the model was comparable with or better than that of current publicly reported outcome measures.[81] We tested measure score validity by correlating the RSMR with that of the previously validated, publicly reported, administrative claims-based MORT-30-AMI (NQF #0230) measure. For more detailed information on the model performance, we refer readers to the CMS Web site at: http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

(f) Calculating the Risk-Standardized Mortality Ratio (RSMR) and Performance Period

We calculate hospital 30-day, all-cause, risk-standardized mortality rates consistent with the methodology used to risk standardize all readmission and mortality measures used in CMS hospital quality programs. Using an HLM statistical methodology for risk adjustment, we calculate the hospital-level risk-standardized mortality rate following AMI hospitalizations by producing a ratio of the number of "predicted" deaths (that is, the adjusted number of deaths at a specific hospital) to the number of "expected" deaths (that is, the number of deaths if an average quality hospital treated the same patients) for each hospital and then multiplying the ratio by the national observed mortality rate.

[81] AMI Mortality Hybrid Measure methodology report. http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html

We propose defining AMI model performance years as outlined in section III.E.5. of this proposed rule. A performance period for the voluntary data submission are those timeframes in which a hospital discharge occurs for an eligible AMI index hospitalization. For performance year 1 of the AMI model, participants voluntarily submitting data will only be asked to submit data for a 2-month period. The 2-month period for AMI voluntary data reporting was identified due to data processing and coordination with other proposed timelines for this model. Data submitted for the first year would be for cases that fulfill the measure specifications described in section III.E.4.a.(3) of this proposed rule, and would be restricted to the data elements from eligible AMI index hospitalizations with discharges occurring between July 1, 2017 and August 31, 2017.

For performance year 2 of the AMI model, AMI voluntary data reporting would be 10 months of data for discharges from eligible AMI hospitalizations occurring between September 1, 2017 and June 30, 2018. For subsequent years of the model, the performance periods for submission of voluntary data will consist of discharges within calendar-year 12-month time periods from July 1 through June 30. The proposed performance periods would enable AMI model participants to receive points toward the AMI model composite quality score for data submission starting in performance year 1. We seek comment on our proposal for defining the data reporting period for performance year 1 episodes for an AMI model participant as eligible AMI index hospitalizations with discharges occurring between July 1, 2017 and August 31, 2017, and for performance year 2 as eligible AMI hospitalizations with discharges occurring between September 1, 2017 and June 30, 2018, with subsequent performance year data reporting periods each being calendar-year 12 month periods and starting every July 1st. Refer to Table 30 for summary of proposed performance periods.

(g) Requirements for Successful Submission of AMI Voluntary Data

In order for CMS to assess if AMI model participants that submit the AMI voluntary data are eligible for points toward the hospital's AMI model composite quality score, we propose to use the following criteria to determine if a participant has successfully submitted AMI voluntary data: submission of the first-captured data values for the five core clinical data elements (age; first-captured heart rate and systolic blood pressure measured within 2 hours of a patient presenting to the hospital; and first-captured troponin and creatinine values measured within 24 hours of a patient presenting to the hospitals), and six linking variables required to merge with the CMS claims data CCN, HIC Number, date of birth, sex, admission date, and discharge date).

All of these data elements must be submitted for each qualifying AMI hospitalization as described in section III.E.5. of this proposed rule. If troponin was not measured in the patient within 24 hours of presentation to the hospital, the hospital will still receive credit for successful data submission if all other clinical data elements (age, heart rate, systolic blood pressure, and creatinine) as well as the six linking variables are all reported in the submission. We recognize that some patients may have clinical signs or symptoms that require emergent treatment; and that in such cases treatment might proceed without first obtaining a troponin level. However hospitals are required to report troponin values on all patients in whom a troponin test was performed within the first 24 hours of presenting to the hospital and to indicate in their data submission each instance in which a troponin value was not measured and therefore not available for a patient.

AMI voluntary data submission must occur within 60 days of the end of the most recent data collection period as described in the listing of reporting periods for all 5 model performance years in section III.E.5. of this proposed rule.

To fulfill AMI voluntary data collection criteria for model performance year 1, hospitals must submit valid data on 50 percent of qualifying AMI hospitalizations (identified by the denominator in the measure authorizing tool (MAT) output). To successfully submit AMI voluntary data for performance years 2 through 5, hospitals must submit valid data for all five core clinical data elements on over 90 percent of qualifying AMI patients (with the exception for troponin values described in this section). Further details on scoring of the voluntary data submission are discussed in section III.E.3.e.(1) of this proposed rule.

Each year, AMI model participants voluntarily submitting data for this measure will receive hospital-specific reports that detail submission results from the most recent performance period. The reports will include the match rate between the hospital's submitted EHR data and corresponding claims data, as well as the proportion of patient data submitted relative to all qualifying AMI admissions with all five core clinical data elements. As the initiative seeks to test and reward hospitals' ability to submit data, hospitals will not be penalized for missing troponin values for patients in whom these values were not measured at the time clinical treatment was provided. If hospitals successfully submit the remaining four clinical data elements and all of the linking variables, a missing troponin value which is due to troponin having not been measured in that patient will not result in an unsuccessful submission as long as hospitals indicate that the troponin value was not measured and therefore not available for that patient. Hospitals will still be rewarded for successfully submitting data in these cases.

We previously described a qualifying AMI patient in section III.E.4.a.(3)(iii) of this proposed rule. This description is important, as these patients are those for whom we seek submission of voluntary data from AMI model participants. We selected the requirement of submitting 90 percent of qualifying AMI patients' data for performance years 2 through 5

because this volume of cases will result in a high probability that we will have a national sample of AMI patient data representative of each hospital's patient case mix. Having 90 percent of the data for qualifying AMI patients in performance years 2 through 5 will enable an accurate and reliable assessment of the potential implementation of a Hybrid AMI mortality (NQF# 2473) measure that utilizes EHR data. In addition, the testing we have performed in hospitals' EHR data indicate that these data elements are captured in over 90 percent of Medicare FFS patients who are 65 years or older and admitted to acute care hospitals for treatment of AMI.

We seek public comment on the proposed requirements to determine successful voluntary submission of AMI data, including the proposal to give hospitals credit for data submission if they submit all troponin values that were actually measured, each of the other four data elements, and all of the linking variables; to not penalize hospitals for failure to submit a troponin value if it was not measured during the admission; and the proposal on the specific minimum percentage requirements for data on the qualifying AMI patients.

b. CABG Model-Specific Measure

(1) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF# 2558)(MORT-30-CABG)

(a) Background

CABG is a common procedure associated with considerable morbidity, mortality, and healthcare spending. In 2010, the National Hospital Discharge Survey (NHDS) estimated that 219,000 patients underwent a total of 397,000 CABG procedures. Among Medicare FFS beneficiaries, there were 139,133 hospitalizations for isolated CABG surgery between July 2012 and June 2015. CABG surgeries are costly procedures that account for the majority of major cardiac surgeries performed nationally. In FY 2009, isolated CABG surgeries accounted for

almost half (47.6 percent) of all cardiac surgery hospital admissions in Massachusetts. This provides an example of the frequency in which a CABG is performed for a patient admitted for cardiac surgery. In 2008, the average Medicare IPPS payment was $30,546 for CABG without valve replacement and $47,669 for CABG with valve replacement surgeries.

The proposed Hospital-level 30-Day Risk-Standardized Mortality Rate (RSMR) following Coronary Artery Bypass Graft (CABG) Surgery (MORT-30-CABG) (NQF# 2558) measure developed by CMS and currently implemented in the HIQR program, assesses hospitals' 30-day, all-cause risk-standardized rate of mortality, which is rate of death after admission for a CABG procedure for patients 65 and older during a 30-day period that begins with the date of the index admission for the specific hospital; an index admission is the hospitalization to which the mortality outcome is attributed. The data indicate that the median hospital-level risk-standardized mortality rate for 2016 public reporting on Hospital Compare was 3.2 percent, with a range of 1.4 percent to 8.3 percent among hospitals. The variation in these rates suggests that important differences in the quality of care delivered across hospitals exist, and that there is room for improvement.

More details about the measure can be found in the 2016 Annual Updates and Specifications Report for CABG Mortality posted on the CMS Web site at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

The proposed MORT-30-CABG (NQF# 2558) measure was endorsed by the NQF in November 2014. This measure has been publicly reported on Hospital Compare since FY 2015 and was incorporated into the HIQR Program for FY 2017 (FY 2015 IPPS/LTCH final rule 79 FR 50227).

(b) Data Source

Measure results for CABG model participants are calculated using Medicare Part A and Part B FFS claims submitted by all non-federal short-term acute care hospitals for the MORT-30-CABG (NQF# 2558) measure. Index admission diagnoses and in-hospital comorbidities are assessed using Medicare Part A claims. Additional comorbidities prior to the index admission are assessed as Part A inpatient, outpatient, and Part B office visit Medicare claims in the 12 months prior to the index (initial) admission. Enrollment and post-discharge mortality status are obtained from Medicare's enrollment database which contains beneficiary demographic, benefits/coverage, and vital status information.

(c) Cohort

The MORT-30-CABG (NQF# 2558) measure includes Medicare FFS beneficiaries, aged 65 years and older, discharged from a non-federal short-term acute care hospitals (including Indian Health Services hospitals) and critical access hospitals, who received a qualifying CABG procedure, and with a complete claims history for the 12 months prior to admission and through 30 days post-procedure.

We propose that the measure will include index admissions to all non-federal acute care hospitals, which includes all hospitals in the CABG model. Hospital performance will only be publically reported for hospitals with 25 or more index admissions in the 3-year measurement period. The CABG model cohort would differ from the hospital cohort that is currently captured in the measure through the HIQR Program. Although performance on the measure will not be publicly reported for hospitals with fewer than 25 cases, such hospitals will receive information about their performance. We refer readers to section III.B.5. of this proposed rule for a discussion of CABG model participant selection. For eligible hospitalizations defined using

ICD-9-CM codes, we refer readers to the CMS Web site at: http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

In order to include a clinically coherent set of patients in the measure, we sought input from clinical experts regarding the inclusion of other concomitant cardiac and non-cardiac procedures, such as valve replacement and carotid endarterectomy. Adverse clinical outcomes following such procedures are higher than those following "isolated" CABG procedures, that is, CABG procedures performed without concomitant high-risk cardiac and non-cardiac procedures. Limiting the measure cohort to "isolated" CABG patients is consistent with published reports of CABG outcomes; therefore, the measure cohort considers only patients undergoing isolated CABG as eligible for inclusion in the measure. We defined isolated CABG patients as those undergoing CABG procedures without concomitant valve or other major cardiac, vascular or thoracic procedures. In addition, our clinical experts, consultants, and Technical Expert Panel (TEP) members agreed that an isolated CABG cohort is a clinically coherent cohort for quality measurement. For detailed information on the cohort definition, we refer readers to the 2016 Annual Updates and Specifications Report for CABG Mortality on the CMS Web site at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

(d) Inclusion and Exclusion Criteria

We propose that an index admission is the hospitalization to which the mortality outcome is attributed. The measure includes the following index admissions for patients:

- Having a qualifying isolated CABG surgery during the index admission;

- Enrolled in Medicare FFS Part A and Part B for the 12 months prior to the date of the index admission, and enrolled in Part A during the index admission; and,
- Aged 65 or over.

Isolated CABG surgeries are defined as those CABG procedures performed without the following concomitant valve or other major cardiac, vascular, or thoracic procedures:

- Valve procedures.
- Atrial and/or ventricular septal defects.
- Congenital anomalies.
- Other open cardiac procedures.
- Heart transplants.
- Aorta or other non-cardiac arterial bypass procedures.
- Head, neck, intracranial vascular procedures.
- Other chest and thoracic procedures.

This measure excludes the following index admissions for patients:

- With inconsistent or unknown vital status or other unreliable demographic (age and gender) data.
- Discharged AMA.
- For patients with more than one qualifying CABG surgery admission in the measurement period, the first CABG admission is selected for inclusion in the measure and the subsequent CABG admission(s) are excluded from the cohort.

(e) Risk-Adjustment

We note that this measure is aligned with the risk-adjustment methodologies adopted for the other mortality measures developed by CMS and implemented under the HIQR Program in

accordance with section 1886(b)(3)(B)(viii)(VIII) of the Act, as finalized in FY 2008 IPPS/LTCH final rule (2008 IPPS/LTCH final rule 71 FR 67960). We also note that the measure risk adjustment takes into account patient age, sex, and comorbidities to allow a fair assessment of hospital performance. The measure defines the patient risk factors for mortality using diagnosis codes collected from all patient claims 1 year prior to patient index hospitalization for CABG surgery. ICD-10-CM diagnosis codes on Parts A and B administrative claims are used to inform the risk prediction for each patient; diagnostic codes from post-acute care settings are included in the measure, but this information is only used to identify a hospital's patient case mix in order to adequately adjust for differences in case mix across hospitals. Use of Parts A and B data does not mean the measure is applicable to post-acute care settings, only that it uses comprehensive data to predict the risk of the outcome and adjust for hospital patient case mix. We note that the patient diagnosis codes are grouped using HCCs. The CCs used in the risk-adjustment model for this measure are provided on the CMS QualityNet Web site: https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069856694.

In summary, age, sex, and comorbidities present at the time of admission are adjusted for differences in hospital case mix (patient risk factors). The measure uses the HLM statistical methodology for risk adjustment.

(f) Calculating the Risk-Standardized Mortality Ratio (RSMR) and Performance Period

We propose to calculate hospital 30-day, all-cause, risk-standardized mortality rates (RSMR) consistent with the methodology used to risk standardize all readmission and mortality measures used in CMS hospital quality programs. Using HLM, we calculate the hospital-level risk-standardized mortality rate following AMI hospitalization by producing a ratio of the

number of "predicted" deaths (that is, the adjusted number of deaths at a specific hospital) to the number of "expected" deaths (that is, the number of deaths if an average quality hospital treated the same patients) for each hospital and then multiplying the ratio by the national raw mortality rate. The RSMR is a point estimate—the best estimate of a hospital's mortality rate based on the hospital's case mix. For more detailed information on the calculation methodology we refer readers to the CMS Web site at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

A 3-year rolling performance period would be consistent with that used for the HIQR Program (FY 2015 IPPS/LTCH final rule 79 FR 50227). Section III.E.5. of this proposed rule, Form, Manner, and Timing of Quality Measure Data Submission, summarizes the proposed measure performance periods for CABG model performance years 1 through 5. We note that improvement on the MORT-CABG-30 (NQF #2558) measure would be determined from the 3-year rolling performance period available for the year preceding the CABG model performance year as explained in Table 30.

We seek comment on this proposal to include Hospital-level 30-Day,All-Cause, Risk-Standardized Mortality Rate (RSMR) following CABG Surgery (NQF #0230) measure in the CABG model to assess quality performance.

The EPM episodes are structured as 90-day periods with the hospital as the primary accountable entity, because we believe 90 days is a period over which hospitals have substantial ability to influence the quality and efficiency of the care that patients receive. We believe that there could be significant benefits for the quality of patient care from using quality measures that examine patient outcomes over a period that extends at least as long as the EPM episode (that is.,

90 days after discharge). In particular, we believe that this approach could help ensure that hospitals are held fully accountable for the quality of the care they deliver during the period covered by the bundle.

However, as discussed in section III.E. of this proposed rule, several of the outcome measures we are proposing for these EPMs (MORT-30-AMI (NQF #0230), AMI excess days, and MORT-30-CABG (NQF #2558)) assess outcomes over a 30-day period following discharge. We are proposing to use these existing 30-day measures, at least initially, because they are in wide use and have gained acceptance among hospitals and because the mortality measures have been reviewed and endorsed by the National Quality Forum.

Nevertheless, we believe that it is appropriate to seek to adapt these measures or to develop new related measures to assess outcomes over a longer timeframe, including timeframes at least as long as the EPM episodes. In developing measures that use a longer timeframe, CMS would perform empirical analyses to ensure that such measures are scientifically robust and to identify appropriate risk-adjustment approaches. Once such measures were available, CMS would consider when and how to incorporate these measures into the EPM quality payment methodology. We invite public comment on refining the existing 30-day measures to extend the period of outcome assessment following admission for AMI or CABG surgery, including the length of the period that should be examined by an extended measure, any important considerations in developing the refined measures, and any factors CMS should consider in incorporating these measures into the EPM quality payment methodologies.

c. SHFFT Model-Specific Measures

(1) Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550) (Hip/Knee Complications)

(a) Background

THA and TKA are commonly performed procedures for the Medicare population that improve quality of life. Between 2009 and 2012, there were 337,419 total hip arthroplasty (THA) procedures and 750,569 total knee arthroplasty (TKA) procedures for Medicare FFS patients 65 years and older.[82] The post-operation complications of these procedures are high considering these are elective procedures, and usually, the complications are devastating to patients. For example, rates for periprosthetic joint infection, a rare but devastating complication, have been reported at 2.3 percent for THA/TKA patients with rheumatoid arthritis after 1 year of follow-up[83] and 1.6 percent in Medicare patients undergoing TKA after 2 years of follow up.[84] Two studies reported 90-day death rates following THA at 0.7 percent[85] and 2.7 percent, respectively.[86] Reported rates for pulmonary embolism following TKA range from

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[82] Suter L, Grady JL, Lin Z et al.: 2013 Measure Updates and Specifications: Elective Primary Total Hip Arthroplasty (THA) And/Or Total Knee Arthroplasty (TKA) All-Cause Unplanned 30-Day Risk-Standardized Readmission Measure (Version 2.0). 2013. http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

[83] Bongartz, T, Halligan CS, Osmon D, et al. Incidence and risk factors of prosthetic joint infection after total hip or knee replacement in patients with rheumatoid arthritis. Arthritis Rheum. 2008; 59(12): 1713–1720.

[84] Kurtz S, Ong K, Lau E, Bozic K, Berry D, Parvizi J. Prosthetic joint infection risk after TKA in the Medicare population. Clin Orthop Relat Res. 2010;468:5.

[85] Cram P, Vaughan-Sarrazin MS, Wolf B, Katz JN, Rosenthal GE. A comparison of total hip and knee replacement in specialty and general hospitals. J Bone Joint Surg Am. Aug 2007;89(8):1675–1684. Soohoo NF, Farng E, Lieberman JR, Chambers L, Zingmond, DS. Factors That Predict Short-term Complication Rates After Total Hip Arthroplasty. Clin Orthop Relat Res. Sep 2010;468(9):2363–2371.

[86] Soohoo NF, Farng E, Lieberman JR, Chambers L, Zingmond, DS. Factors That Predict Short-term Complication Rates After Total Hip Arthroplasty. Clin Orthop Relat Res. Sep 2010;468(9):2363–2371. Cram P, Vaughan-Sarrazin MS, Wolf B, Katz JN, Rosenthal GE. A comparison of total hip and knee replacement in specialty and general hospitals. J Bone Joint Surg Am. Aug 2007;89(8):1675–1684.

0.5 percent to 0.9 percent.[87,88,89] Reported rates for septicemia range from 0.1 percent, during the index admission[90] to 0.3 percent, 90-days following discharge for primary TKA.[91] Rates for bleeding and hematoma following TKA have been reported at 0.94 percent[92] to 1.7 percent.[93]Combined, THA and TKA procedures account for the largest payments for procedures under Medicare.[94] Both hip and knee arthroplasty procedures improve the function and quality of life of patients with disabling arthritis, and the volume and cost associated with these procedures are very high. We believe it is important to assess the quality of care provided to Medicare beneficiaries who undergo one or both of these procedures.

The proposed measure developed by CMS, and currently implemented the HIQR and HVBP Programs and the CJR model, assesses a hospital's risk standardized complication rate, which is the rate of complications occurring after elective primary THA and TKA surgery. The measure outcome is the rate of complications occurring after THA and TKA during a 90-day period that begins with the date of the index admission for a specific hospital; an index admission is the hospitalization to which the complications outcome is attributed. The following outcomes (either one or more) are considered complications in this measure: acute myocardial infarction, pneumonia, or sepsis/septicemia within 7 days of admission; surgical site bleeding,

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[87] Mahomed NN, Barrett JA, Katz JN, et al. Rates and outcomes of primary and revision total hip replacement in the United States medicare population. J Bone Joint Surg Am. Jan 2003;85– A(1):27–32.

[88] Khatod M, Inacio M, Paxton EW, et al. Knee replacement: epidemiology, outcomes, and trends in Southern California: 17,080 replacements from 1995 through 2004. Acta Orthop. Dec 2008;79(6):812–819.

[89] Solomon DH, Chibnik LB, Losina E, et al. Development of a preliminary index that predicts adverse events after total knee replacement. Arthritis & Rheumatism. 2006;54(5):1536–1542.

[90] Browne, JA, Cook C, Hofmann A, Bolognesi MP. Postoperative morbidity and mortality following total knee arthroplasty with computer navigation. Knee. 2010;17(2): 152–156.

[91] Cram P, Vaughan-Sarrazin MS, Wolf B, Katz JN, Rosenthal GE. A comparison of total hip and knee replacement in specialty and general hospitals. J Bone Joint Surg Am. Aug 2007;89(8):1675–1684.

[92] Browne, JA, Cook C, Hofmann A, Bolognesi MP. Postoperative morbidity and mortality following total knee arthroplasty with computer navigation. Knee. 2010;17(2): 152–156.

[93] Huddleston JI, Maloney WJ, Wang Y, Verzier N, Hunt DR, Herndon JH. Adverse Events After Total Knee Arthroplasty: A National Medicare Study. The Journal of Arthroplasty. 2009;24(6, Supplement 1): 95–100.

[94] Bozic KJ, Rubash HE, Sculco TP, Berry DJ., An analysis of Medicare payment policy for total joint arthroplasty. J Arthroplasty. Sep 2008; 23(6 Suppl 1):133–138.

pulmonary embolism or death within 30 days of admission; or mechanical complications, periprosthetic joint infection or wound infection within 90 days of admission. The data indicated that the median hospital-level risk-standardized complication rate for 2008 was 4.2 percent, with a range from 2.2 percent to 8.9 percent in hospitals. The variation in complication rates suggests that there are important differences in the quality of care delivered across hospitals, and that there is room for quality improvement.

In 2010, we developed the proposed measure of hospital-level risk-standardized complication rate (RSCR) following elective primary THA and TKA surgery, which was later endorsed by the NQF (NQF #1550). In its Pre-Rulemaking Report for 2012,[95] the Measure Application Partnership (MAP) also recommended the inclusion of this measure in the HIQR Program; we have not submitted this measure for use in post-acute care settings as the measure was developed for the acute care hospital setting. This measure has been publicly reported on Hospital Compare since FY 2014 and in the HIQR Program since FY 2015 (FY 2015 IPPS/LTCH final rule 79 FR 50062). Finally, we note a comparison of the median hospital-level risk-standardized complication rates for hospitals between April 1, 2011 and March 31, 2014 illustrates a performance gap (median RSCR of 3.1 percent with a range from 1.4 percent to 6.9 percent) indicating there is still room for quality improvement.[96]

(b) Data Sources

Measure results are calculated using Medicare Part A and Part B FFS claims submitted by all non-federal acute care hospitals. Index admission diagnoses and in-hospital comorbidities

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[95] National Quality Forum. MAP Final Reports. Available at: http://www.qualityforum.org/Publications/2012/02/MAP_Pre-Rulemaking_Report__Input_on_Measures_Under_Consideration_by_HHS_for_2012_Rulemaking.aspx . Accessed on April 1 6, 2015, page 78.

[96] Suter L, Zang W, Parzynski C, et al. 2015 Procedure-Specific Complication Measures Update and Specifications: Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Risk-Standardized Complication Measure (Version 4.0). 2015.

are assessed using Medicare Part A claims. Additional comorbidities prior to the index admission are assessed using Part A inpatient, outpatient, and Part B office visit Medicare claims in the 1 to 2 months prior to the index (initial) admission. Enrollment and post-discharge mortality status are obtained from Medicare's enrollment database which contains beneficiary demographic, benefits/coverage, and vital status information.

(c) Cohort

The Hip/Knee Complications (NQF #1550) measure includes Medicare FFS beneficiaries, aged 65 years or older, admitted to non-federal acute care hospitals for elective primary THA or TKA. THA and TKA procedures eligible for inclusion are defined using ICD-9-CM codes 81.51 and 81.54, respectively. The following 24 codes in ICD-10 correspond to these two ICD-9-CM codes.

- ICD-9 code 81.51 (Total Hip Replacement) = ICD-10 codes 0SR90J9, 0SR90JA, 0SR90JZ, 0SRB0J9, 0SRB0JA, 0SRB0JZ.
- ICD-9 code 81.54 (Total Knee Replacement) = ICD-10 codes 0SRC07Z, 0SRC0JZ, 0SRC0KZ, 0SRD07Z, 0SRD0JZ, 0SRD0KZ, 0SRT07Z, 0SRT0JZ, 0SRT0KZ, 0SRU07Z, 0SRU0JZ, 0SRU0KZ, 0SRV07Z, 0SRV0JZ, 0SRV0KZ, 0SRW07Z, 0SRW0JZ, 0SRW0KZ.

We propose that the measure will include index admissions to all non-federal acute care hospitals, which includes all hospitals included in the SHFFT model. Hospital performance will only be publicly reported for hospitals with 25 or more index admissions in the 3-year measurement period. The SHFFT model participant hospital cohort would differ from the hospital cohort that is currently captured in the measure through the HIQR Program. Although performance on the measure will not be publicly reported for hospitals with fewer than 25 cases,

such hospital will receive information about their performance. We refer readers to section III.B.5. of this proposed rule for discussion of the selection of participants for the SHFFT model.

(d) Inclusion and Exclusion Criteria

An index admission is the hospitalization to which the complication outcome is attributed. We note that for purposes of the EPMs where we need to identify episodes that are included in the EPMs, we use the terms anchor and chained anchor hospitalization to identify hospitalizations that initiate EPM episodes for beneficiaries whose care is included in the EPMs. In describing the quality measures themselves in detail in section III.E.4. of this proposed rule, we use the term index hospitalization to identify hospitalizations of beneficiaries whose outcomes are included in the measures. Thus, anchor hospitalizations and index hospitalizations would have varying degrees of overlap depending on the specific quality measure. The MS-DRGs for the anchor or chained hospitalizations included in the SHFFT model will identify beneficiaries that do not overlap with the index hospitalizations used in the SHFFT model measures, since the SHFFT model measures use the elective THA/TKA cases as proxies for hip or femur fracture cases. The measure includes the following index admissions for patients:

- Enrolled in Medicare FFS.
- Aged 65 or over.
- Enrolled in Part A and Part B Medicare for the 12 months prior to the date of index admission and during the index admission.
- Have a qualifying elective primary THA/TKA procedure; elective primary THA/TKA procedures are defined as those procedures without any of the following:

++ Femur, hip, or pelvic fractures coded in principal or secondary discharge diagnosis fields of the index admission.

++ Partial hip arthroplasty (PHA) procedures with a concurrent THA/TKA.

++ Revision procedures with a concurrent THA/TKA.

++ Resurfacing procedures with a concurrent THA/TKA.

++ Mechanical complication coded in the principal discharge diagnosis field.

++ Malignant neoplasm of the pelvis, sacrum, coccyx, lower limbs, or bone/bone marrow or a disseminated malignant neoplasm coded in the principal discharge diagnosis field.

++ Removal of implanted devices/prostheses.

++ Transfer from another acute care facility for the THA/TKA.

The following admissions would be excluded from the measure:

- Admissions for patients discharged AMA.
- Admissions for patients with more than two THA/TKA procedure codes during the index hospitalization.
- Consistent with the FY 2016 IPPS/LTCH proposed rule, admissions for patients without at least 90 days post-discharge enrollment in FFS Medicare; this exclusion is an update to the measure signaled in the HIQR Program section of the FY2016 IPPS/LTCH proposed rule (80 FR 24572 through 24574) to ensure that disproportionate Medicare FFS disenrollment does not bias the measure results.

After applying these exclusion criteria, we randomly select one index admission for patients with multiple index admissions in a calendar year. Therefore, we exclude the other eligible index admissions in that year. Identification and use of a single index admission in a calendar year is done because this measure includes mortality as an outcome and the probability of death increases with each subsequent admission, preventing each admission from being

mutually independent. Therefore only one index admission is selected to maintain measure integrity.

We note that the Hip/Knee Complications (NQF #1550) measure does not capture patients undergoing partial hip arthroplasty procedures. We excluded partial hip arthroplasty procedures primarily because partial hip arthroplasty procedures are done for hip fractures. Therefore, they are not elective procedures. Also, partial hip arthroplasty procedures are typically performed on patients who are older, frailer, and have more comorbid conditions. Although this exclusion is not fully harmonized with MS-DRGs 469 and 470, which includes partial hip arthroplasty procedures, use of this measure will still provide strong incentives for improving and maintaining care quality across joint replacement patients as hospitals typically develop protocols for lower extremity joint arthroplasty that will address peri-operative and post-operative care for both total and partial hip arthroplasty procedures. Fiscal year 2014 claims data indicate that among inpatient claims with MS-DRG 469 or 470, partial hip arthroplasty (ICD-9-CM procedure code: 81.52) accounted for 12 percent, while Total Hip Replacement (ICD-9 code: 81.51) and total knee replacement (ICD-9 code: 81.54) accounted for 87 percent (80 FR 73300 and 73474). We also note that the same surgeons and care teams frequently perform both procedures. Therefore, quality improvement efforts initiated in response to the Hip/Knee Complications (NQF #1550) measure are likely to benefit patients undergoing similar elective procedures, such as partial hip arthroplasty and revision THA/TKA procedures, and possibly even non-elective lower extremity hip fracture surgery as described in section III.E.2.d. of this proposed rule.

(e) Risk-Adjustment

We note that this measure is aligned with the risk-adjustment methodologies adopted for

the HIQR Program and HRRP in accordance with section 1886(b)(3)(B)(viii)(VIII) of the Act (FY 2013 IPPS/LTCH final rule 77 FR 53516 through- 53518 and FY 2015 IPPS/LTCH final rule; 79 FR 50024, 50031, and 50202). We note that the risk-adjustment takes into account the patient case-mix to assess hospital performance. The patient risk factors are defined using the HCCs.[97] The HCCs used in the risk adjustment model for this measure are provided on the CMS QualityNet Web site: (https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772782693). We note that the measure uses ICD-9-CM diagnosis codes on Parts A and B administrative claims for the year prior to and including the index admission. The ICD-9-CM codes are used to inform the risk prediction for each patient. Diagnostic codes from post-acute care settings are utilized for the measure calculation, but this information is only used to identify a hospital's patient case mix in order to adequately adjust for differences in case mix across hospitals. Use of the administrative claims data does not mean the measures are applicable to post-acute care settings, only that they use comprehensive data to predict the risk of the outcome and adjust for hospital patient case mix. The measure methodology defines "complications" as acute myocardial infarction (AMI); pneumonia; sepsis/septicemia; pulmonary embolism; surgical site bleeding; death; wound infection; periprosthetic joint infection; and mechanical complication within 0 to 90-days post the index date of admission, depending on the complication. The decision on the appropriate follow-up period of 0 to 90 days was based on our analysis of 90-day trends in complication rates using the 2008 Medicare FFS Part A Inpatient Data. We found that rates for mechanical complications are elevated until 90 days post the date of index admission. We found that the rates for four other complications—death, surgical site

[97] Pope G, Ellis R, Ash A, et al., Principal Inpatient Diagnostic Cost Group Models for Medicare Risk Adjustment. Health Care Financing Review. 2000;21(3):26.

bleeding, wound infection, and pulmonary embolism—are elevated for 30 days, and that rates for AMI, pneumonia, and sepsis/septicemia level off 7 days after the date of index admission.

(f) Calculating the Risk-Standardized Complication Rate and Performance Period

Analogous to how we calculate hospital risk-standardized readmission rates with all readmission measures and risk-standardized mortality rates with the mortality measures used in CMS hospital quality programs, we calculate the hospital risk-standardized complication rate by producing a ratio of the number of "predicted" complications (that is, the adjusted number of complications at a specific hospital based on its patient population) to the number of "expected" complications (that is, the number of complications if an average quality hospital treated the same patients) for each hospital and then multiplying the ratio by the national raw complication rate. The 3-year rolling performance period would be consistent with that used for HIQR Program (FY 2015 IPPS/LTCH final rule 79 FR 50208 and 50209). Section III.E.5. of this proposed rule summarizes measure performance periods for SHFFT model years 1 through 5. We note that improvement on the Hip/Knee Complications (NQF #1550) measure would be determined from the immediate 3-year rolling performance period available for the year preceding the SHFFT model performance year as explained in Table 33.

We seek comment on this proposal to assess quality performance for SHFFT model participants through implementation of the Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1550) measure.

(2) Hospital-Level Performance Measure(s) of Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty

(a) Background

As part of our goal to move towards outcome measures that assess patient-reported outcomes, we have begun development on a measure to assess improvement in patient-reported outcomes following THA/TKA procedures. The Hospital-Level Performance Measure(s) of Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (hereinafter referred to as "THA/TKA patient-reported outcome-based measure") is currently under development. We specifically chose to focus on THA/TKA procedures since THA/TKAs are important, effective procedures performed on a broad population, and the patient outcomes for these procedures (for example, pain, mobility, and quality of life) can be measured in a scientifically sound way and are also influenced by a range of improvements in care.[98, 99, 100] We also note that THA/TKA procedures are specifically intended to improve function and reduce pain, making patient-reported outcomes the most meaningful outcome metric to assess for these common, costly procedures. Patient-reported outcomes would be assessed separately for THA and TKA procedures, though these results may be combined into a single composite measure for reporting. Therefore, we will refer to a single measure, but acknowledge the possibility of two measures, one for THA patients and one for TKA patients.

During measure development, we discovered that in order to complete measure development, we would need access to a nationally representative sample of THA and TKA inpatient surgical procedure patient-reported outcome data set that is also consistently collected

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[98] Monticone M, Ferrante S, Rocca B, et al. Home-based functional exercises aimed at managing kinesiophobia contribute to improving disability and quality of life of patients undergoing total knee arthroplasty: a randomized controlled trial. *Archives of physical medicine and rehabilitation.* Feb 2013;94(2):231-239.

[99] Galea MP, Levinger P, Lythgo N, et al. A targeted home- and center-based exercise program for people after total hip replacement: a randomized clinical trial. *Archives of physical medicine and rehabilitation.* Aug 2008;89(8):1442-1447.

[100] Moffet H, Collet JP, Shapiro SH, Paradis G, Marquis F, Roy L. Effectiveness of intensive rehabilitation on functional ability and quality of life after first total knee arthroplasty: A single blind randomized controlled trial. *Archives of physical medicine and rehabilitation.* Apr 2004;85(4):546-556.

at the hospital-level and contains risk variables identified by orthopedists. The rationale for requesting access to a national THA and TKA inpatient surgical procedures patient-reported data source are twofold -- (1) a national data source would provide us with hospital-level data representative of the total number of THA and TKA procedures performed in hospitals, as well as representative data on hospital-level case-mix; and (2) access to a national THA and TKA inpatient surgical procedures patient-reported data source would allow us to assess and identify a set of parsimonious data elements that will minimize the data collection burden by patients, physicians and hospitals. We believe access to such data would allow for completion and testing of the current measure under development that can be appropriately used for nationwide hospital performance evaluation. We implemented the initial data collection for this measure initially in the CJR model in order to test and resolve these measurement development issues through the collection of THA and TKA patient-reported outcome data. We propose to test SHFFT model episodes in mainly the same hospitals as the CJR model as discussed in sectionIII.B.4. of this proposed rule. We note that approximately 50 hospitals currently excluded from CJR model participation because they are testing BPCI LEJR episodes would be included in the SHFFT model. Access to this data through the SHFFT and CJR models would address the following:

- Current data sources are not consistently collected nor collected in a uniform process and in a standardized format (that is, data elements are not consistently defined across different data sources). We note that currently available data sources tend to be limited to single hospitals or regional registries which are associated with complex data access sharing requirements.
- Current lack of uniform hospital-level data that can be used in measure development.
- Lack of incentive for physicians and hospitals to collect patient-reported outcome data such as that through the model's financial incentives associated with voluntary data submission.

- Current lack of a technically simple and feasible mechanism for hospitals to submit patient-reported data to CMS. This model would help create and optimize such a mechanism, potentially enabling future measure implementation.

In summary, the voluntary data collection that is already underway in most SHFFT model participants who are also participants in the CJR model would provide data from the patient's perspective that is necessary to finalize and test the measure specifications, including the risk model. Access to this nationally representative voluntarily submitted data would enable us to do the following:

- Determine a parsimonious set of risk factors that are statistically adequate for risk adjustment for patient-reported outcome.
- Examine the differences in hospital performance related to different components in the patient-reported outcome (such as functional status, pain, etc.) to finalize the statistical modeling methodology for risk adjustment.
- Evaluate the reliability of the patient-reported outcome measure.
- Examine validity of the patient-reported outcome measure upon finalization of the risk adjustment model via potential testing methods such as face validity testing with national experts, comparing the measure results to similar results based on other data sources if feasible, etc.

In order to encourage participation with voluntary data submission of patient-reported outcome data, we are proposing to seek and reward voluntary participation in submission of THA/TKA patient-reported outcome-based measure data as outlined in section III.E.4.c.(2)(viii) of this proposed rule. We note that we would not publicly report the THA/TKA voluntary data.

Finally, we intend to use a fully tested and completed THA/TKA patient-reported

outcome-based measure in CMS models or programs when appropriate. If there is a decision to implement the fully developed THA/TKA patient-reported outcome-based measure, we would propose to adopt the measure through notice and comment rulemaking. We refer reviewers to draft measure specifications in the downloads section of the Measure Methodology webpage at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

(b) Data Sources

As previously discussed, this measure is under development, and we propose to reward SHFFT model participants that volunteer to submit provider- and patient- level data elements. We note that there is currently little uniformity across hospitals regarding collection of specific provider- and patient- level data elements that are used to assess patient outcomes after THA and TKA inpatient procedures. In the voluntary data submission for the THA/TKA patient-reported outcome-based measure, we are trying to identify a uniform set of provider- and patient-level data elements that are accurate, valid, and reliable pieces of information that can be used in the determination of improvement in various patient characteristics like those previously listed (that is, pain, mobility, and quality of life). Furthermore, in order to minimize provider and hospital burden associated with data collection and submission of provider- and hospital-level data elements, we propose using a variety of data sources for measure development. We anticipate using the following data sources are:

- Patient-reported data.
- Administrative claims-based data.
- One or both physician-reported and electronic health record data.

Through this voluntary data submission proposal, we hope to identify a uniform set of provider- and patient-level data elements while also identifying data sources that are the least burdensome for the patients, providers, and hospitals. We propose to request that SHFFT model participants provide administrative claims-based data whenever possible, in order to minimize burden on patients, providers, and hospitals. Additionally, we propose to request that SHFFT model participants submit either hospital documentation, chart abstraction, or abstraction from the electronic health records. We propose to request submission of the following data elements as finalized in the CJR model final rule (80 FR 73494 through 73495):

- Pre-operative Assessments (to be collected between 90 and 0 days prior to THA/TKA procedure):

++ Date of Birth.

++ Race and Ethnicity.

++ Date of admission to anchor hospitalization.

++ Date of eligible THA/TKA procedure.

++ Unique Identifier (Medicare Health Insurance Claim Number).

++ Hip-specific PROM Instrument for THA Procedures.

Either VR–12 or PROMIS-Global [collected pre-operatively (90 to 0 days prior to the THA procedure)], the revised list of risk variables [Table 28, collected only pre-operatively (90 to 0 days prior to the THA procedure)], AND either (A) the HOOS Jr. (6 items total) [collected pre-operatively (90 to 0 days prior to the THA procedure)] or (B) the original HOOS Pain Subscale (10 items), AND the original HOOS Function, Daily Living Subscale (17 items, for a total of 27 items) [collected pre-operatively (90 to 0 days prior to the THA procedure).

++ Knee-specific PROM instrument for TKA procedures.

Either (A) the HOOS Jr. (6 items total) [collected both pre-operatively (90 to 0 days prior to the THA procedure) and post-operatively (270 to 365 days after the THA procedure] or (B) the original HOOS Pain Subscale (10 items), AND the original HOOS Function, Daily Living Subscale (17 items, for a total of 27 items) [collected both pre-operatively (90 to 0 days prior to the THA procedure) and post-operatively (270 to 365 days after the THA procedure].

++ Body Mass Index (or height in cm and weight in kg).

++ Pre-operative use of narcotics.

++ Patient-Reported Pain in Non-operative Lower Extremity Joint.

++ Patient-Reported Back Pain (Oswestry Index question).

++ Patient-Reported Health Literacy

● Post-operative Assessments (To be collected between 270 and 365 days following THA/TKA procedure):

++ Date of admission to anchor hospitalization.

++ Date of eligible THA/TKA procedure.

++ Medicare Health Insurance Claim Number (Unique Identifier).

++ Generic PROM Instrument for THA and TKA Procedures.

++ Knee-Specific PROM Instrument for TKA Procedures.

Either VR–12 or PROMIS-Global [collected post-operatively (270 to 365 days after the TKA procedure)], AND either (A) the KOOS Jr. (7 items total) [collected post-operatively (270 to 365 days after the TKA procedure)] OR (B) the original KOOS Stiffness Subscale (2 items), AND the original KOOS Pain Subscale (9 items) AND the original KOOS Function, Daily Living Subscale (17 items, for a total of 28 items) collected post-operatively (270 to 365 days after the TKA procedure)].

++ Hip-Specific PROM Instrument for THA Procedures.

Either VR–12 or PROMIS-Global [collected post-operatively (270 to 365 days after the THA procedure], the revised list of risk variables [Table 28, collected only pre-operatively (90 to 0 days prior to the THA procedure)], AND either (A) the HOOS Jr. (6 items total) [collected post-operatively (270 to 365 days after the THA procedure] or (B) the original HOOS Pain Subscale (10 items), AND the original HOOS Function, Daily Living Subscale (17 items, for a total of 27 items) [collected post-operatively (270 to 365 days after the THA procedure)].

Finally, we note that as the measure continues to undergo development that the list of data elements may be simplified. As stated earlier in this section, we intend to identify a uniform set of provider- and patient-level data elements that are accurate, valid and reliable pieces of information that can be used in the determination of improvement in various patient-reported outcomes like those previously listed (that is, pain, mobility, and quality of life).

In accordance with, and to the extent permitted by, the HIPAA Privacy Rule and other applicable law, we propose to request that participants submit the data specified in the request, which we would limit to the minimum data necessary for us to conduct quality assessment and improvement activities. Regarding the process for data collection, we propose the THA/TKA voluntary data will be submitted to and collected by a CMS contractor in a manner and format similar to existing CMS data submission processes. For example, CMS would supply applicable hospitals with a file template and instructions for populating the file template with data and submitting the data; the hospitals will populate the template, log in to a secure portal, and transmit the file to the appropriate CMS contractor; the CMS contractor would also match the submitted data to Medicare administrative claims-based data and calculate successful submission determination for use in assigning the SHFFT composite quality score as described in section

III.E.3.e.(3). of this proposed rule (or validated subscales or abbreviated versions of these instruments). We believe that voluntary participation in the submission of THA/TKA patient-reported outcome-based measure data will provide the minimum information we would need that would inform us on how to continuously improve the currently specified measure in development.

We note that some of these data elements are closely aligned with data elements in e-clinical measures submitted by eligible professionals for the Medicare EHR Incentives Program for Eligible Professionals. Specifically these EHR Incentives Program measures for eligible professionals are - 1) Functional Status Assessment for Knee replacement (CMS 66); and 2) Functional Status Assessment for Hip replacement (CMS 56). We refer reviewers to CMS.gov EHR Incentives Program 2014 Eligible Professional June 2015 zip file update at http://cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/eCQM_2014_EP_June2015.zip for full measure specifications. We believe it is possible that many health IT vendors are already certified to capture, calculate and report these provider-level measures of functional status on total knee and total hip arthroplasty, and therefore we anticipate that the provider-level data elements that are identical to the THA/TKA patient-reported outcome voluntary data elements previously listed may not be as burdensome for the SHFFT model participants to voluntarily submit.

(c) Cohort

The measure cohort(s) includes Medicare FFS beneficiaries, aged 65 years or older, admitted to non-federal acute care hospitals for elective primary THA or TKA. We would exclude from the cohort patients with fractures and mechanical complications or those undergoing revision procedures. The THA/TKA patient-reported outcome-based measure cohort

is harmonized with the Hip/Knee Complications (NQF #1550) measure and with the cohort definition in the CJR model final rule (80 FR 73477). THA and TKA patient-reported outcomes will be assessed separately but may be combined into a single composite measure for reporting.

(d) Inclusion and Exclusion Criteria

The measure cohort inclusion criteria are all patients undergoing elective primary THA/TKA procedures. Exclusion criteria will consist of patients undergoing non-elective procedures (that is, patients with fractures resulting in THA/TKA), as it is infeasible to routinely capture pre-operative patient-reported assessments in these patients; patients with mechanical complications of prior hip and knee joint procedures and those undergoing revision THA/TKA will also be excluded, as their patient-reported outcomes may be influenced by prior care experiences and therefore may not adequately represent care quality of the hospital performing the revision procedure.

(e) Outcome

The measure will assess change between pre- and post-operative patient-reported outcomes for THA and TKA separately or as a composite measure for both procedures. The measure will use one or more of the following patient-reported outcome instruments (or validated subscales or abbreviated versions of these instruments) to calculate the measure score: the Patient Reported Outcomes Measurement Information Systems (PROMIS)-Global or the Veterans Rand 12 Item Health Survey (VR- 12), and the Hip dysfunction and Osteoarthritis Outcome Score/Knee injury and Osteoarthritis Outcome Score (HOOS/KOOS) instruments to measure pre- and postoperative improvement or both. These candidate instruments were selected by a TEP based upon their meaningfulness to patients and clinicians, performance characteristics such as reliability, responsiveness and validity, and their perceived burden to both

patients and providers. The pre-operative data collection timeframe will be 90 to 0 days before surgery, and the post-operative data collection timeframe will be 270 to 365 days following surgery. The approach to calculating the improvement or worsening of patient outcomes represented by the pre- and postoperative patient-reported survey results has not yet been determined, but will use one or more surveys to define the improvement or worsening of patient-reported outcomes to reliably identify differences between hospitals of varying performance.

(f) Risk-Adjustment (if applicable)

We note that the measure's risk model has yet to be developed. In order to develop the risk model, final risk variable selection for the risk model will involve empirical testing of candidate risk variables as well as consideration of the feasibility and reliability of each variable. The risk model will account for the hospital level response rate as well as measureable patient-level factors relevant to patient-reported outcomes following elective THA/TKA procedures. To the extent feasible, the risk model methodology will adhere to established statistical recommendations.[101]

(g) Calculating the Risk-Standardized Rate

We note that the approach to reporting this measure(s) has yet to be developed. The measure will assess change in patient-reported outcomes between the pre-operative (90 to 0 days prior to the elective primary THA/TKA procedure) and post-operative (270-365 days following the elective primary THA/TKA procedure) periods.

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[101] Ash AS, Fiengerg SE, Louis TA, Normand ST, Stukel TA, Utts J. STATISTICAL ISSUES IN ASSESSING HOSPITAL PERFORMANCE, Commissioned by the Committee of Presidents of Statistical Societies. Original report submitted to CMS on November 28, 2011, Revised on January 27, 2012. Available at:http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Statistical-Issues-in-Assessing-Hospital-Performance.pdf . Accessed on April 15, 2015.

(h) Performance period for successful submission of THA/TKA Patient-Reported-Outcome-Based Voluntary Data

We propose defining data reporting performance periods for each performance year of the SHFFT model as outlined in Table 29. Performance periods for voluntary reporting of THA/TKA patient-reported outcome-based measure data are those timeframes in which a hospital admission occurs for an eligible THA/TKA voluntary data submission procedure. Data submitted for the first SHFFT model performance year would be for cases that fulfill the measure specifications described in section III.E.4.c.(2)(i) of this proposed rule, and would be restricted to the pre-operative data elements on cases performed between September 1, 2016 and June 30, 2017. We note that SHFFT model participants generally would have the opportunity for voluntary data submission on cases performed in this timeframe through the hospitals' participation in the CJR model, which uses the same timeframe for voluntary submission of pre-operative data elements on cases. The proposed timing allows matching of the patient-reported data with relevant administrative claims-based data in order to accurately calculate the percent of eligible elective primary THA/TKA patients for which THA/TKA voluntary data was successfully submitted. For SHFFT model performance year 2, THA/TKA voluntary data reporting would be 10 months of post-operative data for cases performed between September 1, 2016 and June 30, 2017, and 12 months of pre-operative data for cases performed between July 1, 2017 and June 30, 2018. For SHFFT model performance year 3 and subsequent years of the model, the performance periods for submission of voluntary data will consist of 12- month time periods.

TABLE 29: DURATION OF PERFORMANCE PERIODS FOR PRE- AND POST-OPERATIVE THA/TKA VOLUNTARY DATA SUBMISSION

SHFFT Model Performance Year	Duration of performance period	Patient population eligible for THA/TKA Voluntary Data Submission	Requirements for Successful THA/TKA Voluntary Data Submission*
2017 Performance Year 1	10 months	All patients undergoing elective primary THA/TKA procedures performed between September 1, 2016 and June 30, 2017.	● Submit PRE-operative data on primary elective THA/TKA procedures for ≥ 60% or ≥75 procedures performed between September 1, 2016 and June 30, 2017.
2018 Performance Year 2	10 months	All patients undergoing elective primary THA/TKA procedures performed between September 1, 2016 and June 30, 2018.	● Submit POST-operative data on primary elective THA/TKA procedures for ≥60% or ≥ 75 procedures performed between September 1, 2016 and June 30, 2017. ● Submit PRE-operative data on primary elective THA/TKA procedures for ≥70% or ≥ 100 procedures performed between July 1, 2017 and June 30, 2018.
2019 Performance Year 3	24 months	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2017 and June 30, 2019.	● Submit POST-operative data on primary elective THA/TKA procedures for ≥ 70% or ≥ 100 procedures performed between July 1, 2017 and June 30, 2018. ● Submit PRE-operative data on primary elective THA/TKA procedures for ≥ 80% or ≥200 procedures performed between July 1, 2018 and June 30, 2019.
2020 Performance Year 4	24 months	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2018 and June 30, 2020.	● Submit POST-operative data on primary elective THA/TKA procedures for ≥ 80% or ≥200 procedures performed between July 1, 2018 and June 30, 2019. ● Submit PRE-operative data on primary elective THA/TKA procedures for ≥ 80% or ≥200 procedures performed between July 1, 2019 and June 30, 2020.

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*
2021 Performance Year 5	24 months	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2019 and June 30, 2021.	● Submit POST-operative data on primary elective THA/TKA procedures for ≥ 80% or ≥200 procedures performed between July 1, 2019 and June 30, 2020. ● Submit PRE-operative data on primary elective THA/TKA procedures for ≥ 80% or ≥200 procedures performed between July 1, 2020 and June 30, 2021.

The proposed performance periods would enable SHFFT model participants to receive points toward the SHFFT model composite quality score starting in performance year 1, even though complete pre-operative and post-operative data collection requires a minimum 9- through 12-month time period. This 9- through 12-month time period, between the procedure and post-operative data collection, was defined through clinician and stakeholder input and provides for both sufficient elapsed time for maximum clinical benefit of THA/TKA procedures on patient-reported outcomes and accommodates common clinical care patterns in which THA/TKA patients return to their surgeon 1 year after surgery. We emphasize that SHFFT model participants that are also participating in the CJR model do not need to submit data twice to satisfy the successful submission requirements of both models. If those hospitals successfully submit voluntary data for the CJR model they will be credited with successful submission under the SHFFT model.

We seek comment on our proposed measure reporting periods for the performance years of the SHFFT model.

(i) Requirements for Successful Submission of THA/TKA Patient-Reported-Outcome-Based Voluntary Data

In order for CMS to assign points in the SHFFT model composite quality score for successful participant submission of THA/TKA voluntary data, requirements to determine if the submitted data will inform measure development have been identified.

We believe that the following criteria should be used to determine if a participant has successfully submitted THA/TKA voluntary data. We note that successful THA/TKA voluntary data submission requires completion of all of the following:

- Submission of the data elements listed in section III.E.4.c.(2)(ii) of this proposed rule.
- Data elements listed in section III.E.4.c.(2)(ii) of this proposed rule must be submitted on at least 80 percent of their eligible elective primary THA/TKA patients.
- THA/TKA voluntary data submission must occur within 60 days of the end of the most recent data collection period.

To successfully submit THA/TKA voluntary data for performance years 1 through 5, SHFFT model hospitals must submit both pre-operative and post-operative patient reported outcome data on an increasing proportion of eligible elective primary THA/TKA patients over the performance years as described in Table 29 of this proposed rule. Performance periods for which we propose to have THA/TKA voluntary data submitted are displayed in Table 29 of this proposed rule. Table 29 also summarizes the performance periods for pre-operative and post-operative THA/TKA voluntary data. Finally, SHFFT model hospitals volunteering to submit THA/TKA data would be required to submit pre-operative data on all eligible patients and post-operative data elements only on those patients at least 366 days out from surgery. Therefore, hospitals are not expected to collect and submit post-operative THA/TKA voluntary data on patients who are fewer than 366 days from the date of surgery.

We previously described a THA/TKA eligible patient in section III.E.4.c.(2)(iii) of this proposed rule. This description is important as these patients are those in which we seek submission of voluntary data. We also selected the requirement of submitting an increasing percent of eligible elective primary THA/TKA patients' data starting at 60 percent in performance year 1 and reaching 80 percent by performance years 4 and 5 because this volume of cases would result in a high probability that we will have a have a national sample of THA/TKA patient data representative of each hospital's patient case mix. Having at least 80 percent of the eligible elective primary THA/TKA patients would enable an accurate and reliable assessment of patient-reported outcomes for use in measure development. We note that data used for outcome measure development must adequately represent the population that is anticipated to be measured and in this case that population would be those experiencing elective primary THA/TKA inpatient surgical procedures. Furthermore, we considered setting the requirement at 100 percent of the eligible elective primary THA/TKA patients, but concluded that a requirement of 100 percent data collection may not be feasible for all hospitals or may be excessively burdensome to achieve. Therefore we set the requirement in SHFFT model performance year 4 and beyond at 80 percent of the eligible elective primary THA/TKA patients. We believe acquisition of 80 percent of the eligible elective primary THA/TKA patients will provide representative data for measure development while decreasing patient, provider and hospital burden.

The proposal for voluntary submission of THA/TKA data is included in § 512.413(b). We seek public comment of these requirements to determine successful voluntary submission of THA/TKA data. We also seek comment specifically on the requirement for data collection on an increasing percentage of eligible patients starting with at least 60 percent in SHFFT model

performance year 1 and increasing to 80 percent of the eligible elective primary THA/TKA patients by SHFFT model performance year 4.

d. Measure Used for All EPMs

(1) Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey (NQF #0166)

(a) Background

The HCAHPS Survey (NQF #0166) is a CMS survey and a national, standardized, publicly reported survey of patients' experience of hospital care. The HCAHPS Survey is endorsed by the NQF (#0166); CMS is the measure steward. The HCAHPS Survey, also known as CAHPS® Hospital Survey, is a survey instrument and data collection methodology for measuring patients' perceptions of their hospital experience. The HCAHPS Survey asks recently discharged patients 32 questions about aspects of their hospital experience that they are uniquely suited to address. The core of the survey contains 21 items that ask "how often" or whether patients experienced a critical aspect of hospital care. The survey also includes four items to direct patients to relevant questions, five items to adjust for the mix of patients across hospitals, and two items that support congressionally mandated reports (77 FR 53513 through 53515). Eleven HCAHPS measures (seven composite measures, two individual items, and two global items) are currently publicly reported on the Hospital Compare Web site for each hospital participating in the HIQR Program (79 FR 50259). Each of the seven currently reported composite measures is constructed from two or three survey questions. The seven composites summarize the following:

- How well doctors communicate with patients.
- How well nurses communicate with patients.

- How responsive hospital staff are to patients' needs.
- How well hospital staff helps patients manage pain.
- How well the staff communicates with patients about medicines.
- Whether key information is provided at discharge.
- How well the patient was prepared for the transition to post-hospital care.

Lastly, the two individual items address the cleanliness and quietness of patients' rooms, while the two global items report patients' overall rating of the hospital, and whether they would recommend the hospital to family and friends. We propose to adopt a measure in the EPMs that uses HCAHPS survey data to assess quality performance and capture patient experience of care.

(b) Data Sources

The HCAHPS Survey is administered to a random sample of adult inpatients between 48 hours and 6 weeks after discharge. The HCAHPS survey data is collected on inpatient experience, is not limited to Medicare beneficiaries, and does not distinguish between types of Medicare beneficiaries. Patients admitted in the medical, surgical, and maternity care service lines are eligible for the survey; the survey is not restricted to Medicare beneficiaries. Hospitals may use an approved survey vendor or collect their own HCAHPS data (if approved by CMS to do so) (for a detailed discussion see 79 FR 50259). To accommodate hospitals, the HCAHPS Survey can be implemented using one of the following four different survey modes:

- Mail.
- Telephone.
- Mail with telephone follow-up.
- Active Interactive Voice Recognition (IVR).

Regardless of the mode used, hospitals are required to make multiple attempts to contact patients. Hospitals may use the HCAHPS Survey alone, or include additional questions after the 21 core items discussed previously. Hospitals must survey patients throughout each month of the year, and hospitals participating in the HIQR Program must target at least 300 completed surveys over 4 calendar quarters in order to attain the reliability criterion CMS as set for publicly reported HCAHPS scores (see 79 FR 50259). The survey itself and the protocols for sampling, data collection, coding, and file submission can be found in the current HCAHPS Quality Assurance Guidelines manual, available on the HCAHPS Web site located at: http://www.hcahpsonline.org. (The HCAHPS Survey is available in several languages, and all official translations of the HCAHPS Survey instrument are available in the current HCAHPS Quality Assurance Guidelines at http://www.hcahpsonline.org/qaguidelines.aspx.)

(c) Cohort

Hospitals, or their survey vendors, submit HCAHPS data in calendar quarters (3 months). Consistent with other quality reporting programs, we propose that HCAHPS scores would be publicly reported on Hospital Compare based on 4 consecutive quarters of data. For each public reporting, the oldest quarter of data is rolled off, and the newest quarter is rolled on (see 79 FR 50259).

(d) Inclusion and Exclusion Criteria

The HCAHPS Survey is broadly intended for patients of all payer types who meet the following criteria:

- Eighteen years or older at the time of admission.
- Admission includes at least 1 overnight stay in the hospital.
- Non-psychiatric MS–DRG/principal diagnosis at discharge.

- Alive at the time of discharge.

There are a few categories of otherwise eligible patients who are excluded from the sample frame as follows:

- "No-Publicity" patients—Patients who request that they not be contacted.
- Court/Law enforcement patients (that is, prisoners); patients residing in halfway houses are included.
- Patients with a foreign home address (U.S. territories—Virgin Islands, Puerto Rico, Guam, American Samoa, and Northern Mariana Islands are not considered foreign addresses and are not excluded).
- Patients discharged to hospice care (Hospice-home or Hospice-medical facility).
- Patients who are excluded because of state regulations.
- Patients discharged to nursing homes and skilled nursing facilities.

The HCAHPS Survey is intended for short-term, acute care hospitals. Both IPPS and Critical Access Hospitals participate in the survey; specialty hospitals, psychiatric hospitals and children's hospitals do not.

(e) Case-Mix Adjustment

To ensure that HCAHPS scores allow fair and accurate comparisons among hospitals, CMS adjusts for factors that are not directly related to hospital performance but which affect how patients answer survey items. This includes the mode of survey administration and characteristics of patients that are out of a hospital's control. Patient-mix adjustments (also known as case-mix adjustment) control for patient characteristics that affect ratings and that are differentially distributed across hospitals. Most of the patient-mix items are included in the "About You" section of the survey, while others are taken from hospital administrative records.

Based on the HCAHPS mode experiment, and consistent with previous studies of patient-mix adjustment in HCAHPS and in previous hospital patient surveys, we employ the following variables in the patient-mix adjustment model:

- Self-reported general health status (specified as a linear variable).
- Education (specified as a linear variable).
- Type of service (medical, surgical, or maternity care).
- Age (specified as a categorical variable).
- Admission through emergency room (discontinued in 2010).
- Lag time between discharge and survey.
- Age by service line interaction.
- Language other than English spoken at home.

Once the data are adjusted for patient mix, there is a fixed adjustment for the mode of survey administration (mail, telephone, mail with telephone follow-up, and active Interactive Voice Response). Information on patient-mix adjustment (risk adjustment) and survey mode adjustment of HCAHPS scores can be found at http://www.hcahpsonline.org/modeadjustment.aspx.

(f) HCAHPS Scoring

Regarding the HCAHPS Survey (NQF #0166) measure, we identified the methodology used to assess hospitals in the HIQR Program as reasonable for use in the EPMs since this is a survey that many hospitals and patients are familiar with. In determining HCAHPS performance, we propose to utilize the HCAHPS Linear Mean Roll-up (HLMR) score. The HLMR summarizes performance across 10 of the 11 publicly reported HCAHPS measures for IPPS hospitals with 100 or more completed HCAHPS surveys in a 4-quarter period. All of the

publicly reported measures are included except for how well hospital staff helps patients manage pain since revisions are under consideration for that measure. The HLMR is calculated by taking the average of the linear mean scores (LMS) for each of the 10 publicly reported HCAHPS measures. We note that the HLMR is not current publicly reported but may be calculated using the LMS, which are publicly reported in the Patient Survey Results in the Hospital Compare downloadable database found on Data.Medicare.gov at https://data.medicare.gov/data/hospital-compare?sort=relevance&tag=patient%20survey%20results. The LMS, which was created for the calculation of HCAHPS Star Ratings, summarizes all survey responses for each HCAHPS measure; a detailed description of LMS can be found in HCAHPS Star Rating Technical Notes, at http://www.hcahpsonline.org/StarRatings.aspx.

We propose that EPM participants must have at least 100 completed HCAHPS surveys over a given 4-quarter period to be evaluated on HCAHPS for the EPMs. The responses to the survey items used in each of the 10 HCAHPS measures described previously are combined and converted to a 0 to 100 linear-scaled score as follows:

- "Never" = 0; "Sometimes" = 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 propose to be consistent with the HIQR Program, which uses 4 quarters of data for HCAHPS (79 FR 50259). For the EPMs, we propose to use the most recently available HCAHPS 4-quarter roll-up to calculate the HLMR score for the initial year of the EPMs. The proposed measure performance period is discussed in section III.E.5. of this proposed rule, and

summarizes measure performance periods for performance years 1 through 5 of the EPM performance years. We note that improvement on the HCAHPS Survey (#0166) measure would be determined from the measure performance period available for the year immediately preceding the EPM model performance year. We seek comment on this proposal to include the HCAHPS Survey (NQF #0166) measure in the EPMs to assess quality performance and capture patient experience of care.

e. Potential Future Measures

CMS recognizes that there remain gaps in quality measures targeting AMI, CABG, and hip fracture care. Specifically with regard to hip fracture care, examples of potential measures suitable for consideration for inclusion in the SHFFT model in future performance years include: 1) claims-based or hybrid risk-standardized hospital-level mortality, complication, and/or readmission measures intended for assessing hospital or provider performance for patients with hip fracture; and 2) patient-reported outcome data-based measures of functional status, symptom burden, number of days at home and/or return to home and/or independent living suitable for patients with hip fractures and/or patients undergoing total hip or knee arthroplasty as referred to in 79 FR 50259. Additionally we would consider including measures of all–cause harm across the models in future years and appropriateness of procedures. CMS also recognizes that care for patients with AMI, CABG, and hip fractures extends across care settings and providers, and includes care provided by a multitude of clinicians and possible post-acute care facilities (for example, inpatient rehabilitation facilities, intermediate care facilities, and/or home health services). CMS welcomes comments on measure concepts for future measures that potentially could be included in the AMI, CABG, and SHFFT models, including measures that are attributable to acute care and post-acute care facilities and clinicians. CMS also welcomes

information about existing patient-centered outcomes measures that address quality gaps relevant to the AMI, CABG, and SHFFT models. Any changes to the measures included in the AMI, CABG, and SHFFT models would be subject to future rulemaking.

5. Form, Manner, and Timing of Quality Measure Data Submission

We believe it is important to be transparent and to outline the form, manner and timing of quality measure data submission so that accurate measure results are provided to hospitals, and that timely and accurate calculation of measure results are consistently produced to determine annual reconciliation payment. We propose that data submission for Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0230)(MORT-30-AMI); Excess Days in Acute Care after Hospitalization for an Acute Myocardial Infarction (AMI Excess Days); Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF# 2558)(MORT-30-CABG); and Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550)(Hip/Knee Complications) be accomplished through the existing HIQR Program processes. Since these measures are claims-based measures, hospitals will not need to submit data.

We propose that the same mechanisms used in the HIQR Program to collect HCAHPS Survey (NQF #0166) measure data also be used in the AMI, CABG, and SHFFT models (79 FR 50259). For the hospitals that voluntarily submit data for the Hybrid AMI mortality measure, we anticipate, if it is technically feasible, for data submission processes to be broadly similar to those summarized for the HIQR Program for electronic clinical quality measures. We propose to allow hospitals to submit the data elements using either QRDA-1 or to submit to data elements

using a simpler spreadsheet in performance year 1. We propose to require hospitals to submit data elements using only QRDA-1 in performance years 2 through 5. We would create a template for data reporting, provide a secure portal for data submission, and provide education and outreach on how to use these mechanisms for data collection and where to submit the hybrid AMI voluntary data. We describe processes for voluntary data collection in section III.E.4.c.(2)(ii) of this proposed rule. The use of QRDA for reporting of EHR data is aligned with requirements used by the HIQR Program for electronic clinical quality measures. We seek comment on the proposal to collect EHR data through either QRDA-1 or through a simple spreadsheet in performance year 1 and to collect EHR data through only QRDA-1 in performance years 2 through 5.

The proposed quality measure performance periods for required and voluntary reporting measures by the performance year of the AMI, CABG, and SHFFT models are displayed in Tables 30, 31, 32, 33, and 34.

TABLE 30: SUMMARY OF PROPOSED QUALITY MEASURE PERFORMANCE PERIODS BY YEAR OF THE AMI MODEL

Measure Title	Model Performance Year				
	1st	**2nd**	**3rd**	**4th**	**5th**
MORT-30-AMI*	July 1, 2014–June 30, 2017.	July 1, 2015–June 30, 2018.	July 1, 2016–June 30, 2019.	July 1, 2017–June 30, 2020.	July 1, 2018–June 30, 2021.
AMI Excess Days	July 1, 2014–June 30, 2017.	July 1, 2015–June 30, 2018.	July 1, 2016–June 30, 2019.	July 1, 2017–June 30, 2020.	July 1, 2018–June 30, 2021.

* Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0230) (MORT-30-AMI)
** Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction (AMI Excess Days)

TABLE 31: SUMMARY OF PROPOSED QUALITY MEASURE PERFORMANCE PERIODS BY YEAR OF THE CABG MODEL

Measure Title	Model Year				
	1st	**2nd**	**3rd**	**4th**	**5th**
MORT-30-CABG*	July 1, 2014–June 30, 2017.	July 1, 2015–June 30, 2018.	July 1, 2016–June 30, 2019.	July 1, 2017–June 30, 2020.	July 1, 2018–June 30, 2021.

* - Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF# 2558) (MORT-30-CABG)

TABLE 32: SUMMARY OF PROPOSED QUALITY MEASURE PERFORMANCE PERIODS BY YEAR OF THE VOLUNTARY DATA SUBMISSION

	Model Performance Year				
	1st	2nd	3rd	4th	5th
Submission of EHR data elements for the Hybrid AMI Mortality Measure	July 1, 2017–August 31, 2017	September 1 2017 – June 30, 2018	July 1 2018 – June 30, 2019	July 1 2019 – June 30, 2020	July 1, 2020 – June 30, 2021
Submission of functional status data for elective primary THA/TKA procedures	September 1, 2016– June 30, 2017	July 1, 2017 – June 30, 2018	July 1, 2018 – June 30, 2019	July 1, 2019 – June 30, 2020	July 1, 2020– June 30, 2021

TABLE 33: SUMMARY OF PROPOSED QUALITY MEASURE PERFORMANCE PERIODS BY YEAR OF THE SHFFT MODEL

Measure title	Model Performance Year				
	1st	2nd	3rd	4th	5th
Hip/Knee Complications*	April 1, 2014–March 31, 2017.	April 1, 2015–March 31, 2018.	April 1, 2016–March 31, 2019.	April 1, 2017–March 31, 2020.	April 1, 2018–March 31, 2021.

*Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550) (Hip/Knee Complications)

TABLE 34: SUMMARY OF PROPOSED QUALITY MEASURE PERFORMANCE PERIODS BY YEAR FOR REQUIRED MEAURES FOR ALL EPMS

Measure Title	Model Performance Year				
	1st	2nd	3rd	4th	5th
HCAHPS*	July 1, 2016–June30, 2017.	July 1, 2017–June30, 2018.	July 1, 2018–June30, 2019.	July 1, 2019–June30, 2020.	July 1, 2020–June30, 2021.

*Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey (NQF #0166)

6. Display of Quality Measures and Availability of Information for the Public from the AMI, CABG, and SHFFT Models

We believe that the display of measure results is an important way to educate the public on hospital performance and increase the transparency of the model. We propose to display quality measure results on the Hospital Compare Website (http://www.hospitalcompare.hhs.gov). We believe that the public and hospitals are familiar with this Web site and how the information is displayed. The proposed measures have been displayed on Hospital Compare over the past few years. Finally, , we believe that the public and hospitals' familiarity with the Hospital Compare Web site will make it simpler to access data. We seek comment on this proposal.

III. Provisions of the Proposed Regulations

F. Compliance Enforcement and Termination of an Episode Payment Model

1. Overview and Background

We must have certain mechanisms to enforce compliance with the requirements of the EPMs. The following discussion details the enforcement mechanisms we propose to make available to CMS for the EPMs when an EPM participant or certain other individuals and entities fails to comply with the requirements of these models.

Section 510.410 established that CMS will enforce the CJR model requirements against CJR participant hospitals, and will hold such hospital responsible for its own and its CJR collaborators' compliance with CJR model requirements. Given that CJR participant hospitals may receive reconciliation payments, and choose to distribute or share those payments with its CJR collaborators, CMS believed that enhanced scrutiny and monitoring of CJR participant hospitals was necessary and appropriate. We also noted in the CJR final rule that by making the CJR participant hospitals responsible for compliance with the model, CMS indirectly will be accounting for CJR collaborators' compliance, in addition to any direct monitoring of such CJR collaborators that HHS (including CMS and OIG) conducts. Further, § 510.410 established that upon discovering an instance of CJR collaborator noncompliance with the CJR model, CMS, HHS, or a respective designee may take remedial action against the CJR participant hospital, including requiring such hospital to terminate a sharing arrangement with a CJR collaborator and to prohibit further engagement in the CJR model by such collaborator, and CMS may also increase a participant hospital's repayment. Section 510.410 as well as the Section 1115A of the Social Security Act authorizes CMS to reduce or eliminate a participant hospital's reconciliation payment as well as increase a participant hospital's repayment amount. We propose an

enforcement structure that would be consistent with the CJR model, as we believe the CJR model and the EPMs share many of the same policy characteristics.

2. Proposed Compliance Enforcement for EPMs

We propose that CMS would have the remedial actions detailed in section §512.460(b)(2) available for use against any EPM participant where such EPM participant or its EPM collaborator, collaboration agent or downstream collaboration agent is not compliant with applicable requirements in any of the ways listed in § 512.460(b)(1). These mechanisms will support CMS's goal for EPMs to maintain or improve quality of care, reduce program expenditures, safeguard program integrity, protect against fraud and abuse and deter noncompliance of EPM requirements. Further, preventing EPM participants from avoiding the high cost and high severity patients or from targeting low cost and low severity patients will further CMS's goal under the CR incentive payment to reduce cardiovascular mortality, improve health-related quality of life, and reduce the risk of hospital admission. Additionally, these mechanisms will support CMS's goal for EPMs to provide beneficiaries with complete and accurate information, including notices which promote increasing consumer engagement and freedom of choice. Given that EPM participants may choose to gainshare with their EPM collaborators, and those EPM collaborators may have distribution arrangements with any collaboration agent, and those collaboration agents may have downstream distribution arrangements with any downstream collaboration agent, we believe that enhanced scrutiny and monitoring of EPM participants and their EPM collaborators, collaboration agents, and downstream collaboration agents is necessary and appropriate. Similar to the CJR model, we propose to hold the EPM participant responsible for its own and its EPM collaborators' compliance with the EPM requirements. In this proposed rule, we are adding EPM participant

responsibility for the other individuals and entities with financial arrangements under the EPM requirements as well. This is based in part on the addition of ACOs and hospitals, including CAHs, as EPM collaborators. Specifically, we believe that because we are allowing additional entities and individuals to be EPM collaborators, collaboration agents, or downstream collaboration agents, we must ensure that such entities and individuals comply with all requirements of the EPMs, such as notifying beneficiaries of the model and maintaining access to care. Overall, we have concluded that EPM participants should ensure that any entity or individual participating in the model should only be permitted to enter into certain financial arrangements that comply with model requirements and safeguard program integrity. Upon discovering an instance of noncompliance by an EPM collaborator, collaboration agent, or any downstream collaboration agent with the requirements of the EPM, CMS, HHS, or a designee of such Agencies may take remedial action against the EPM participant, including requiring such EPM participant to terminate a sharing arrangement with an EPM collaborator and prohibit further engagement by the EPM participant in sharing arrangements with the EPM collaborator. Where a participant is terminated from an EPM, we propose that the EPM participant would remain liable for all negative NPRA generated from episodes of care that occurred prior to termination. Any information collected by CMS in relation to termination of a participant from the model would be shared with our program-integrity colleagues at HHS, the Department of Justice, and their respective designees. Should such participant, or one of its EPM collaborators, collaboration agents, or downstream collaboration agents, be noncompliant with the requirements of the EPMs or engage in unlawful behavior related to participation in the EPMs, we note that such information could be used in proceedings unrelated to the enforcement mechanisms in this section

These remedial actions are necessary to safeguard program integrity and protect against abuse or fraud. Further, we believe the proposed remedial actions would deter noncompliance of EPM requirements.

In summary, we propose in § 512.460 that EPM participants must comply with all requirements outlined in part 512. Except as specifically noted in this part, the regulations under this part must not be construed to affect the applicable payment, coverage, program integrity, or other requirements under this chapter (such as those in parts 412 and 482).

Further, we propose in § 512.460 that CMS may take the remedial actions later discussed in this section, if an EPM participant or its related EPM collaborators, collaboration agents or downstream collaboration agents --

- Fails to comply with any applicable requirements of this part or is identified as noncompliant through monitoring by HHS (including CMS and OIG) of the applicable model, including but not limited to--

++ Avoiding potentially high cost or high severity patients;

++ Targeting potentially low cost or low severity patients;

++ Failing to provide medically appropriate services or systematically engaging in the over or under delivery of appropriate care;

++ Failing to provide beneficiaries with complete and accurate information, including required notices;

++ Failing to allow beneficiary choice of medically-necessary options, including non-surgical options; or

++ Failing to follow the requirements related to sharing arrangements.

- Has signed a sharing arrangement, distribution arrangement, or downstream distribution arrangement that is noncompliant with the requirements of this part;
- Takes any action that threatens the health or safety of patients;
- Avoids at risk Medicare beneficiaries, as this term is defined in § 425.20;
- Avoids patients on the basis of payer status;
- Is subject to sanctions or final actions of an accrediting organization or federal, state, or local government agency that could lead to the inability to comply with the requirements of this part;
- Takes any action that CMS determines for program integrity reasons is not in the best interests of the applicable episode payment model, or fails to take any action that CMS determines for program integrity reasons should have been taken to further the best interests of EPM;
- Is subject to action by HHS (including OIG and CMS) or the Department of Justice to redress an allegation of fraud or significant misconduct, including intervening in a False Claims Act qui tam matter, issuing a pre demand or demand letter under a civil sanction authority, or similar actions; or
- Is subject to action involving violations of the physician self-referral law, civil monetary penalties law, Federal anti-kickback statute, antitrust laws, or any other applicable Medicare laws, rules, or regulations that are relevant to EPM.

We propose the remedial actions to include the following:

- Issuing a warning letter to the EPM participant.
- Requiring the EPM participant to develop a corrective action plan, commonly referred to as a CAP.

- Reducing or eliminating the EPM participant's reconciliation payment.
- Reducing or eliminating the EPM participant's CR incentive payment.
- Requiring the EPM participant to terminate a sharing arrangement with an EPM collaborator and prohibit further engagement by the EPM participant in sharing arrangements with the EPM collaborator.
- Terminating the EPM participant's in the EPM. Where a participant is terminated from an EPM, the EPM participant will remain liable for all negative NPRA generated from episodes of care that occurred prior to termination.

Further we propose that CMS may add 25 percent to a repayment amount on an EPM participant's reconciliation report if all of the following conditions are true:

- CMS has required a corrective action plan from the EPM participant.
- The EPM participant owes a repayment amount to CMS.
- The EPM participant fails to timely comply with the corrective action plan or is noncompliant with the EPM's requirements.

The proposals for compliance enforcement are included in § 512.460. We seek comment on our proposals.

3. Proposed Termination of an Episode Payment Model

We further propose under §512.900, CMS may terminate any episode payment model for reasons including but not limited to the following::

- CMS no longer has the funds to support the applicable model.
- CMS terminates the applicable model in accordance with section 1115A(b)(3)(B) of the Act. As provided by section 1115A(d)(2) of the Act, termination of the model is not subject to administrative or judicial review.

G. Monitoring and Beneficiary Protection

1. Introduction and Summary

With the AMI, CABG, and SHFFT models, we are proposing to expand upon the CJR model implemented in 2016, as we believe the proposed EPMs represent additional opportunities to improve beneficiary access, patient outcomes, and overall quality of care across a broader spectrum of clinical conditions. EPM policies are intended to support making care more easily-accessible to consumers when and where they need it, increasing consumer engagement and thereby informing consumer choices. Given the similarity between the CJR model and the proposed EPMs, we are proposing to extend some waivers to these EPMs that initially were offered under the CJR model and that we believe are clinically-appropriate for the proposed episodes. These waivers would offer AMI model, CABG model, and SHFFT model participants additional flexibilities with respect to furnishing telehealth services and post-discharge home visits and waiving the 3-day stay requirement for covered SNF services when clinically-appropriate and are discussed further in section III.J. of this proposed rule.

We believe that the proposed EPMs will improve beneficiary access and outcomes, but we do note that these same opportunities could be used to try to steer beneficiaries into lower-cost services without an appropriate emphasis on maintaining or increasing quality. Therefore, we direct readers to section III.D of this proposed rule for discussion of the methodology for incorporating quality into the payment structure and the measures utilized for these models, which we believe can help identify and mitigate these possibilities.

2. Beneficiary Choice

As with the CJR model, we propose that participation in the proposed EPMs by hospitals would be mandatory in the selected geographic areas covered under each EPM. An individual

beneficiary would not be able to opt out of an EPM episode of care provided by an EPM participant in the applicable model. We do not believe that it is appropriate or consistent with other Medicare programs to allow a patient to opt out of a payment system that is unique to a particular geographic area. For example, the state of Maryland has a unique payment system under Medicare, but that payment system does not create an alternative care delivery system, nor does it in any way impact beneficiary decisions. Moreover, we do not believe that an ability to opt out of a payment system is a factor in upholding beneficiary choice or is otherwise advantageous to beneficiaries or even germane to beneficiary decisions, given that the proposed EPMs would not increase beneficiary cost-sharing. However, we also believe that full notification and disclosure of the EPMs and their possible implications is critical for beneficiary understanding and protection. Further, it is important to create safeguards for beneficiaries to ensure that care recommendations are based on clinical needs and not inappropriate cost savings. This is particularly important when one entity is held accountable for payments across multiple provider settings as will be done in the proposed EPMs. It also is important for beneficiaries to know that they can raise any concerns with their physicians, with 1-800-Medicare, or with their local Quality Improvement Organizations.

As with the CJR model and other episode-based payment models, the proposed EPMs would not limit a beneficiary's ability to choose among Medicare providers or the range of services that would be available to them. Beneficiaries would continue to choose any Medicare participating provider, or any provider that has opted out of Medicare, with the same costs, copayments and responsibilities as they have with other Medicare services. Although the proposed EPMs would allow EPM participants to enter into sharing arrangements with certain providers and may recommend to beneficiaries such preferred providers within the constraints of

current law, hospitals may not restrict beneficiaries to a list of preferred or recommended providers that surpass any restrictions that already exist under current statutes and regulations. Moreover, an EPM participant may not charge any EPM collaborator a fee to be included on a list of preferred providers or suppliers, nor may such EPM participant accept such payments, which would be considered to be outside the realm of risk-sharing arrangements. Although the emergent nature of some of the services covered under the proposed EPMs' episodes may limit beneficiaries' abilities to plan where they will be treated for these services, such constraint should be no different than it would be in the absence of the EPMs. Thus, these proposed EPMs would not create any new restriction of beneficiary freedom to choose providers, including surgeons, hospitals, post-acute care, or any other providers or suppliers.

3. Beneficiary Notification

We believe that beneficiary notification and engagement is essential because under the proposed EPMs, there would be a change in the way EPM participants are paid, which could affect the care beneficiaries receive. While we believe that existing Medicare provisions can be effective in protecting beneficiary freedom of choice and access to appropriate care, we also believe that the additional safeguards implemented with the CJR model would also be appropriate under the proposed EPMs. We believe that appropriate beneficiary notification should -- (1) explain the model; (2) advise beneficiaries and their families or caregivers of the beneficiaries' clinical needs and care-delivery choices; and (3) clearly specify that any non-hospital provider holding a risk-sharing arrangement with the EPM participant should be identified to the beneficiary as a financial partner of such EPM participant for the purposes of services covered under the proposed EPMs' episodes. Through these policies, we seek to enhance beneficiaries' understanding of their care, improve their abilities to share in the

decision-making, and give them the opportunity to consider competing benefits even as they are presented with cost-saving recommendations. We believe that appropriate beneficiary notification should do all of the following:

- Explain the model and how it may or may not impact their care.
- Inform patients that they retain freedom of choice to choose providers and services.;
- Explain how patients can access care records and claims data through an available patient portal and through sharing access to care-givers to their Blue Button® electronic health information.
- Advise patients that all standard Medicare beneficiary protections remain in place, including the ability to report concerns of substandard care to Quality Improvement Organizations (QIO) and 1-800-MEDICARE.

However, we acknowledge that because of the emergent nature of admissions related to services covered under the proposed EPMs, in particular the AMI and SHFFT models, many patients initially admitted for such episodes may not, at the time of admission, be capable of receiving appropriate notification. In addition, there may be situations in which it is not determined until after an admission that the patient would be covered under an EPM's episode of care. In such situations, because the decision to admit may not be made in advance, it would be appropriate that the notifying entity be the EPM participant. Nonetheless, consistent with CJR policy, we are proposing that EPM participants must: (1) require all providers and suppliers that execute EPM sharing arrangements with such EPM participants to share with beneficiaries or beneficiary representatives certain notification materials, to be developed or approved by CMS, that detail the applicable EPM; and (2) where feasible, provide such information in advance of admissions for services covered under EPM episodes. When, due to the emergent nature of the

admission, it is not feasible to provide such notification in advance of admissions, we propose that the EPM participant would be responsible for providing such notifications as soon as reasonably practicable but no later than discharge from the hospital accountable for the episode. Under our proposal, EPM participants would be required to provide such notifications as a condition of any EPM sharing arrangements. Where an EPM participant does not have such sharing arrangements with providers or suppliers that furnish services to beneficiaries during EPM episodes of care, or where admissions for covered episodes of care are ordered by physicians who do not have such EPM sharing arrangements, we propose that the EPM participant must provide such beneficiary-notification materials at the earliest time that is reasonably practicable but no later than discharge from the hospital accountable for the episode. Further, we propose that participants of an ACO that has entered into a sharing arrangement with the EPM participant provide written notice to any EPM beneficiary of the applicable EPM's structure and the existence of the ACO's sharing arrangement with the EPM participant. Under this proposal, the ACO must require any ACO participants with which such ACO has relevant distribution arrangements, to provide the written notification. We propose the ACO must provide such beneficiary notification no later than the time at which the beneficiary first receives services from such ACO's participant and/or an ACO PGP member collaboration agent during the EPM episode. We understand that various providers and suppliers, including hospitals, may be ACO participants; therefore, if, due to the emergent nature of a particular admission, it is not feasible to provide such notification in advance of such admission, the ACO participant would be responsible for providing such notification as soon as reasonably practicable but no later than discharge from the hospital accountable for the episode. The purpose of this proposed policy is to ensure that all beneficiaries who initiate EPM episodes and/or their designated representatives

receive the beneficiary notification materials as early as possible. We believe that this proposal targets beneficiaries for whom information is relevant, and increases the likelihood that patients will become engaged and seek to understand the applicable EPMs and their potential impact on their care.

We propose that all providers and suppliers that are required to provide notice to beneficiaries of the EPM model (participant and collaborator hospitals, PGPs, physicians, non-physician practitioners, post-acute care providers and suppliers, and ACOs) must be able to, upon request by CMS, indicate compliance with the beneficiary notification requirements outlined in this section and in the final rule. The participant hospital or collaborator should be able to generate a list of beneficiaries that received such notification and when the notification was received and provide it to CMS or its designee upon request. We note that the method employed to document beneficiary notification may vary; for example, some hospitals and collaborators may retain a list of all beneficiaries that received the notification, document in the medical record that the beneficiary received the beneficiary notification, add a barcode to the notification form to be scanned into the medical record, or employ another method of recordkeeping. Regardless of the method used for recordkeeping, the entity must be able to provide CMS or its designee with a list of all beneficiaries that received the notification materials in a specified time period. This requirement will aid CMS in monitoring participant hospital and collaborator compliance with the final rule.

We note that Medicare beneficiaries are accustomed to receiving similar notices of rights and obligations from healthcare providers prior to the start of inpatient care, or, as appropriate, under emergency conditions. In following the same guidelines established for the CJR model, we aim to limit confusion and to provide consistent direction to hospitals which may be

participating in both the CJR model and EPMs. We invite comment on ways in which the timing and source of beneficiary notification might be modified to best serve the needs of beneficiaries without creating unnecessary administrative work for providers.

4. Monitoring for Access to Care

Given that an EPM participant would receive a reconciliation payment when such participant reduces average costs per case and meets quality thresholds, such EPM participant could have an incentive to avoid complex, high-cost cases by not admitting patients at all or by transferring patients to nearby facilities or specialty referral centers that would be outside of the model. We intend to monitor the EPM participants' claims data – for example, to compare each EPM participant's case mix relative to a pre-model historical baseline to determine whether complex patients are being systematically excluded. We propose to publish these data as part of the EPMs' evaluations to promote transparency and an understanding of the EPMs' effects. We also propose to continue to review and audit EPM participants if we have reason to believe that they are compromising beneficiary access to care. For example, we would review claims data to determine whether there is an unusual pattern of referral to regional hospitals located outside of the applicable EPM's catchment area or a clinically-unexplained increase or decrease in CABGs or rates of other related surgical procedures not covered under the EPMs.

5. Monitoring for Quality of Care

As we noted previously, in any payment system that promotes efficiencies of care delivery, there may be opportunities to direct patients away from higher-cost services at the expense of better outcomes and higher quality. However, we believe that professionalism, the quality measures proposed for the applicable EPM, and clinical standards can be effective in preventing denials of medically-necessary care in both the inpatient and post-acute care settings

during the 90 days post-discharge. Accordingly, we believe that the potential for the denial of medically-necessary care within EPMs will not be greater than that which currently exists under the IPPS. However, we also believe that we have the authority and responsibility to audit EPM participants' and their EPM collaborators' medical records and claims to verify that beneficiaries receive medically-necessary services, and we propose to perform such auditing activities as we deem appropriate. We also propose to monitor arrangements between EPM participants and their EPM collaborators to ensure that such arrangements do not result in the denial of medically-necessary care or other programmatic or patient abuses. This is consistent with the policy that has been established for the CJR model.

With respect to post-acute care, we believe that requiring EPM participants to engage patients in shared decision-making is the most important safeguard to prevent inappropriate recommendations for lower-cost care, and that such a requirement can be best effected by requiring EPM participants to make shared decision making a condition of any EPM sharing arrangements with practitioners who provide these services. We also believe the 90-day episode is sufficiently long so as to create financial accountability and to encourage the provision of high-quality care that minimizes the risk of complications and readmissions that typically could occur within such time period. Clinical standards of care also constrain physician patterns of practice, and we believe that the risk associated with deviations from those standards provides further deterrence to compromising care.

We believe that these safeguards are all enhanced by beneficiary knowledge and engagement. Therefore, we are proposing to require that, similar to CJR participant hospitals, EPM participants must, as part of discharge planning, account for potential financial bias by providing each patient with a complete list of all available post-acute care options in the

applicable service area consistent with medical need, including beneficiary cost-sharing and quality information (where available and as applicable). We expect that the treating physician as well as all other treating practitioners continue to identify and discuss all medically-appropriate options with the beneficiary, and that the EPM participant will discuss the various facilities and providers available to meet the clinically-identified needs. These proposed requirements for EPM participants would supplement the discharge-planning requirements under existing conditions of participation (CoPs). We also specifically note that neither the CoPs nor this proposed transparency requirement preclude EPM participants from recommending preferred providers within the constraints created by current law, as coordination of care and optimization of care are important factors for successful participation in EPMs. We invite comment on this proposal, including additional opportunities to ensure high-quality care.

6. Monitoring for Delayed Care

We are proposing the EPMs in part to incent EPM participants to create efficiencies in the delivery of care within a 90-day episode following an acute clinical event. Theoretically, such EPMs also could create incentives for EPM participants or their EPM collaborators to delay services until after such 90-day window has closed. Consistent with the CJR model, we believe that existing Medicare safeguards are sufficient to protect beneficiaries in the EPMs.

First, our experience with other episode-based payment models such as the BPCI initiative has shown that providers focus first on appropriate care and then on efficiencies only as obtainable in the setting of appropriate care. We believe that a 90-day post-discharge episode is sufficient to minimize the risk that EPM participants and their EPM collaborators would compromise services furnished in relation to a beneficiary's care. While we recognize that ongoing care for underlying conditions may be required after the 90-day episode of care, we

believe that EPM participants would be unlikely to postpone key services beyond a 90-day period because the consequences of delaying care beyond such episode duration would be contrary to usual standards of care.

However, we also note that additional monitoring would occur as a function of the proposed EPMs. As with the CJR model, we propose as part of the payment definition (see section III.D.7. of this proposed rule) that certain post-episode payments occurring in the 30-day window subsequent to the end of the 90-day episode would be counted as an adjustment against savings. We believe that including such a payment adjustment would create an additional deterrent to delaying care beyond the episode duration. In addition, we believe the data collection and calculations used to determine such adjustment would provide a mechanism to check whether providers are inappropriately delaying care. Finally, we note that the proposed quality measures create additional safeguards as such measures are used to monitor and influence clinical care at the institutional level.

In accordance with section 1115A of the Act, we are proposing to codify these proposals in regulation in the proposed 42 CFR part 512. We invite public comment on our proposed requirements for notification of beneficiaries and our proposed methods for monitoring participants' actions and compliance as well as on other methods to safeguard delivery of high-quality, clinically-appropriate care.

H. Access to EPM Records and Record Retention

Consistent with the Shared Savings Program, the BPCI initiative, CJR model, and other Innovation Center models, we propose specific access to EPM records and record retention requirements for individuals and entities involved with the EPM. For the CJR model, the record access and retention requirements were originally located in Subpart F (Financial Arrangements

and Beneficiary Incentives). However, we propose to include them in Subpart B (Episode Payment Model Participants) for the EPM and move them to Subpart B for the CJR model as discussed in section V.L. of this proposed rule, so that these requirements can be applied to categories of information that are broader than those solely related to financial arrangements and beneficiary incentives, as discussed later in this section.

We propose that EPM participants, EPM collaborators, collaboration agents, downstream collaboration agents, and any other individuals or entities performing EPM activities must allow both scheduled and unscheduled access to all books, contracts, records, documents, and other evidence (including data related to utilization and payments, quality of care criteria, billings, lists of EPM collaborators, sharing arrangements, distribution arrangements, downstream distribution arrangements, and the documentation required under § 512.500(d) and § 512.525(d)) sufficient to enable the audit, evaluation, inspection, or investigation of six categories of information. We further propose that all such books, contracts, records, documents, and other evidence be maintained for a period of 10 years from the last day of the EPM participant's participation in the EPM or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless CMS determines a particular record or group of records should be retained for a longer period and notifies the EPM participant at least 30 calendar days before the disposition date; or there has been a dispute or allegation of fraud or similar fault against the EPM participant, EPM collaborator, collaboration agent, downstream collaboration agents, or any other individual or entity performing EPM activities in which case the records must be maintained for 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

In the CJR model, we applied these record access and retention obligations only to participant hospitals and CJR collaborators (80 FR 73432 through 73433). However, because we propose additional types of EPM collaborators and types of financial arrangements in section III.I. of this proposed rule for the EPM, as well as define EPM activities as those related to promoting accountability for the quality, cost, and overall care for EPM beneficiaries, we propose to apply the record access and retention obligations to EPM participants and all individuals and entities with EPM financial arrangements where payments are substantially based on quality of care and the provision of EPM activities, as well as to other individuals and entities providing EPM activities. While this proposal is an expansion of the current record access and retention obligations under the CJR model to additional categories of individuals and entities, we believe the expansion is necessary and appropriate for the six categories of information to which we propose that the access and retention requirements would apply. Access to this information from those individuals and entities providing EPM activities that are the basis of care redesign in the EPM provides an important program safeguard by allowing monitoring for compliance with EPM requirements. The alternative of limiting the requirements solely to EPM participants and EPM collaborators as we finalized for the CJR model would result in no record access and retention obligation for certain individuals and entities that have financial arrangements under the EPM and engage in EPM activities, thereby limiting the Government's ability to audit, evaluate, inspect, or investigate compliance with EPM requirements. We similarly propose changes to the individuals and entities subject to record access and retention obligations under the CJR model as discussed in section V.L. of this proposed rule.

We have identified six categories of information related to key EPM parameters for which we propose that the record access and retention requirements would apply. Like the CJR model, we propose that one category of information consists of those documents related to the individual's or entity's compliance with EPM requirements. Given the individuals and entities who must comply with the requirements of the EPM either directly or through their arrangements, including EPM participants, EPM collaborators, collaboration agents, and downstream collaboration agents, an important program safeguard is record access and retention that allow compliance with the EPM requirements to be monitored and assessed.

Additionally, similar to the CJR model, we propose that a second category of information consists of documents related to the calculation, distribution, receipt, or recoupment of gainsharing payments, alignment payments, distribution payments, and downstream distribution payments. This list includes all types of payments proposed under EPM financial arrangements as discussed in section III.I. of this proposed rule and is different from the current CJR model requirement to the extent that we propose additional types of EPM financial arrangements in view of our proposal that ACOs can be EPM collaborators. Because of the proposed EPM requirements for these types of payments that are designed to ensure that all financial arrangements are for the sole purpose of aligning the financial incentives of individuals and entities with the goals of the EPM participant to improve the quality and efficiency of EPM episode care, we believe that these records of all the individuals and entities who enter such arrangements should be accessible and retained to allow compliance with the EPM requirements for the payments to be monitored and assessed. We propose similar changes to this category of information under the CJR model as discussed in section V.L. of this proposed rule

The third category of information for which we propose to require record access and retention is related to an EPM participant's obligation to repay to CMS any reconciliation payment or CR incentive payments owed. The CR incentive payment has been added to this provision which otherwise applied to the CJR model because we propose a CR incentive payment in section VI. of this proposed rule for AMI and CABG model participants in selected MSAs, while the CJR model does not include this payment. Requiring record access and retention about repayment obligations under the EPM provides an important program integrity safeguard for repayments to CMS.

We propose to require record access and retention on the quality of the services furnished to an EPM beneficiary during an EPM episode as the fourth category of information. While the CJR model specified the quality of services furnished without further limitation in the record access and retention requirements, given our EPM proposals that require gainsharing, distribution, and downstream distribution payments to be substantially based on quality of care and EPM activities, we believe that it is appropriate to specify that the record access and retention requirements apply specifically to the services furnished to an EPM beneficiary during an EPM episode. The quality of services furnished without further limitation could result in an overly broad record access and retention requirement for services that are delivered outside of EPM episodes, where these services are not subject to EPM requirements. Services furnished to EPM beneficiaries during EPM episodes are the services for which we will also be monitoring for access to care, delayed care, and quality of care, important activities to safeguard the program and Medicare beneficiaries, so access to documents to support this monitoring is necessary. We propose similar changes to this category of information under the CJR model as discussed in section V.L. of this proposed rule

Given the beneficiary notification requirements that we propose for the EPM in section III.G. of this proposed rule, we propose to require access to records and record retention about the sufficiency of EPM beneficiary notifications. The beneficiary notification requirement is an important beneficiary protection under the EPM, and the access to records and record retention requirements provide a program integrity safeguard to monitor for compliance with this requirement. We propose to add this same category of information for the CJR model as discussed in section V.L. of this proposed rule.

Finally, we propose to establish CEHRT use attestation for EPM participants so that an EPM participant could be in a Track 1 EPM that meets the proposed requirements in the Quality Payment Program proposed rule to be an Advanced APM as discussed in section III.A.2 of this proposed rule. Thus, we propose to require access to records and record retention about the accuracy of each Track 1 EPM participant's submissions under CEHRT use requirements. Specifically, attestation to CEHRT use and submission of clinician financial arrangements lists are key requirements for Track 1 EPMs that are Advanced APMs, and the access to records and record retention requirements provide a program integrity safeguard by allowing us to assess the completeness and accuracy of the EPM participant's compliance with the requirements for those submissions. We propose to add this same category of information for the CJR model as discussed in section V.L. of this proposed rule.

We believe the proposed requirements regarding access to EPM records and record retention are necessary to safeguard program integrity and protect against abuse, in view of the EPM design and requirements as discussed throughout this proposed rule that would lead to achieving the EPM goals of improved EPM episode quality and efficiency. We also believe that by providing access to EPM records, we promote transparency of activities under the EPM.

Furthermore, we believe the proposed access to records and record retention requirements would promote the compliance of EPM participants, EPM collaborators, collaboration agents, downstream collaboration agents, and any other individuals or entities providing EPM activities with EPM requirements by ensuring that compliance with these requirements can be monitored and assessed. Finally, these records may be necessary in the event that an EPM participant appeals any matter that is subject to dispute resolution through CMS. As such, CMS would have the resources necessary to prepare and respond to any such appeal.

The proposals for access to records and record retention are included in § 512.110. We seek comment on our proposals, including whether it is necessary, reasonable and appropriate to impose these access and retention obligations on all of the proposed categories of individuals and entities for all the proposed categories of information to be retained and made accessible. In addition, we seek comment on whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the EPM are met.

I. Financial Arrangements under the EPM

1. Background

In November, 2015 we finalized regulations for financial arrangements for the CJR model (80 FR 73550 through 73553), an episode payment model that is similar to the three new proposed EPMs. In this rulemaking, we propose three new episode payments models that fall under the overarching term EPM, specifically the AMI model, CABG model, and SHFFT model. Both the CJR model and the three proposed EPMs place financial responsibility for the episode on the hospital where the episode begins with a hospitalization and require participation of hospitals in the selected MSAs for the models. Like LEJR episodes under the CJR model, the AMI, CABG, and SHFFT episodes in the proposed EPMs would be broadly defined to include

most Part A and Part B services and extend 90 days following discharge from the hospitalization that initiates the EPM episode. During the design of the EPMs, we considered proposing the same CJR financial arrangements that were finalized through notice and comment rulemaking because the EPMs have a similar design to the CJR model with the same goals of improving the quality and efficiency of model episodes. We expect that the types of financial arrangements needed to align the financial incentives of CJR participants and EPM participants with other providers and suppliers caring for CJR beneficiaries or EPM beneficiaries during episodes to improve episode quality and efficiency would be similar. We also believe that program integrity safeguards that would provide protections against abuse under the financial relationships permitted for the EPMs should be comparable to those for the CJR model. However, we believe that it is possible to improve on the current regulatory structure for financial relationships that we established for the CJR model in our proposals for the EPMs. Our EPM proposals reflect changes from the current CJR model regulations that generally fall into the following four categories:

- Removing duplication of requirements in similar provisions.
- Streamlining and reorganizing the provisions for clarity and consistency.
- Providing additional flexibility in response to feedback from CJR participant hospitals and other stakeholders.
- Expanding the scope of financial arrangements under the EPM.

We note that in section V.J. of this proposed rule, we propose changes to the CJR model financial arrangements regulations in Part 510 to parallel those we propose for the EPMs. These proposals would result in the same provisions and requirements for CJR model and EPM financial arrangements when the first performance year of the EPMs begins on July 1, 2017.

2. Overview of EPM Financial Arrangements

For purposes of this section, the term "EPM" refers to one model specifically among the AMI model, CABG model, or SHFFT model and should be read throughout Subpart F—Financial Arrangements and Beneficiary Incentives (§§ 512.500 through 512.525) of the proposed regulations as a single one of these three proposed EPMs. For example, when reading the proposed regulations for the CABG model, § 512.500(b)(6), the provision would read as, "The board or other governing body of the [CABG model] participant must have responsibility for overseeing the [CABG model] participant's participation in the [CABG model], its arrangements with [CABG model] collaborators, its payment of gainsharing payments, its receipt of alignment payments, and its use of beneficiary incentives in the [CABG model]." We use this approach because we mean for the proposed requirements to apply to every participant in the EPM regardless of whether the EPM is the AMI, CABG, or SHFFT model.

As discussed in section III.D.2.b. of this proposed rule, we propose that each EPM would be a retrospective episode payment model, under which Medicare payments for items and services included in an EPM episode would continue to be made to all providers and suppliers under the existing FFS payment systems, and episode payment would be based on later reconciliation of actual spending for an EPM episode under the FFS payment systems to the EPM episode's quality-adjusted target price. If the actual episode spending is less than the quality-adjusted target price, the EPM participant financially responsible for the EPM episode would receive a reconciliation payment, assuming the EPM composite quality score for the EPM participant is in the "acceptable," "good," or "excellent" quality category. If an EPM episode's actual spending exceeds the quality-adjusted target price, then, beginning in

performance year 2, the EPM participant would begin to repay the difference to Medicare up to the stop-loss threshold.

Similar to the CJR model (80 FR 73412), we believe that EPM participants may wish to enter into financial arrangements with providers and suppliers caring for EPM beneficiaries to share financial risks and rewards under the EPM, in order to align the financial incentives of those providers and suppliers with the EPM goals of improving the quality and efficiency of EPM episodes. We further believe that EPM participants may wish to enter into financial arrangements with ACOs that participate in EPM care redesign and EPM beneficiary care management and whose ACO participants and ACO providers/suppliers care for EPM beneficiaries. We expect that EPM participants would identify key providers and suppliers caring for EPM beneficiaries, as well as ACOs to which EPM beneficiaries are aligned, in their communities and referral regions. The EPM participants then could establish close partnerships with these individuals and entities to promote accountability for the quality, cost, and overall care for EPM beneficiaries, including managing and coordinating care; encouraging investment in infrastructure, enabling technologies, and redesigned care processes for high quality and efficient service delivery; the provision of items and services during an EPM episode in a manner that reduces costs and improves quality; and carrying out other obligations or duties under the EPM. These providers, suppliers, and ACOs may invest substantial time and other resources in these activities, yet they would neither be the direct recipients of any reconciliation payments from Medicare, nor directly responsible for repaying Medicare for excess episode spending. Therefore, we believe it is possible that an EPM participant that may receive a reconciliation payment from Medicare or may need to repay Medicare may want to enter into financial arrangements with other providers, suppliers, or ACOs to share risks and rewards

under the EPM. We expect that all financial relationships established between EPM participants and providers, suppliers, or ACOs for purposes of the EPM would be those permitted only under applicable law and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.

In addition to providers, suppliers, and ACOs with which the EPM participant may want to enter into financial arrangements to share risks and rewards under the proposed EPMs, we expect that EPM participants may choose to engage with organizations that are neither providers nor suppliers to assist with matters such as episode data analysis; local provider and supplier engagement; care redesign planning and implementation; beneficiary outreach; beneficiary care coordination and management; monitoring EPM participants' compliance with the EPM's terms and conditions; or other EPM-related activities. Such organizations may play important roles in an EPM participant's plans to implement an EPM based on the experience these organizations may bring, such as prior experience with bundled payment initiatives, care coordination expertise, familiarity with a particular local community, or knowledge of Medicare claims data. We expect that all relationships established between EPM participants and these organizations for purposes of the EPM would be those permitted only under existing law and regulation, including any relationships that would include the EPM participant's sharing of EPM risks and rewards with such organizations. We also expect that all of these relationships solely would be based on the level of engagement of the organization's resources to directly support the participants' EPM implementation.

Finally, because the proposed broadly defined EPM episodes would extend 90 days post-discharge from their respective anchor or chained anchor hospitalizations, similar to the CJR model (80 FR 73433), we believe that EPM participants caring for EPM beneficiaries may

want to offer beneficiary engagement incentives to encourage adherence to recommended treatment and active patient engagement in recovery. Such incentives should be closely related to the provision of high quality EPM care and advance a clinical goal for an EPM beneficiary, and should not serve as inducements for beneficiaries to seek care from the EPM participants or other specific suppliers and providers. The incentives may help an EPM participant reach their quality and efficiency goals for EPM episodes, while also benefitting beneficiaries' health and the Medicare Trust Fund if the EPM participant improves the quality and efficiency of episodes through care redesign that results in EPM beneficiary reductions in hospital readmissions, complications, days in acute care, and mortality, while recovery continues uninterrupted or accelerates.

3. EPM Collaborators

Given the financial incentives of episode payment under the EPM, an EPM participant may want to engage in financial arrangements with individuals and entities making contributions to the EPM participant's episode performance on spending or quality. Such arrangements would allow the EPM participant to share all or some of the reconciliation payments they may be eligible to receive from CMS, or the EPM participant's internal cost savings that result from care for beneficiaries during EPM episodes. Likewise, such arrangements could allow the EPM participant to share the responsibility for the funds needed to repay Medicare with individuals and entities engaged in providing care to EPM beneficiaries, if those individuals and entities have a role in the EPM participant's episode spending or quality performance. We propose to use the term "EPM collaborator" to refer to these individuals and entities.

Since each proposed EPM's episode duration is 90 days following discharge from the anchor or chained anchor hospitalization and such episodes are broadly defined as discussed in

section III.C.3.b. of this proposed rule, many providers and suppliers other than the EPM participant will furnish related services to beneficiaries during EPM episodes. Those providers and suppliers may include SNFs, HHAs, LTCHs, IRFs, physicians, nonphysician practitioners, providers or suppliers of outpatient therapy services, PGPs, hospitals, and critical access hospitals (CAHs). In addition, ACOs may be actively involved in coordinating the care of beneficiaries during EPM episodes. The proposed definition of EPM collaborator includes each of these categories of individuals and entities as eligible to be an EPM collaborator. The proposed list of types of EPM collaborators is the same list as CJR collaborators, but with the addition of hospitals, CAHs, and ACOs.

We expect that hospitals and CAHs that are not EPM participants may frequently play roles in care delivered to EPM beneficiaries during a chained anchor hospitalization as discussed in section III.C.4.a.(5) of this proposed rule or following discharge from an anchor or chained anchor hospitalization that initiates an EPM episode. For example, an AMI model participant without cardiac surgery or interventional cardiology capacity may need to transfer certain AMI model beneficiaries after initial admission to transfer hospitals or transfer CAHs for revascularization through PCI or through CABG. A transfer hospital may, itself, be participating in the AMI and CABG models (a CAH cannot be an AMI or CABG model participant), but the AMI model episode would be the responsibility of the AMI model participant that first admitted the beneficiary. In addition, hospital or CAH readmission during the proposed EPM episodes would be common for beneficiaries post-anchor or post-chained anchor hospitalization discharge for AMI, CABG, and SHFFT model beneficiaries, and, because care for these clinical conditions may sometimes be provided at transfer hospitals that initiate EPM episodes as EPM participants, we expect that readmissions during such episodes

may sometimes be to other hospitals or CAHs that are not EPM participants near beneficiaries' home communities. Thus, we believe it is important to allow EPM participants to enter into financial arrangements with other hospitals and CAHs that care for EPM beneficiaries, in order to align the financial incentives of such other hospitals and CAHs with the EPM goals of improving the quality and efficiency of EPM episodes.

Many accountable care organizations and other stakeholders have expressed strong interest in being collaborators in episode payment models generally, including sharing potential financial risks and rewards with model participants. Multiple commenters on the CJR proposed rule stated that robust accountable care organizations have proven track records of providing Medicare providers and suppliers with care redesign and care management assistance for Medicare beneficiaries, as well as managing the overall care of accountable care organization-aligned beneficiaries to improve the quality and efficiency of care (80 FR 73417). They reasoned that accountable care organizations might be able to provide CJR participant hospitals with care coordination assistance at reduced cost due to economies of scale and existing accountable care organization resources, as well as potentially assume a percentage of downside risk, in order to mitigate that risk to CJR participant hospitals. In the CJR Final Rule (80 FR 73417), we did not adopt accountable care organizations as CJR collaborators, responding that we decided to limit the testing of gainsharing relationships to solely those between hospitals and providers and suppliers enrolled in Medicare because we expected enrolled providers and suppliers to be most directly and specifically engaged with the CJR participant hospitals in care redesign and episode care for CJR beneficiaries who had surgeries at those hospitals. We also noted that a number of scenarios discussed by commenters to support their request to allow accountable care organizations to be CJR collaborators could be

achieved outside of the context of gainsharing relationships between the CJR participant hospitals and those organizations.

With the steady growth in the number of accountable care organizations and accountable care organization-aligned beneficiaries, we have further considered the potential for accountable care organizations to be EPM collaborators. Our current proposed EPMs include beneficiaries with cardiovascular disease as well as beneficiaries with hip fracture who commonly are older with multiple comorbidities, and accountable care organizations have expertise in care coordination and accountability for the quality and expenditures for health care for accountable care organization-aligned beneficiaries over an annual period.

While we propose to exclude certain accountable care organization-aligned beneficiaries from EPM episodes, we note that the challenges of attributing savings and changes in the quality of care for beneficiaries simultaneously in EPMs and total cost-of-care models or programs, such as accountable care organizations, remain under consideration without full resolution, as discussed further in section III.D.6. of this proposed rule. Local relationships between providers, suppliers, and accountable care organizations vary in the care of beneficiaries, and it would be difficult for CMS at this time to provide standard program or model rules that would fairly distribute savings among different models and programs for overlapping periods of beneficiary care, when variable local arrangements determine which entity provides the resources for coordinating and managing a particular beneficiary's care over time. Finally, we note that accountable care organizations are groups of physicians, hospitals, and other health care providers and suppliers that come together to furnish coordinated, high quality care to their aligned Medicare beneficiaries to ensure that these beneficiaries, especially the chronically ill, get the right care at the right time, while avoiding unnecessary duplication of

services and preventing medical errors. Accountable care organizations' goals of delivering high quality care and spending health care dollars more wisely are the same as those of hospitals that would participate in the EPMs. Therefore, we believe it is especially important to further encourage collaborative partnerships between accountable care organizations and EPM participants that maximize their organizational efficiency and effectiveness, given their shared goals.

In considering the accountable care organizations that could be EPM collaborators engaged in collaborative relationships with EPM participants, we limited our consideration to accountable care organizations under Medicare because the EPM is an episode payment model for Medicare FFS beneficiaries. We note that in section III.D.6. of this proposed rule, we propose to exclude from the proposed EPM episodes beneficiaries who are aligned to the Next Generation ACO model or tracks of the Comprehensive ESRD Care Model incorporating downside risk for financial losses. Downside risk for financial losses and prospective alignment of beneficiaries are important criteria in selection of these models and tracks of models for this proposed exclusion. We also seek comment in that section on extending this exclusion proposal to Track 3 of the Shared Savings Program. Because we propose to allow financial arrangements under the EPM only with those entities that are involved in the delivery of care to EPM beneficiaries with goals of improving the quality and efficiency of EPM episodes, we do not believe it would be appropriate to permit Next Generation ACOs to be EPM collaborators because their aligned beneficiaries would be excluded from the EPM. Similarly, because we propose that beneficiaries eligible for Medicare on the basis of ESRD be excluded from the EPM as discussed in section III.C.4.a. of this proposed rule, we do not believe that participants in the Comprehensive ESRD Care initiative which predominantly include beneficiaries eligible

for Medicare on the basis of ESRD should be permitted to be EPM collaborators. Finally, we note that the Pioneer ACO model ends in CY 2016, so that model will not overlap with the EPM which is proposed to begin on July 1, 2017.

Thus, we propose that "ACOs," meaning those ACOs as defined at § 425.20 of regulations that are participating in the Shared Savings Program, be permitted to be EPM collaborators. This proposal would allow locally variable financial arrangements that could account for the way care in EPM episodes is coordinated and managed in communities, and ensure that entities with appropriate skills and experience are permitted to share the proposed EPM's risks and rewards with EPM participants. Medicare has a close relationship with such ACOs, which are regulated by CMS, so we can verify that these ACOs meet current Shared Savings Program requirements that could make them suitable for a role as EPM collaborators. Finally, in this way, ACO participants and ACO providers/suppliers may be engaged in EPM care redesign directly through their ACO, instead of bypassing the ACO to become involved directly in the EPM through the EPM participant. We are limiting our proposal of entities that are not providers or suppliers but that are permitted to be EPM collaborators to ACOs alone. We propose to allow financial arrangements under the EPM only with those entities that are involved in the delivery of care to EPM beneficiaries.

We propose in § 512.2 that ACOs and the following types of providers and suppliers may be EPM collaborators:

- SNF.
- HHA.
- LTCH.
- IRF.

- Physician.
- Nonphysician practitioner.
- Provider or supplier of outpatient therapy services.
- PGP.
- Hospital.
- CAH
- ACO.

We seek comment on the proposed definition of EPM collaborators. In addition to general comment, we are specifically interested in comment on the proposal to include hospitals, CAHs, and ACOs in the definition of EPM collaborators. Furthermore, we seek comment specifically on the accountable care organizations that we propose to include in the definition of ACO and which accountable care organizations should be included and excluded from the definition of ACO that may be EPM collaborators to best advance the goals of the EPM and program generally. Finally, we also seek comment on the regulatory and practical implications of establishing that ACOs may be EPM collaborators under the EPM, including without limitation how the requirements under the EPM would relate to how financial arrangements within ACOs are currently regulated under the Medicare Shared Savings Program.

4. Sharing Arrangements under the EPM

a. General

Similar to the CJR model (80 FR 73430), we propose that certain financial arrangements between an EPM participant and an EPM collaborator be termed "sharing arrangements." A sharing arrangement would be a financial arrangement to share only -- (1) EPM reconciliation payments; (2) the EPM participant's internal cost savings; and (3) the EPM participant's

repayment amount. Where a payment from an EPM participant to an EPM collaborator is made pursuant to a sharing arrangement, we define that payment as a "gainsharing payment." A gainsharing payment may be composed only of -- (1) EPM reconciliation payments; (2) the EPM participant's internal cost savings; or (3) both. A "reconciliation payment" is defined as a payment made by CMS to an EPM participant as determined in accordance with § 512.305(d) and as discussed in section III.D.5. of this proposed rule. "Internal cost savings" are the measurable, actual, and verifiable cost savings realized by the EPM participant resulting from care redesign undertaken by such participant in connection with providing items and services to beneficiaries within specific EPM episodes. Internal cost savings does not include savings realized by any individual or entity that is not the EPM participant. Where a payment from an EPM collaborator to an EPM participant is made pursuant to an EPM sharing arrangement, we define that payment as an "alignment payment." An alignment payment may consist only of a portion of the "repayment amount," which is the amount owed by an EPM participant to CMS, as reflected on a reconciliation report. An EPM participant must not make a gainsharing payment or receive an alignment payment except in accordance with a sharing arrangement. We propose that a sharing arrangement must comply with the provisions of § 512.500 and all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.

We propose that the EPM participant must develop, maintain, and use a set of written policies for selecting individuals and entities to be EPM collaborators, and that the selection criteria must include the quality of care delivered by the potential EPM collaborator. The selection criteria cannot be based directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the EPM

participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent. With the exception of adding "past or anticipated" to the selection criteria for EPM collaborators, these proposed criteria are similar to the existing requirements of the CJR model (80 FR 73430). By adding this language, all previous and future referrals between or among the EPM participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent are encompassed. We do not believe it would be appropriate for sharing arrangements to be based on criteria that include the volume or value of past or anticipated referrals because the sole purpose of sharing arrangements is to create financial alignment between EPM participants and EPM collaborators toward the EPM goals of improving the quality and efficiency of episode care. Thus, we proposed to require EPM participants to select EPM collaborators based on criteria that include the quality of care furnished by the potential EPM collaborator to ensure that the selection of EPM collaborators takes into consideration the likelihood of their future performance in improving the quality of episode care. In addition, requiring that selection criteria include quality of care furnished by the potential EPM collaborator provides a safeguard against abuse.

Finally, we propose that if an EPM participant enters into a sharing arrangement, its compliance program must include oversight of sharing arrangements and compliance with the applicable requirements of the EPM. Requiring oversight of sharing arrangements to be include in the compliance program provides a program integrity safeguard.

The proposals for the general provisions for sharing arrangements under the EPM are included in § 512.500(a). We seek comment about all of the provisions set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the EPM are met.

b. Requirements

We propose a number of specific requirements for sharing arrangements to help ensure that their sole purpose is to create financial alignment between EPM participants and EPM collaborators toward the goals of the EPM through program integrity safeguards. We propose that the sharing arrangement must be in writing, signed by the parties, and entered into before care is furnished to EPM beneficiaries under the sharing arrangement. In addition, participation in a sharing arrangement must be voluntary and without penalty for nonparticipation. It is important that providers, suppliers, and ACOs with ACO participants and ACO providers/suppliers rendering items and services to EPM beneficiaries during EPM episodes have the freedom to provide medically necessary items and services to EPM beneficiaries without any requirement that they participate in a sharing arrangement, in order to safeguard beneficiary freedom of choice, access to care, and quality of care. Similarly, we believe that if a provider, supplier, or ACO enters into a sharing arrangement with an EPM participant, that sharing arrangement must precede the provision of care to the EPM beneficiary under the sharing arrangement. We expect the sharing arrangement to set out the mutually agreeable terms for the financial arrangement between the parties to guide and reward EPM care redesign for future EPM episodes, rather than reflect the quality and financial results of EPM episodes that have already occurred and where the financial outcome of the sharing arrangement terms would be known before signing.

We propose that the sharing arrangement must require the EPM collaborator and its employees, contractors, and subcontractors to comply with certain requirements that are important for program integrity under the arrangement. We note that the terms contractors and subcontractors, respectively, include collaboration agents and downstream collaboration agents as defined later in this section. The sharing arrangement must require all of the individuals and entities in this group to comply with the applicable provisions of Part 512, including requirements regarding beneficiary notifications, access to records, record retention, and participation in any evaluation, monitoring, compliance, and enforcement activities performed by CMS or its designees, because these individuals and entities all would play a role in EPM care redesign and be part of financial arrangements under the EPM. The sharing arrangement must also require all individuals and entities in the group to comply with the applicable Medicare provider enrollment requirement at § 424.500, including having a valid and active TIN or NPI, during the term of the sharing arrangement. This is to ensure that the individuals and entities have the required enrollment relationship with CMS under the Medicare program, although we note that they are not responsible for complying with requirements that do not apply to them. Finally, the sharing arrangement must require individuals and entities to comply with all other applicable laws and regulations.

We propose that the sharing arrangement must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care so that financial relationships between EPM participants and EPM collaborators do not negatively impact beneficiary protections under the EPM. The sharing arrangement must require the EPM collaborator to have a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the EPM, just as we require EPM participants to have a compliance program

for this purpose as a program integrity safeguard. We understand that some stakeholders may have interpreted the substantially similar requirement in the CJR model as obligating CJR collaborators to adopt specific compliance programs components (for example, an externally staffed hotline to receive complaints) and the perceived cost of adopting those components may be a disincentive for certain individuals and entities to be CJR collaborators in the CJR model. However, we note that the CJR compliance program requirement does not mandate that a CJR collaborator's compliance program take a particular form or include particular components. OIG has repeatedly and consistently emphasized that there is no "one size fits all" compliance program (for example, refer to OIG compliance program guidance for Individual and Small Group Physician Practices, 65 Fed. Reg. 59434, 59434-52 (October 5, 2000)). Like OIG, we understand the variances and complexities within the industry and appreciate differences in the size and resources of different providers and suppliers, particularly the financial constraints on individual physicians and nonphysician practitioners and small PGPs. Accordingly, we do not believe that the compliance program requirement for CJR collaborators as properly understood should be a disincentive for individuals or small PGPs to become CJR collaborators. Thus, we propose to adopt a substantially similar requirement for the EPM. We seek comment on the anticipated effect of the proposed compliance program requirement for EPM collaborators, particularly with regard to individual physicians and nonphysician practitioners and small PGPs, and whether alternative compliance program requirements for all or a subset of EPM collaborators should be adopted to mitigate any effect of the proposal that could make participation as an EPM collaborator infeasible for any provider, supplier, or other entity on the proposed list of types of EPM collaborators.

It is necessary that EPM participants have adequate oversight over sharing arrangements to ensure that all arrangements meet the requirements of this section and provide program integrity protections. Therefore, we propose that the board or other governing body of the EPM participant have responsibility for overseeing the EPM participant's participation in the EPM, its arrangements with EPM collaborators, its payment of gainsharing payments, its receipt of alignment payments, and its use of beneficiary incentives in the EPM.

For purposes of financial arrangements under the EPM, we propose to define activities related to promoting accountability for the quality, cost, and overall care for EPM beneficiaries, including managing and coordinating care; encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery; the provision of items and services during an EPM episode in a manner that reduces costs and improves quality; or carrying out any other obligation or duty under the EPM as "EPM activities." In addition to the quality of care provided during episodes, we believe the activities that would fall under this proposed definition encompass the totality of activities upon which it would be appropriate for certain financial arrangements under the EPM to be based in order to value the contributions of providers, suppliers, and other entities toward meeting the EPM goals of improving the quality and efficiency of episodes. We seek comment on the proposed definition of EPM activities as an inclusive and comprehensive framework for capturing direct care and care redesign for EPM episodes that contribute to improving the quality and efficiency of these episodes. We propose to use the term EPM activities in identifying certain obligations of parties in a sharing arrangement that are described as "changes in care coordination or delivery" in the CJR regulations governing the contents of the written agreement memorializing the sharing arrangement. We note that as discussed in section V.J. of this proposed rule, we propose to

define and use the term CJR activities in the CJR regulations just as we propose to define and use the term EPM activities in the EPM regulations.

We propose that the written agreement memorializing a sharing arrangement must specify a number of parameters of the arrangement, including the following:

- The purpose and scope of the sharing arrangement.
- The identities and obligations of the parties, including specified EPM activities and other services to be performed by the parties under the sharing arrangement.
- The date of the sharing arrangement.
- Management and staffing information, including type of personnel or contractors that will be primarily responsible for carrying out EPM activities.
- The financial or economic terms for payment, including the following:

++ Eligibility criteria for a gainsharing payment.

++ Eligibility criteria for an alignment payment.

++ Frequency of gainsharing or alignment payment.

++ Methodology and accounting formula for determining the amount of a gainsharing payment that is substantially based on quality of care and the provision of EPM activities.

++ Methodology and accounting formula for determining the amount of an alignment payment.

Finally, we propose to require that the terms of the sharing arrangement must not induce the EPM participant, EPM collaborator, or any employees, contractors, or subcontractors of the EPM participant or EPM collaborator to reduce or limit medically necessary services to any Medicare beneficiary or restrict the ability of an EPM collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies, and treatments. These

requirements are to ensure that the quality of care for EPM beneficiaries is not negatively affected by sharing arrangements under the EPM.

The proposals for the requirements for sharing arrangements under the EPM are included in § 512.500(b). We seek comment about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the EPM are met.

c. Gainsharing Payment, Alignment Payment, and Internal Cost Savings Conditions and Restrictions

We propose a number of conditions and limitations for gainsharing payments, alignment payments, and internal cost savings as program integrity protections for the payments to and from EPM collaborators. We propose to require that gainsharing payments be derived solely from reconciliation payments, internal costs savings, or both; that they be distributed on an annual basis, not more than once per calendar year; that they not be a loan, advance payment, or payment for referrals or other business; and that they be clearly identified as a gainsharing payment at the time they are paid.

We believe that gainsharing payment eligibility for EPM collaborators should be conditioned on two requirements -- (1) meeting quality of care criteria; and (2) rendering items and services to EPM beneficiaries during EPM episodes -- as safeguards to ensure that eligibility for gainsharing payments is solely based on aligning financial incentives for EPM collaborators with the EPM goals of improving EPM episode quality and efficiency. The second requirement, which is discussed later in this section, would also apply to eligibility of an EPM collaborator to make an alignment payment. With respect to the first requirement, we propose that to be eligible to receive a gainsharing payment, an EPM collaborator must meet quality of care criteria for the

performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment. The quality of care criteria that are established by the EPM participant must be directly related to EPM episodes. With regard to the second requirement, to be eligible to receive a gainsharing payment, or to be required to make an alignment payment, an EPM collaborator other than a PGP or an ACO must have directly furnished a billable item or service to an EPM beneficiary during an EPM episode that occurred in the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount. For purposes of this requirement, we consider a hospital, CAH or post-acute care provider to have "directly furnished" a billable service if one of these entities billed for an item or service for an EPM beneficiary during an EPM episode that occurred in the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount. The phrase "performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount" does not mean the year in which the gainsharing payment was made. These requirements ensure that there is a required relationship between eligibility for a gainsharing payment and the quality of direct care for EPM beneficiaries during EPM episodes for these EPM collaborators. We believe the provision of direct care is essential to the implementation of effective care redesign, and the requirement provides a safeguard against payments to EPM collaborators other than a PGP or an ACO that are unrelated to direct care for EPM beneficiaries during EPM episodes.

We propose to establish similar requirements for PGPs and ACOs that vary because these entities do not themselves directly furnish billable services. To be eligible to receive a gainsharing payment or required to make an alignment payment, a PGP must have billed for an item or service that was rendered by one or more members of the PGP to an EPM beneficiary during an EPM episode that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount. To be eligible to receive a gainsharing payment or required to make an alignment payment, an ACO must have had an ACO provider/supplier that directly furnished, or an ACO participant that billed for, an item or service that was rendered to an EPM beneficiary during an EPM episode that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount. With respect to ACOs, an "ACO participant" and "ACO provider/supplier" have the meaning set forth in § 425.20 of regulations. Like the proposal for EPM collaborators that are not PGPs or ACOs, these proposals also require a linkage between the EPM collaborator that is the PGP or ACO and the provision of items and services to EPM beneficiaries during EPM episodes by PGP members or ACO participants or ACO providers/suppliers, respectively.

Moreover, we further propose that because PGPs and ACOs do not directly furnish items and services to beneficiaries, in order to be eligible to receive a gainsharing payment or be required to make an alignment payment, the PGP or ACO must have contributed to EPM activities and been clinically involved in the care of EPM beneficiaries during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment

amount. For example, a PGP or ACO might have been clinically involved in the care of EPM beneficiaries by providing care coordination services to EPM beneficiaries during and/or after inpatient admission; engaging with an EPM participant in care redesign strategies, and actually performing a role in implementing such strategies that are designed to improve the quality of care for EPM episodes and reduce EPM episode spending; or in coordination with providers and suppliers (such as members of the PGP, ACO participants, ACO providers/suppliers, the EPM participant, and post-acute care providers), implementing strategies designed to address and manage the comorbidities of EPM beneficiaries.

Because internal cost savings may be shared through gainsharing payments with EPM collaborators, we propose certain requirements for their calculation as a safeguard against fraud and abuse. First, the methodology for accruing, calculating and verifying internal cost savings must be transparent, measurable, and verifiable in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book). Second, because we believe it is necessary that the internal cost savings reflect care redesign under the EPM in order to be eligible to be shared through gainsharing payments, the methodology used to calculate internal cost savings must reflect the actual, internal cost savings achieved by the EPM participant through the documented implementation of EPM activities identified by the EPM participant and must exclude any savings realized by any individual or entity that is not the EPM participant and "paper" savings from accounting conventions or past investment in fixed costs. We note that unlike the current CJR model policy where we require that sharing arrangements document the methodology for accruing, calculating, and verifying the internal cost savings generated by the participant hospital based on the care redesign elements specifically associated with the particular collaborator (80 FR 73431), we do not propose to

require in the EPM that the calculation of internal cost savings be tied to the activities of any specific EPM collaborator. Rather, we believe it is appropriate for EPM participants to calculate internal cost savings based on the implementation of EPM activities and then provide gainsharing payments to EPM collaborators that may include internal cost savings, reconciliation payments, or both based on a methodology that meets the requirements described later in this section. We propose this same change to the internal cost savings calculation requirements for the CJR model in section V.J. of this proposed rule.

We propose to limit the total amount of gainsharing payments for a performance year to EPM collaborators that are physicians, nonphysician practitioners, or PGPs. For EPM collaborators that are physicians or nonphysician practitioners, that limit is 50 percent of the Medicare-approved amounts under the PFS for items and services furnished by that physician or nonphysician practitioner to the EPM participant's EPM beneficiaries during EPM episodes that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being made. For EPM collaborators that are PGPs, that limit is 50 percent of the Medicare-approved amounts under the PFS for items and services billed by the PGP and furnished to the EPM participant's EPM beneficiaries by members of the PGP during EPM episodes that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being made. These limits are consistent with those in the CJR model (80 FR 73430).

We propose that the amount of any gainsharing payments must be determined in accordance with a methodology that is substantially based on quality of care and the provision of EPM activities. The methodology may take into account the amount of such EPM activities

provided by an EPM collaborator relative to other EPM collaborators. While we emphasize that financial arrangements may not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the EPM participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent so that their sole purpose is to align the financial incentives of the EPM participant and EPM collaborators toward the EPM goals of improved EPM episode care quality and efficiency, we believe that accounting for the relative amount of EPM activities by EPM collaborators in the determination of gainsharing payments does not undermine this objective. Rather, the proposed requirement allows flexibility in the determination of gainsharing payments where the amount of an EPM collaborator's provision of EPM activities (including direct care) to EPM beneficiaries during EPM episodes may contribute to both the internal cost savings and EPM participant's reconciliation payment that may be available for making a gainsharing payment. Greater contributions of EPM activities by one EPM collaborator versus another EPM collaborator that result in greater differences in the funds available for gainsharing payments may be appropriately valued in the methodology used to make gainsharing payments to those EPM collaborators in order to reflect these differences in EPM activities among EPM collaborators. For example, a physician who is an EPM collaborator who treats 100 EPM beneficiaries during EPM episodes that result in high quality, less costly care could receive a larger gainsharing payment than a physician who is an EPM collaborator who treats 10 EPM beneficiaries during episodes that similarly result in high quality, less costly care.

However, we do not believe it would be appropriate to allow the selection of EPM collaborators or the opportunity to make or receive a gainsharing payment or an alignment payment to take into the account the amount of EPM activities provided by a potential or actual EPM collaborator relative to other potential or actual EPM collaborators because these financial relationships are not to be based directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the EPM participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent. Specifically, with respect to the selection of EPM collaborators or the opportunity to make or receive a gainsharing payment or an alignment payment, we do not believe that the amount of EPM activities provided by a potential or actual EPM collaborator relative to other potential or actual EPM collaborators could be taken into consideration by the EPM participant without a significant risk that the financial arrangement in those instances could be based directly or indirectly on the volume or value of past or anticipated referrals or business generated by, between or among the parties. Similarly, if the methodology for determining alignment payments was allowed to take into the account the amount of EPM activities provided by an EPM collaborator relative to other EPM collaborators there would be a significant risk that the financial arrangement could directly account for the volume or value of past or anticipated referrals or business generated by, between or among the parties and, therefore, we propose that the methodology for determining alignment payments may not directly take into account the volume or value of past or anticipated referrals or business generated by, between or among the parties.

We propose a change to this same standard for gainsharing payments under the CJR model as discussed in section V.J. of this proposed rule. We seek comment on this proposal for gainsharing payments, where the methodology could take into account the amount of EPM activities provided by an EPM collaborator relative to other EPM collaborators. We are particularly interested in comments about whether this standard would provide sufficient additional flexibility in the gainsharing payment methodology to allow the financial reward of EPM collaborators commensurate with their level of effort that achieves improvements in EPM episode quality and efficiency. In addition we are interested in comment on whether additional safeguards or a different standard is needed to allow for greater flexibility to provide certain performance-based payments consistent with the goals of program integrity, protecting against abuse and ensuring the goals of the EPM are met.

We propose that for a performance year, the aggregate amount of all gainsharing payments that are derived from a reconciliation payment must not exceed the amount of the reconciliation payment the EPM participant receives from CMS. In accordance with the prior discussion, no entity or individual, whether a party to a sharing arrangement or not, may condition the opportunity to make or receive gainsharing payments or to make or receive alignment payments on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the EPM participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent. We propose that an EPM participant must not make a gainsharing payment to an EPM collaborator that is subject to any action for noncompliance with this part or the fraud and abuse laws, or for the provision of substandard care in EPM episodes or other integrity problems. Finally, the

sharing arrangement must require the EPM participant to recoup any gainsharing payment that contained funds derived from a CMS overpayment on a reconciliation report or was based on the submission of false or fraudulent data. These requirements provide program integrity safeguards for gainsharing under sharing arrangements.

With respect to alignment payments, we propose that alignment payments from an EPM collaborator to an EPM participant may be made at any interval that is agreed upon by both parties. They must not be issued, distributed, or paid prior to the calculation by CMS of a repayment amount reflected in a reconciliation report; loans, advance payments, or payments for referrals or other business; or assessed by an EPM participant if it does not owe a repayment amount. The EPM participant must not receive any amounts under a sharing arrangement from an EPM collaborator that are not alignment payments.

We also propose certain limitations on alignment payments that are consistent with the CJR model (80 FR 73430). For a performance year, the aggregate amount of all alignment payments received by the EPM participant must not exceed 50 percent of the EPM participant's repayment amount. Given that the EPM participant would be responsible for developing and coordinating care redesign strategies in response to its EPM participation, we believe it is important that the participant retain a significant portion of its responsibility for repayment to CMS. For example, upon receipt of a reconciliation report indicating that the EPM participant owes $100 to CMS, the EPM participant would be permitted to receive no more than $50 in alignment payments, in the aggregate, from its EPM collaborators. In addition, the aggregate amount of all alignment payments from an EPM collaborator to the EPM participant may not be greater than 25 percent of the EPM participant's repayment amount for an EPM collaborator that is not an ACO and 50 percent of the EPM participant's repayment amount for an EPM

collaborator that is an ACO. We propose to allow a higher percentage of the EPM participant's repayment amount to be paid by an ACO than by EPM collaborators that are not ACOs in recognition that some ACOs are sizable organizations with significant financial and other resources. In addition, their expertise in managing the cost and quality of care for Medicare beneficiaries over a period of time may make some ACOs uniquely capable of sharing a higher percentage of downside risk under the EPM with the EPM participant under a sharing arrangement between the ACO and EPM participant that meets all requirements for such arrangements, including that participation in the sharing arrangement must be voluntary and without penalty for nonparticipation as discussed previously. We seek comment on our proposed aggregate and individual EPM collaborator limitations on alignment payments, and particularly on the proposed limitation that would apply to ACOs that are EPM collaborators.

The following examples illustrate the effects of the proposed limitations on alignment payments. In one scenario, upon receipt of a reconciliation report indicating that the EPM participant owes $100 to CMS, the EPM participant would be permitted to receive no more than $25 in an alignment payment from a single entity or individual that is one of the EPM participant's EPM collaborators that is not an ACO. In the second scenario where an ACO is an EPM collaborator, upon receipt of that same reconciliation report, the EPM participant would be permitted to receive no more than $50 in an alignment payment from the ACO. Finally, in accordance with the prior discussion, the methodology for determining alignment payments must not directly account for the volume or value of past or anticipated referrals or business otherwise generated by, between or among the EPM participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent.

We propose that all gainsharing payments and any alignment payments must be administered by the EPM participant in accordance with GAAP and Government Auditing Standards (The Yellow Book). Additionally, we propose that all gainsharing payments and alignment payments must be made by check, electronic funds transfer, or another traceable cash transaction. While the CJR model required gainsharing payments and alignment payments to be made by electronic funds transfer (EFT) (80 FR 73431), we propose a different requirement for the EPM to provide additional flexibility for entities making gainsharing payments and alignment payments. We make this proposal to mitigate the administrative burden that the EFT requirement would place on the financial arrangements between certain EPM participants and EPM collaborators, especially individual physicians and nonphysician practitioners and small PGPs, which could discourage participation of those suppliers as EPM collaborators. We propose a change to this same standard under the CJR model as discussed in section V.J. of this proposed rule. We seek comment on the effect of this proposal on reducing the administrative barriers to individual physician and nonphysician practitioner and small PGP participation in the EPM as EPM collaborators.

The proposals for the conditions and restrictions on gainsharing payments, alignment payments, and internal cost savings under the EPM are included in § 512.500(c). We seek comment about all of the conditions and restrictions set out in the preceding discussion, including the feasibility of implementing the proposed safeguards in the context of the current regulatory framework applicable to ACOs and whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the EPM are met.

d. Documentation Requirements

To ensure the integrity of the sharing arrangements, we propose that EPM participants must meet a variety of documentation requirements for these arrangements. Specifically, the EPM participant must --

- Document the sharing arrangement contemporaneously with the establishment of the arrangement;
- Maintain accurate current and historical lists of all EPM collaborators, including EPM collaborator names and addresses; update such lists on at least a quarterly basis; and publicly report the current and historical lists of EPM collaborators on a webpage on the EPM participant's website; and
- Maintain and require each EPM collaborator to maintain contemporaneous documentation with respect to the payment or receipt of any gainsharing payment or alignment payment that includes at a minimum the--

++ Nature of the payment (gainsharing payment or alignment payment);

++ Identity of the parties making and receiving the payment;

++ Date of the payment;

++ Amount of the payment;

++ Date and amount of any recoupment of all or a portion of an EPM collaborator's gainsharing payment; and

++ Explanation for each recoupment, such as whether the EPM collaborator received a gainsharing payment that contained funds derived from a CMS overpayment on a reconciliation report, or was based on the submission of false or fraudulent data.

In addition, we propose that the EPM participant must keep records for all of the following:

- Its process for determining and verifying its potential and current EPM collaborators' eligibility to participate in Medicare.
- Its plan to track internal cost savings.
- Information on the accounting systems used to track internal cost savings;
- A description of current health information technology, including systems to track reconciliation payments and internal cost savings; and
- Its plan to track gainsharing payments and alignment payments.

Finally, we propose that the EPM participant must retain and provide access to, and must require each EPM collaborator to retain and provide access to, the required documentation in accordance with § 512.110.

The proposals for the requirements for documentation of sharing arrangements under the EPM are included in § 512.500(c). We seek comment about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the EPM are met.

5. Distribution Arrangements under the EPM

a. General

Similar to the CJR model, we propose that certain financial arrangements between EPM collaborators and other individuals or entities called "collaboration agents" be termed "distribution arrangements." A distribution arrangement is a financial arrangement between an EPM collaborator that is an ACO or PGP and a collaboration agent for the sole purpose of sharing a gainsharing payment received by the ACO or PGP. A collaboration agent is an individual or entity that is not an EPM collaborator and that is either a PGP member that has entered into a distribution arrangement with the same PGP in which he or she is an owner or

employee or an ACO participant or ACO provider/supplier that has entered into a distribution arrangement with the same ACO in which it is participating. Where a payment from an EPM collaborator to a collaboration agent is made pursuant to an EPM distribution arrangement, we define that payment as a "distribution payment." A collaboration agent may only make a distribution payment in accordance with a distribution arrangement which complies with the provisions of § 512.505 and all other applicable laws and regulations, including the fraud and abuse laws.

The proposals for the general provisions for distribution arrangements under the EPM are included in § 512.505(a). We seek comment about all of the provisions set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the EPM are met.

b. Requirements

We propose a number of specific requirements for distribution arrangements as a program integrity safeguard to help ensure that their sole purpose is to create financial alignment between EPM collaborators and collaboration agents toward the goals of the EPM to improve the quality and efficiency of EPM episodes. These requirements largely parallel those proposed in § 512.500(b) and (c) for sharing arrangements and gainsharing payments based on similar reasoning for these two types of arrangements and payments. We propose that all distribution arrangements must be in writing and signed by the parties, contain the date of the agreement, and be entered into before care is furnished to EPM beneficiaries under the distribution arrangement. Furthermore, we propose that participation must be voluntary and without penalty for nonparticipation, and the distribution arrangement must require the collaboration agent to comply with all applicable laws and regulations.

Like our proposal for gainsharing payments, we propose that the opportunity to make or receive a distribution payment must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the EPM participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent. We propose more flexible standards for the determination of the amount of distribution payments from ACOs and PGPs for the same reasons we propose this standard for the determination of gainsharing payments. Specifically, for ACOs we propose that the amount of any distribution payments must be determined in accordance with a methodology that is substantially based on quality of care and the provision of EPM activities and that may take into account the amount of such EPM activities provided by a collaboration agent relative to other collaboration agents. We believe that the amount of a collaboration agent's provision of EPM activities (including direct care) to EPM beneficiaries during EPM episodes may contribute to the EPM participant's internal cost savings and reconciliation payment that may be available for making a gainsharing payment to the EPM collaborator with which the collaboration agent has a distribution arrangement. Greater contributions of EPM activities by one collaboration agent versus another collaboration agent that result in different contributions to the gainsharing payment made to the EPM collaborator with which those collaboration agents both have a distribution arrangement may be appropriately valued in the methodology used to make distribution payments to those collaboration agents. Accordingly, we believe this is the appropriate standard for determining the amount of distribution payments from an ACO to its collaboration agents.

We note that for distribution payments made by a PGP to PGP members, the requirement that the amount of any distribution payments must be determined in accordance with a methodology that is substantially based on quality of care and the provision of EPM activities may be more limiting in how a PGP pays its members than is allowed under existing law. Therefore, to retain existing flexibility for distribution payments by a PGP to PGP members, we propose that the amount of the distribution payment from a PGP to PGP members must be determined either using the methodology previously described for distribution payments from an ACO or in a manner that complies with §411.352(g). We note that the proposed option to allow the amount of the distribution payment from a PGP to a PGP member to be determined in a manner that complies with §411.352(g) is not currently permitted under the CJR model, although we propose this change for the CJR model in section V.J. of this proposed rule. This proposal would allow a PGP the choice either to comply with the general standard that the amount of a distribution payment must be substantially based on quality of care and the provision of EPM activities or to provide its members a financial benefit through the EPM without consideration of the PGP member's individual quality of care. In the latter case, PGP members who are not collaboration agents (including those who furnished no services to EPM beneficiaries) would be able receive a share of the profits from their PGP that includes the monies contained in a gainsharing payment. We believe this is an appropriate exception to the general standard for determining the amount of distribution payment under the EPM from a PGP to a PGP member because CMS has determined under the physician self-referral law that payments from a group practice as defined under §411.352 to its members that comply with §411.352(g) are appropriate.

We seek comment on this proposal and specifically whether there are additional safeguards or a different standard is needed to allow for greater flexibility in calculating the

amount of distribution payments that would avoid program integrity risks and whether additional or different safeguards are reasonable, necessary, or appropriate for the amount of distribution payments from a PGP to its members.

Similar to our proposed requirements for sharing arrangements for those EPM collaborators that furnish or bill for items and services, except for a distribution payment from a PGP to a PGP member that complies with §411.352(g), we propose that a collaboration agent is eligible to receive a distribution payment only if the collaboration agent furnished or billed for an item or service rendered to an EPM beneficiary during an EPM episode that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed. We note that all individuals and entities that fall within our proposed definition of collaboration agent may either directly furnish or bill for items and services rendered to EPM beneficiaries. This proposal ensures that, absent the alternative safeguards afforded by a PGP's distribution payments in compliance with §411.352(g), there is the same required relationship between direct care for EPM beneficiaries during EPM episodes and distribution payment eligibility that we require for gainsharing payment eligibility. We believe this requirement provides a safeguard against payments to collaboration agents that are unrelated to direct care for EPM beneficiaries during EPM episodes when the amount of the distribution payment is not determined in a manner that complies with §411.352(g).

Except for a distribution payment from a PGP to a PGP member that complies with §411.352(g), we propose the same limitations on the total amount of distribution payments to physicians, nonphysician practitioners, and PGPs as we propose for gainsharing payments. In the case of a collaboration agent that is physician or nonphysician practitioner, we propose to

limit the total amount of distribution payments paid for a performance year to the collaboration agent to 50 percent of the total Medicare-approved amounts under the PFS for items and services furnished by the collaboration agent to the EPM participant's EPM beneficiaries during EPM episodes that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed. In the case of a collaboration agent that is a PGP, we propose that the limit would be 50 percent of the total Medicare-approved amounts under the PFS for items and services billed by the PGP for items and services furnished by members of the PGP to the EPM participant's EPM beneficiaries during EPM episodes that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed. We believe that, absent the alternative safeguards afforded by a PGP's distribution payments in compliance with §411.352(g), these proposed limitations on distribution payments, which are the same as those for gainsharing payments to physicians, nonphysician practitioners, and PGPs, are necessary to eliminate any financial incentives for these individuals or entities to engage in a financial arrangement as an EPM collaborator versus as a collaboration agent. Furthermore, we believe that PGPs should be able to choose whether to engage in financial arrangements directly with EPM participants as EPM collaborators or in distribution arrangements with the ACO in which they are an ACO participant if that ACO plays a role in EPM care redesign as an EPM collaborator, without having a different limit on their maximum financial gain from one arrangement versus another.

We further propose that with respect to the distribution of any gainsharing payment received by a PGP or ACO, the total amount of all distribution payments must not exceed the

amount of the gainsharing payment received by the EPM collaborator from the EPM participant. Like gainsharing and alignment payments, we propose that all distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction. The collaboration agent must retain the ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments. Finally, the distribution arrangement must not induce the collaboration agent to reduce or limit medically necessary items and services to any Medicare beneficiary or reward the provision of items and services that are medically unnecessary.

We propose that the EPM collaborator must maintain contemporaneous documentation regarding distribution arrangements in accordance with § 512.110, including:

- The relevant written agreements;
- The date and amount of any distribution payment(s);
- The identity of each collaboration agent that received a distribution payment; and
- A description of the methodology and accounting formula for determining the amount of any distribution payment.

We propose that the EPM collaborator may not enter into a distribution arrangement with any individual or entity that has a sharing arrangement with the same EPM participant. This proposal ensures that the proposed separate limitations on the total amount of gainsharing payment and distribution payment to PGPs, physicians, and nonphysician practitioners that are substantially based on quality of care and the provision of EPM activities are not exceeded in absolute dollars by a PGP, physician, or nonphysician practitioner's participation in both a sharing arrangement and distribution arrangement for the care of the same EPM beneficiaries during EPM episodes. Allowing both types of arrangements for the same individual or entity for

care of the same EPM beneficiaries during EPM episodes could also allow for duplicate counting of the individual or entity's same quality of care and provision of EPM activities in the methodologies for both gainsharing and distribution payments, leading to financial gain that is disproportionate to the quality of care and provision of EPM activities by that individual or entity. Finally, we propose that the EPM collaborator must retain and provide access to, and must require collaboration agents to retain and provide access to, the required documentation in accordance with § 512.110.

The proposals for requirements for distribution arrangements under the EPM are included in § 512.505(b). We seek comment about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the EPM are met. In addition, we seek comment on how the regulation of the financial arrangements under this proposal may interact with how these or similar financial arrangements are regulated under the Medicare Shared Savings Program.

6. Downstream Distribution Arrangements under the EPM

a. General

We propose that the EPM allow for certain financial arrangements within an ACO between a PGP and its members. Specifically, we propose that certain financial arrangements between a collaboration agent that is both a PGP and an ACO participant and other individuals termed "downstream collaboration agents" be termed a "downstream distribution arrangement." A downstream distribution arrangement is a financial arrangement between a collaboration agent that is both a PGP and an ACO participant and a downstream collaboration agent for the sole purpose of sharing a distribution payment received by the PGP. A downstream collaboration

agent is an individual who is not an EPM collaborator or a collaboration agent and who is a PGP member that has entered into a downstream distribution arrangement with the same PGP in which he or she is an owner or employee, and where the PGP is a collaboration agent. Where a payment from a collaboration agent to a downstream collaboration agent is made pursuant to a downstream distribution arrangement, we define that payment as a "downstream distribution payment." A collaboration agent may only make a downstream distribution payment in accordance with a downstream distribution arrangement which complies with the requirements of this section and all other applicable laws and regulations, including the fraud and abuse laws.

The proposals for the general provisions for downstream distribution arrangements under the EPM are included in § 512.510(a). We seek comment about all of the provisions set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the EPM are met.

b. Requirements

We propose a number of specific requirements for downstream distribution arrangements as a program integrity safeguard to help ensure that their sole purpose is to create financial alignment between collaboration agents that are PGPs which are also ACO participants and downstream collaboration agents toward the goals of the EPM to improve the quality and efficiency of EPM episodes. These requirements largely parallel those proposed in § 512.500(b) and (c) and § 512.505(b) for sharing and distribution arrangements and gainsharing and distribution payments based on similar reasoning for these three types of arrangements and payments. We propose that all downstream distribution arrangements must be in writing and signed by the parties, contain the date of the agreement, and entered into before care is furnished to EPM beneficiaries under the downstream distribution arrangement. Furthermore, we propose

that participation must be voluntary and without penalty for nonparticipation, and the downstream distribution arrangement must require the downstream collaboration agent to comply with all applicable laws and regulations.

Like our proposals for gainsharing and distribution payments, we propose that the opportunity to make or receive a downstream distribution payment must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the EPM participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent. We propose the more flexible standard for the determination of the amount of downstream distribution payments for the same reasons we propose this standard for the determination of distribution payments by a PGP to PGP members. Specifically, the amount of any downstream distribution payments must be determined either in a manner that complies with §411.352(g) or in accordance with a methodology that is substantially based on quality of care and the provision of EPM activities and that may take into account the amount of such EPM activities provided by a downstream collaboration agent relative to other downstream collaboration agents. We believe that the amount of a downstream collaboration agent's provision of EPM activities (including direct care) to EPM beneficiaries during EPM episodes may contribute to the EPM participant's internal cost savings and reconciliation payment that may be available for making a gainsharing payment to the EPM collaborator that is then shared through a distribution payment to the collaboration agent with which the downstream collaboration agent has a downstream distribution arrangement. Greater contributions of EPM activities by one downstream collaboration agent versus another downstream collaboration agent that result in different

contributions to the distribution payment made to the collaboration agent with which the downstream collaboration agents both have a downstream distribution arrangement may be appropriately valued in the methodology used to make downstream distribution payments to those downstream collaboration agents. Just as we propose an alternative to a methodology that is substantially based on quality of care and the provision of EPM activities for determining the amount of a distribution payment from a PGP to a PGP member, we similarly propose an alternative that the amount of a downstream distribution payment from a PGP to a PGP member may be determined in a manner that complies with §411.352(g)

Similar to our proposed requirements for distribution arrangements for those EPM collaborators that are PGPs, we propose that, except for a downstream distribution arrangement that complies with §411.352(g), a downstream collaboration agent is eligible to receive a downstream distribution payment only if the PGP billed for an item or service furnished by the downstream collaboration agent to an EPM beneficiary during an EPM episode that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprise the gainsharing payment from which the ACO made the distribution payment to the PGP that is an ACO participant. This proposal ensures that, absent the alternative safeguards afforded by a PGP's downstream distribution payments in compliance with §411.352(g), there is the same required relationship between direct care for EPM beneficiaries during EPM episodes and downstream distribution payment eligibility that we require for gainsharing and distribution payment eligibility. We believe this requirement provides a safeguard against payments to downstream collaboration agents that are unrelated to direct care for EPM beneficiaries during EPM episodes when the amount of the downstream distribution payment is not determined in a manner that complies with §411.352(g).

We propose the same limitations on downstream distribution payments to downstream collaboration agents as we propose for distribution payments by EPM collaborators that are PGPs. We propose that, absent the alternative safeguards afforded by compliance with§411.352(g), the total amount of downstream distribution payments paid for a performance year to the downstream collaboration agent would be limited to 50 percent of the total Medicare-approved amounts under the PFS for services billed by the PGP and furnished by the downstream collaboration agent to the EPM participant's EPM beneficiaries during EPM episodes that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment from which the ACO made the distribution payment to the PGP. We believe that, absent the alternative safeguards afforded by a PGP's downstream distribution payments in compliance with§411.352(g), this proposed limitation on downstream distribution payments that is the same as those for distribution payments to physicians and nonphysician practitioners is necessary to eliminate any financial incentives for a PGP member to engage in a specific financial arrangement as a collaboration agent versus a downstream collaboration payment.

We further propose that the total amount of all downstream distribution payments made to downstream collaboration agents must not exceed the amount of the distribution payment received by the collaboration agent (that is, the PGP that is an ACO participant) from the ACO that is an EPM collaborator. Like gainsharing, alignment, and distribution payments, we propose that all downstream distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction. The downstream collaboration agent must retain the ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments. The distribution arrangement must not induce a downstream collaboration agent

to reduce or limit medically necessary items and services to any Medicare beneficiary or reward the provision of items and services that are medically unnecessary.

We propose that the PGP must maintain contemporaneous documentation regarding downstream distribution arrangements in accordance with § 512.110, including all of the following:

- The relevant written agreements.
- The date and amount of any downstream distribution payment(s).
- The identity of each downstream collaboration agent that received a downstream distribution payment.
- A description of the methodology and accounting formula for determining the amount of any downstream distribution payment.

We propose that the PGP may not enter into a downstream distribution arrangement with any PGP member who has a sharing arrangement with an EPM participant or distribution arrangement with the ACO the PGP is a participant in. This proposal ensures that the proposed separate limitations on the total amount of gainsharing payment, distribution payment, and downstream distribution payment to PGP members that are substantially based on quality of care and the provision of EPM activities are not exceeded in absolute dollars by a PGP member's participation in more than one type of arrangement for the care of the same EPM beneficiaries during EPM episodes. Allowing more than one arrangement for the same PGP member for the care of the same EPM beneficiaries during EPM episodes could also allow for duplicate counting of the PGP member's same quality of care and provision of EPM activities in the methodologies for the different payments. Finally, we propose that the PGP must retain and provide access to,

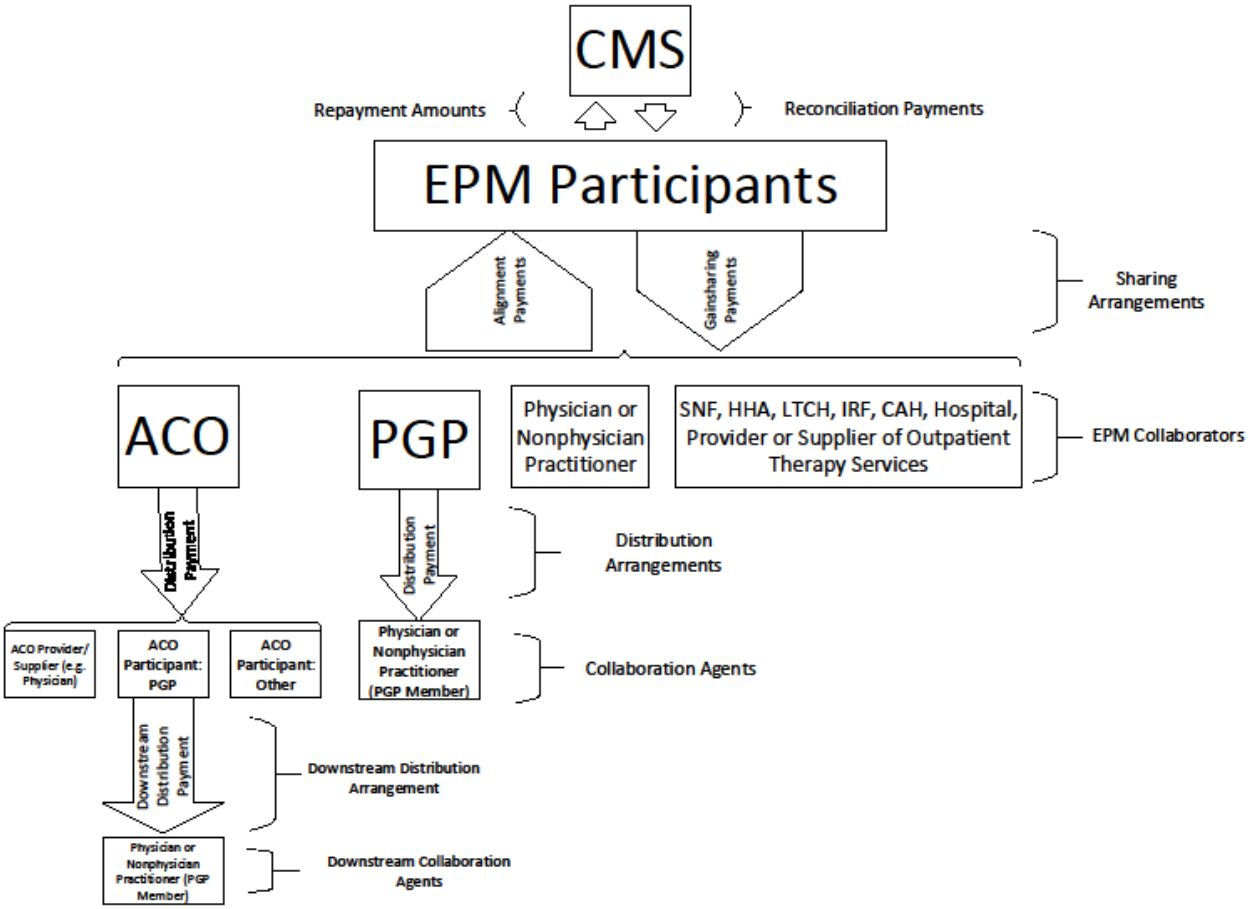
and must require downstream collaboration agents to retain and provide access to, the required documentation in accordance with § 512.110.

The proposals for requirements for downstream distribution arrangements under the EPM are included in § 512.510(b). We seek comment about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the EPM are met.

7. Summary of Proposals for Sharing, Distribution, and Downstream Distribution Arrangements under the EPM

Figure 2 summarizes the proposals for the defined terms and financial arrangements discussed in sections III.I.4. through 6. of this proposed rule.

Figure 2: PROPOSED EPM FINANCIAL ARRANGEMENTS



8. Enforcement Authority

OIG authority is not limited or restricted by the provisions of the EPM, including the authority to audit, evaluate, investigate, or inspect the EPM participant, EPM collaborators, collaboration agents, or any other person or entity or their records, data, or information, without limitations. Additionally, no EPM provisions limit or restrict the authority of any other Government Agency to do the same.

The proposals for enforcement authority under the EPM are included in § 512.520. We seek comment about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the EPM are met.

9. Beneficiary Engagement Incentives under the EPM

a. General

Similar to our reasoning for the CJR model (80 FR 73433 through 73437), we believe that the EPM would incentivize EPM participants to furnish directly and otherwise coordinate items and services throughout the EPM episodes that lead to higher quality care for EPM beneficiaries and lower EPM episode spending. We believe that one mechanism that may be useful to EPM participants in achieving these goals is the provision of certain items and services as in-kind patient engagement incentives to the EPM beneficiary during the EPM episode. Under such an approach, the costs of the patient engagement incentives would be borne by the EPM participant. However, we believe that certain conditions on these incentives are necessary to ensure that their provision is solely for the purpose of achieving the EPM goals of improving episode quality and efficiency.

We propose that the incentive must be provided directly by the EPM participant or by an agent of the EPM participant under the EPM participant's direction and control to the EPM beneficiary during an EPM episode. We considered whether this policy on beneficiary incentives should extend to providers and suppliers other than the EPM participant that furnish services during the EPM episode, or to other entities altogether, such as ACOs that are EPM collaborators. However, as discussed in section III.B.3. of this proposed rule, given our belief that the EPM participant is best positioned to coordinate the care of beneficiaries in the EPM,

we believe that EPM participants are also better suited than other individuals and entities to provide beneficiary incentives.

We propose that the item or service provided as an incentive must be reasonably connected to medical care provided to an EPM beneficiary during an EPM episode. For example, EPM participants could provide incentives such as post-surgical or cardiac monitoring equipment to track patient weight and vital signs for post-surgical or post-AMI patients discharged directly to home, but could not provide theater tickets, which would bear no reasonable connection to the patient's medical care. Similarly, EPM participants might provide cardiac or post-surgical monitoring equipment, but not broadly used technology that is more valuable to the beneficiary than equipment that is reasonably necessary for the patient's post-hospital discharge care, such as a smartphone. In such circumstances, a reasonable inference arises that the technology would not be reasonably connected to the medical care of the patient. Among other things, this safeguard precludes incentives that might serve to inappropriately induce beneficiaries to receive other medical care that is not included in the episode. We also propose that the incentive must be a preventive care item or service or an item or service that advances a clinical goal, as described later in this section, for a beneficiary in an EPM episode by engaging the beneficiary in better managing his or her own health.

We further propose that the item or service provided as an incentive must not be tied to the receipt of items or services outside the EPM episode and that the item or service must not be tied to the receipt of items or services from a particular provider or supplier. These provisions provide safeguards against the provision of in-kind patient engagement incentives to steer beneficiaries toward certain providers or suppliers for care.

We propose that the availability of the items or services provided as incentives must not be advertised or promoted except that a beneficiary may be made aware of the availability of the items or services at the time the beneficiary could reasonably benefit from them. This condition provides a safeguard against the advertisement of in-kind patient engagement incentives to certain beneficiaries that could increase an EPM participant's number of EPM episodes and shift the patient severity for an EPM participant compared to historical EPM episodes by encouraging more beneficiaries with less severe clinical conditions in the EPM to seek care at the EPM participant. Such changes could produce financial gain for the EPM participant that is not related to improvements in EPM quality and efficiency by resulting in the EPM participant's quality-adjusted target prices for EPM episodes being higher than would be appropriate based on the lower average patient severity during the EPM performance years. We do not intend for any of the financial arrangements proposed for the EPM, including beneficiary incentives, to alter an EPM participant's market share of care for a clinical condition in the EPM, nor do we intend for these arrangements to shift the patient severity for an EPM participant or cause access problems for Medicare beneficiaries. Finally, we propose that the cost of the items or services must not be shifted to another federal health care program, as defined at section 1128B(f) of the Act.

Our proposals for the general provisions for beneficiary incentives are included in § 512.525(a). We seek comment on our proposed general provisions for beneficiary incentives and welcome comment on additional or alternative program integrity safeguards.

b. Technology Provided to an EPM Beneficiary

In some cases, items or services involving technology may be useful as beneficiary engagement incentives that can advance a clinical goal of the EPM by engaging a beneficiary in managing his or health during the 90 days following discharge from the anchor or chained

anchor hospitalization. However, we believe specific enhanced safeguards are necessary for these items and services to prevent abuse, and our proposals are consistent with the CJR model policies (80 FR 73437). Specifically, we propose that items or services involving technology provided to a beneficiary may not exceed $1,000 in retail value for any one beneficiary in any one EPM episode, and that items or services involving technology provided to a beneficiary must be the minimum necessary to advance a clinical goal as discussed in this section for a beneficiary in an EPM episode.

We propose additional enhanced requirements for items of technology exceeding $100 in retail value as an additional safeguard against misuse of these items as beneficiary engagement incentives. Specifically, we propose that these items of technology remain the property of the EPM participant and be retrieved from the beneficiary at the end of the EPM episode. The EPM participant must document all retrieval attempts, including the ultimate date of retrieval. However, because we understand that EPM participants may not always be able to retrieve these items after the EPM episode ends, such as when a beneficiary dies or moves to another geographic area, documented, diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement.

Our proposals for enhanced requirements for technology provided to EPM beneficiaries as beneficiary engagement incentives under the EPM are included in § 512.525(b). We seek comment on our proposed requirements for beneficiary engagement incentives that involve technology and welcome comment on additional or alternative program integrity safeguards for this type of beneficiary engagement incentive, including whether the financial thresholds proposed in this section are reasonable, necessary, and appropriate.

c. Clinical Goals of the EPM

As discussed in section III.C.3. of this proposed rule, the proposed EPMs are broadly defined to include most Part A and Part B items and services furnished during EPM episodes that extend 90 days following discharge from the anchor or chained anchor hospitalization that begins the episode, excluding only those Part A and Part B services that are unrelated to the EPM episode based on hospital readmissions or diagnoses for which care is unrelated to the EPM episode diagnosis and procedures based on clinical rationale. Therefore, we believe that in-kind patient engagement incentives may appropriately be provided for managing acute conditions arising from EPM episodes, as well as chronic conditions if the condition is likely to have been affected by care during the EPM episode or when substantial services are likely to be provided for the chronic condition during the EPM episode.

We propose that the following are the clinical goals of the EPM, which may be advanced through beneficiary incentives:

- Beneficiary adherence to drug regimens.
- Beneficiary adherence to a care plan.
- Reduction of readmissions and complications resulting from treatment for the EPM clinical condition.
- Management of chronic diseases and conditions that may be affected by treatment for the EPM clinical condition.

Our proposals for the clinical goals of the EPM that a beneficiary engagement incentive that is not a preventive care item or service must be intended to advance are included in § 512.525(c). We seek comment on our proposed clinical goals of the EPM, as well as whether the advancement of additional or different clinical goals through beneficiary engagement incentives

may better advance the overarching goals of the EPM while maintaining appropriate program integrity safeguards.

d. Documentation of Beneficiary Engagement Incentives

As a program safeguard against misuse of beneficiary engagement incentives under the EPM, we propose that EPM participants must maintain documentation of items and services furnished as beneficiary engagement incentives that exceed $25 in retail value. In addition, we propose to require that the documentation established contemporaneously with the provision of the items and services must include at least the following:

- The date the incentive is provided.
- The identity of the beneficiary to whom the item or service was provided.

We further propose that the documentation regarding items of technology exceeding $100 in retail that are required to be retrieved from the beneficiary at the end of an EPM episode must also include contemporaneous documentation of any attempt to retrieve technology. We reiterate that documented, diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement. Finally, we propose that the EPM participant must retain and provide access to the required documentation in accordance with § 512.110.

Our proposals for the documentation requirements for beneficiary engagement incentives under the EPM are included in § 512.525(c). We seek comment on our proposed documentation requirements, including whether additional or different documentation requirements may provide better program integrity safeguards.

10. Compliance with Fraud and Abuse Laws

Certain arrangements between and among EPM participants and third parties or beneficiaries may implicate civil monetary penalty (CMP) law (subsections 1128A(a)(5), (b)(1),

and (b)(2) of the Act), the Federal Anti-kickback statute (subsections 1128B(b)(1) and (2) of the Act), or the physician self-referral law (section 1877 of the Act). In many cases, arrangements that implicate these laws can be structured to comply with them by using existing safe harbors and exceptions. Section 1115A(d)(1) of the Act authorizes the Secretary to waive certain specified fraud and abuse laws as may be necessary solely for purposes of testing of payment models under section 1115A(b) of the Act. A waiver is not needed for an arrangement that does not implicate the fraud and abuse laws or that implicates the fraud and abuse laws but either fits within an existing exception or safe harbor, as applicable, or does not otherwise violate the law. Accordingly, pursuant to section 1115A(d)(1) of the Act, the Secretary will consider whether waivers of certain fraud and abuse laws are necessary to test the EPM as such models develop. Such waivers, if any, would be promulgated separately from this proposed regulation by OIG (as to sections 1128A and 1128B of the Act) and CMS (as to section 1877 of the Act), to which the respective authorities have been delegated.

Requirements for the EPM will bear on the need for and scope of any fraud and abuse waivers that might be granted for the EPM. Because of the close nexus between the regulations governing the structure and operations of the EPM and the development of any fraud and abuse waivers necessary to carry out the provisions of the EPM, CMS and OIG may, when considering the need for or scope of any waivers, consider comments submitted in response to this proposed rule and provisions of the EPM's final rule.

J. Proposed Waivers of Medicare Program Requirements

1. Overview

Under the CJR model, we stated that it may be necessary and appropriate to provide additional flexibilities to hospitals participating in the CJR model, as well as other providers that

furnish services to beneficiaries in CJR episodes. The purpose of such flexibilities is to increase CJR-episode quality and decrease episode spending or internal costs or both of providers and suppliers that results in better, more coordinated care for beneficiaries and improved financial efficiencies for Medicare, providers, and beneficiaries. These additional flexibilities were implemented through our waiver authority under section 1115A of the Act, which affords broad authority for the Secretary to waive statutory Medicare program requirements as necessary to carry out the provisions of section 1115A.

In proposing to test the EPMs described in this proposed rule, we continue to believe that certain program waivers, similar to those adopted under the CJR model, will offer providers and suppliers more flexibility so that they may increase coordination of care and management of beneficiaries in EPM episodes. However, before adopting the same waivers as we adopted in the CJR model for the proposed EPMs, we believe further examination is necessary to determine if doing so increases financial vulnerability for the Medicare program or creates inappropriate clinical incentives that may reduce the quality of beneficiary care.

Based on our analysis of data available from current models being tested and other available clinical data, specific program requirements for which we propose waivers under the AMI, CABG, and SHFFT models and for which we invite comments are included in the sections that follow. In addition, for providers or suppliers of cardiac rehabilitation and intensive cardiac rehabilitation services furnished to EPM beneficiaries during an AMI and CABG episode, we are proposing to waive the physician definition to allow a qualified nonphysician practitioner to perform specific physician functions.

We propose that these waivers of program requirements would apply to the care of beneficiaries who are in the proposed AMI, CABG, or SHFFT episodes at the time when such

waivers would be used to bill for services furnished to the beneficiary, even if the episode is later cancelled as described in section III.C.4.b. of this proposed rule. Thus, it may have been appropriate for the hospital to have used a waiver if there was a reasonable expectation that the beneficiary was in the model at the time the waiver was used. However, if a service is found to have been billed and paid by Medicare under circumstances allowed only by a program requirement waiver for a beneficiary not in the proposed AMI, CABG, or SHFFT models at the time the service was furnished, CMS would recoup payment for that service from the provider or supplier who was paid, and require that provider or supplier to repay the beneficiary for any coinsurance previously collected.

We also generally seek comment on any additional Medicare program requirements that may be necessary to waive using our authority under section 1115A of the Act in order to effectively test the proposed EPMs that we could consider in the context of our early model implementation experience to inform any future proposals we may make. While we cannot finalize program requirement waivers that we have not specifically proposed, we will continually monitor the use of program waivers in each EPM to ensure that the appropriate outcomes in provider/supplier financial incentives and patient care are achieved.

2. Summary of Waivers Adopted Under the CJR Model

As part of the CJR model implemented in 2016, we issued regulatory waivers of the following Medicare program requirements:

- Section 510.600 of the regulations waives the direct supervision requirement to allow clinical staff to furnish certain post-discharge home visits under the general, rather than direct, supervision of a physician or nonphysician practitioners. This waiver allows a CJR beneficiary who does not qualify for home health benefits to receive up to 9 post-discharge visits in his or

her home or place of residence any time during the episode. All other Medicare rules for coverage and payment of services incident to a physician's service continue to apply.

- Section 510.615 waives current Medicare billing rules to allow the separate billing of these post-discharge home visits for CJR beneficiaries during a 90-day post-operative global surgical period. All other Medicare rules for global-surgery billing during the 90-day post-operative period continue to apply

- Section 510.605 of the regulations allows a Medicare-approved telehealth service to be furnished to a CJR beneficiary regardless of the beneficiary's geographic location, and in his or her home or place of residence. CMS also waives certain telehealth payment provisions. Specifically, Medicare will not pay the originating site facility fee if the service originates in the beneficiary's home or place or residence, and the telehealth home visits will be paid using unique HCPCS codes with payment based on comparable office visits, less the practice expense portion of the payment paid for these comparable visits when furnished in-person. All other requirements for Medicare coverage and payment of telehealth services continue to apply.

- Section 510.610 of the regulations waives the 3-day hospital stay requirement before a beneficiary may be discharged from a hospital to a qualified SNF, which CMS define as SNFs that are rated an overall of 3 stars or better on the Nursing Home Compare website. This waiver applies to episodes being tested under the CJR model for specific performance years. For example, under CJR, the waiver applies beginning in performance year 2 (as hospitals are not bearing risk in their first year). All other Medicare rules for coverage and payment of Part A-covered SNF services continue to apply.

- Section 510.620 of the regulations waives the deductible and coinsurance statutory requirements to the extent necessary to make reconciliation payments or receive repayments

based on the episodic payment methodology under the final payment model for CJR participant hospitals. The reconciliation or repayments do not affect the beneficiary's cost sharing amounts for services furnished under the CJR model.

3. Analysis of Current Model Data

We believe that before we adopt the same regulatory waivers offered under the CJR model, we must determine if doing so would: (1) be clinically-appropriate; (2) not introduce financial vulnerabilities to the Medicare program; and, more importantly, (3) not decrease desired outcomes of patient care. To make this determination, we analyzed waiver usage data and post-acute care usage from Medicare claims data current being tested in other EPMs. In addition, we analyzed the latest arithmetic and geometric means for the MS-DRGs associated with the proposed AMI, CABG, and SHFFT models published as Table 5 in the IPPS FY 2016 Correction Notice to the Final Rule (CMS-1632-CN; 80 FR 60055). The following summarizes the available data.

a. Analysis of Waiver Usage

Waiver usage data is currently not available from the CJR model, thus we reviewed waiver usage data from the BPCI model. Waivers were offered for all 48 episodes under the BPCI model. However, we note that such waivers were significantly different from those adopted under the CJR model. For example, many BPCI model awardees were concerned about the difficulties in accurately identifying beneficiaries in BPCI episodes, which we believe might have been a disincentive to using the waiver of the SNF 3-day hospital stay. For the CJR model, we attempted to address this by codifying that the SNF stay would be covered if the beneficiary was in the episode at the time that the SNF waiver was utilized. With respect to the home visit, the BPCI model only allows 3 visits in a 90-day period (less if the episode is shorter), and

awardees might not consider it worth the effort to incorporate this limited number of visits into their care design for episode beneficiaries. For the CJR model, we increased this allowance to 9 post-discharge visits in a 90- day period to allow for one visit a week for the two thirds of the 90-days post-discharge when the beneficiary was not receiving post-acute care. Finally, in the BPCI model we waived the geographic restrictions for telehealth visits, whereas for the CJR model we allow telehealth visits originating in the home, regardless of geographic location.

Given that the waivers offered under the BPCI model differ from the waivers in the CJR model, and presumably for the waivers that we propose in this proposed rule, the BPCI model data shows --

- The use of the home visit and telehealth waiver is minimal; and
- The waiver of the SNF 3-day rule may be getting the most use.

b. Analysis of Discharge Destination – Post-Acute Care Usage

The following Table 35 shows the discharge destination and post-acute care usage for the cardiac related episodes (CABG, PCI, and AMI) in the BPCI model.

TABLE 35: DISCHARGE DESTINATION FOR BPCI CARDIAC DIAGNOSES*
(Source: Medicare Claims Data)

		DISCHARGE DESTINATION (in rounded percentages)			
MS-DRG	**MS-DRG TITLE**	**Home W/O Home Health**	**Home With Home Health**	**SNF**	**Other**
CABG					
231	W PTCA W MCC	14	30	43	13
232	W PTCA W/O MCC	28	49	15	8
233	W CARDIAC CATH W MCC	12	34	40	14
234	W CARDIAC CATH W/O MCC	20	46	27	7
235	W/O CARDIAC CATH W MCC	13	34	36	17
236	W/O CARDIAC CATH W/O MCC	23	50	19	8
PCI					
246	W DES W MCC OR 4+ VES/STENTS	66	18	13	3
247	W DES STENT W/O MCC	89	8	3	0
248	W NON DES W MCC OR 4+ VES/STENTS	68	17	12	3
249	W NON-DES W/O MCC	85	10	5	0
250	W/O CAS W MCC	63	25	8	4
251	W/O CAS W/O MCC	86	10	4	0
AMI					
280	DISCHARGED ALIVE W MCC	42	22	34	2
281	DISCHARGED ALIVE W CC	57	20	22	1
282	DISCHARGED ALIVE W/O CC/MCC	71	17	10	2

* ABBREVIATIONS:
PTCA - Percutaneous Transluminal Coronary Angioplasty
CC - Complications
MCC - Major Complications
DES - Drug-Eluting Stent
CAS - Coronary Artery Stent)
VES – Vessels

Analysis of the data in Table 35 shows --

- Patients with CABG have high post-acute care usage;
- Patients with PCI have very little post-acute care usage; and
- Patients with AMI have average post-acute care usage compared to patients with PCI and CABG.

Analysis of the CJR model data shows post-acute care usage of about 30 days for MS-DRGs associated with the CJR model.

c. Analysis of Hospital Mean Length of Stay Data

Table 36 shows the geometric and arithmetic mean length of stay (LOS) for MS-DRGs associated with the proposed CABG, AMI (including PCI) and SHFFT models.

TABLE 36: GEOMETRIC AND ARITHMETIC MEAN LENGTH OF STAY FOR BPCI CARDIAC DIAGNOSES AND SHFFT* (Source: FY 2016 IPPS Correction Notice; Table 5)*

MS-DRG	MS-DRG TITLE	GEOMETRIC MEAN LOS	ARITHMETIC MEAN LOS
CABG			
231	W PTCA W MCC	9.9	11.7
232	W PTCA W/O MCC	7.9	8.6
233	W CARDIAC CATH W MCC	11.6	13.0
234	W CARDIAC CATH W/O MCC	8.0	8.6
235	W/O CARDIAC CATH W MCC	8.9	10.3
236	W/O CARDIAC CATH W/O MCC	6.0	6.5
PCI			
246	W DES W MCC OR 4+ VES/STENTS	4.1	5.5
247	W DES STENT W/O MCC	2.2	2.7
248	W NON DES W MCC OR 4+ VES/STENTS	4.8	6.3
249	W NON-DES W/O MCC	2.5	3.1
250	W/O CAS W MCC	4.2	5.7
251	W/O CAS W/O MCC	2.4	2.9
AMI			
280	DISCHARGED ALIVE W MCC	4.5	5.8
281	DISCHARGED ALIVE W CC	2.9	3.6
282	DISCHARGED ALIVE W/O CC/MCC	2.0	2.4
SHFFT			
480	HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT W MCC	6.7	7.9
481	HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT W CC	4.6	5.0
482	HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT W/O CC/MCC	3.7	4.0

* ABBREVIATIONS:
PTCA - Percutaneous Transluminal Coronary Angioplasty
CC- Complications
MCC – Major Complications
DES - Drug-Eluting Stent

CAS - Coronary Artery Stent)
VES - Vessels

Analysis of data in Table 36 shows --

- Patients under all CABG MS-DRGs have a mean LOS of 6 days up to 11-13 days;
- Patients under all PCI MS-DRGs have a mean LOS of about 2 days up to about 6 days;
- Patients under all AMI MS-DRGs have a mean LOS of about 2 days up to about 6 days; and
- Patients under all SHFFT MS-DRGs have a mean LOS of about 4 days up to about 8 days.

Analysis of the CJR model data shows the mean LOS for MS-DRGs associated with the CJR model of about 3 days up to about 7 days.

Based on our analysis of the available data, we believe that minimal program and patient outcome vulnerabilities exist with proposing to adopt the same CJR regulatory waivers to the following program requirements for EPMs:

- The direct supervision requirement for certain post-discharge home visits and the Medicare billing requirement that will allow the separate billing of these post-discharge home visits for EPM beneficiaries during a 90-day post-operative global surgical period.
- The telehealth geographic site requirement and the requirement that will allow in-home telehealth visits.
- The deductible and coinsurance statutory requirements to the extent necessary to make reconciliation payments or receive repayments based on the episodic payment methodology under the final payment model for EPM participants.

Therefore, as discussed in the sections that follow, we will be proposing to adopt waivers for these program requirements for EPMs.

In addition, based on our analysis of the available data, we believe some program and patient outcome vulnerabilities may exist with proposing to adopt the same CJR regulatory waivers for the following program requirements for some EPMs:

- The SNF 3-day rule, for episodes beginning on or after April 1, 2018.
- The number of post-discharge home visits allowed during the model episode.

Therefore, as discussed in the sections that follow, we are proposing to adopt model-specific limits to the number of post-discharge home visits and to offer the waiver of the SNF 3-day rule on a model-specific basis.

4. Post-Discharge Home Visits

As with the LEJR episodes, we expect that the broadly-defined EPM episodes with a duration of 90 days following hospital discharge as we propose in section III.A.1. of this proposed rule will result in EPM participants redesigning care by increasing care coordination and management of beneficiaries following surgeries. We believe that beneficiaries might have substantial mobility limitations during EPM episodes following discharge to their homes or places of residence that may interfere with their ability to travel easily to physicians' offices or other health care settings. Adopting new strategies to increase beneficiary adherence to and engagement with recommended treatment and follow-up care following discharge from the hospital or post-acute care setting will also be important to high-quality episode care. Scientific evidence exists to support the use of home nursing visits among Medicare beneficiaries in

improving care coordination following hospital discharge.[102] In addition, we believe the financial incentives in the EPMs will encourage hospitals to closely examine the most appropriate post-acute care settings for beneficiaries so that the clinically-appropriate setting of the lowest acuity is recommended following discharge from the anchor hospitalization. We expect that all these considerations will lead to greater interest on the part of hospitals and other providers and suppliers caring for EPM beneficiaries in furnishing services to beneficiaries in their homes or places of residence. Such services could include visits by licensed clinical staff other than physicians and nonphysician practitioners.

In order for Medicare to pay for home health services, a beneficiary must be determined to be "homebound." Specifically, sections 1835(a) and 1814(a) of the Act require that a physician certify (and recertify) that in the case of home health services under 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.

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[102] Naylor MD, Brooten D, Campbell R, Jacobsen BS, Mezey MD, Pauly MV, Schwartz JS. JAMA. 1999:281(7):613-620. doi:10/1001/jama.281.7.613

Absent this condition, it would be expected that the beneficiary typically could get the same services in an outpatient or other setting. Thus, the homebound requirement provides a way to help differentiate between patients that require medical care at home versus patients who could more appropriately receive care in less-costly outpatient settings. Additional information regarding the homebound requirement is available in the Medicare Benefit Manual (Pub 100-02); Chapter 7, "Home Health Services," section 30.1.1, "Patient Confined to the Home."

We considered whether a waiver of the homebound requirement would be appropriate under the AMI, CABG and SHFFT models, particularly beginning in performance year 2, where hospitals begin to bear repayment responsibility for excess episode spending. Waiving the homebound requirement would allow additional beneficiaries to receive home health care services in their home or place of residence. As previously discussed, physician certification that a beneficiary meets the homebound requirement is a prerequisite for Medicare coverage of home health services, and waiving the homebound requirement could result in lower episode spending in some instances. For example, if a beneficiary is allowed to have home health care visits, even if the beneficiary is not considered homebound, the beneficiary may avoid a hospital readmission. All other requirements for the Medicare home health benefit would remain unchanged. Thus, under such a waiver, only beneficiaries who otherwise meet all program requirements to receive home health services would be eligible for coverage of home health services without being homebound.

However, we are not proposing to waive the homebound requirement under the proposed EPMs for several reasons. Based on the typical clinical course of beneficiaries after procedures in the proposed EPMs, we believe that many beneficiaries would meet the homebound requirement for home health services immediately following discharge from the anchor

hospitalizations or following discharge to their home or place of residence from a SNF that furnished post-acute care services immediately following the hospital discharge, so they could receive medically-necessary home health services under existing program rules. Home health episodes are 60 days in duration, and payment adjustments are made for beneficiaries who require only a few visits during the episode or who are discharged during the episode. For those EPM beneficiaries who could benefit from home visits by licensed clinical staff for purposes of assessment and monitoring of their clinical conditions, care coordination, and improving adherence with treatment but who are not homebound, we do not believe that paying for these visits as home health services under Medicare is necessary or appropriate, especially given that Medicare payments for home health services are set based on the clinical care furnished to beneficiaries who are truly homebound. Finally, in other CMS episode payment models, such as the BPCI initiative and the CJR model, we have not waived the homebound requirement for home health services.

For EPMs, we propose to adopt program requirement waivers similar to the post-discharge home visit waivers implemented for the CJR model. We propose to waive the "incident to" rule set forth in § 410.26(b)(5), to allow an EPM beneficiary who does not qualify for home health services to receive post-discharge visits in his or her home or place of residence any time during the episode. The waiver would not apply to beneficiaries who would qualify for home health services under the Medicare program, as set forth under § 409.42. Therefore, these visits would not be billed for such beneficiaries. Under the proposed waiver, we would allow licensed clinical staff, such as nurses, either employed by a hospital or not, to furnish the service under the general supervision of a physician, who may be either an employee or a contractor of the hospital. We would allow services furnished under the waiver to be billed under the PFS by

the physician or nonphysician practitioner or by the hospital to which the supervising physician has reassigned his or her benefits. In the latter scenario, we note that the post-discharge home visit services will not be "hospital services," even when furnished by clinical staff of the hospital.

Under the CJR model, we allow up to 9 post-discharge home visits to be billed and paid during each 90-day post-anchor hospitalization CJR episode. This limit on the number of visits is based on the average post-acute care LOS of approximately 30 to 45 days for CJR episodes and the incentives under CJR to improve efficiency, which may shorten post-acute care stays. Thus, 9 visits represent a home visit on average of once per week for two-thirds of the 90-day episode duration, the period of time when the typical beneficiary may have concluded post-acute care in an efficient episode.

Since current model data shows that the average post-acute care LOS may vary or in some case post-acute care may not be used at all, for EPMs, we are proposing to use model-specific limits on post-discharge home visits as follows:

a. AMI Model:

Current model data show that most beneficiaries with AMI diagnoses, regardless of AMI medical treatment or PCI treatment for AMI, are not discharged to post-acute care. Based on no post-acute care usage, we are proposing that a beneficiary in the AMI model could receive up to 13 home visits, which represents a home visit on average of once per week for the entire 90-day AMI episode.

b. CABG Model

Current model data show that most beneficiaries with CABG diagnoses are discharged to SNFs or to home health. Assuming an average post-acute care LOS of 30 days, we are proposing that a beneficiary in the CABG model could receive up to 9 home visits, which

represents a home visit on average of once per week for 60 days, or two-thirds of a 90-day CABG episode.

c. SHFFT Model

Current model data show that most beneficiaries with SHFFT diagnoses are discharged to SNFs with average post-acute care LOSs of 30 days. Thus, we are proposing that a beneficiary in the SHFFT model could receive up to 9 home visits, which represents a home visit on average of once per week for 60 days, or two-thirds of a 90-day SHFFT episode.

We believe that a home visit of once a week to a non-homebound beneficiary who has concluded or has not used post-acute care and who could also receive services in the physician's office or hospital outpatient department as needed, along with telehealth visits in the home from a physician or nonphysician practitioner as proposed in the next section, should be sufficient to allow comprehensive assessment and management of the beneficiary throughout the AMI, CABG, or SHFFT episode.

Similar to the CJR model, we propose that the service be billed with HCPCS code GXXXX (EPM – AMI, CABG, or SHFFT model home visit for patient assessment performed by clinical staff for an individual not considered homebound, including, but not necessarily limited to patient assessment of clinical status, safety/fall prevention, functional status/ambulation, medication reconciliation/management, compliance with orders/plan of care, performance of activities of daily living, and ensuring beneficiary connections to community and other services; for use only in the Medicare-approved EPM – AMI, CABG, or SHFFT model; may not be billed for a 30-day period covered by a transitional care management code) and paid at approximately $50 under the PFS. The standard PFS rate setting methodologies establish relative value units (RVUs) based on the resources required to furnish the typical service. Final RVUs under

the CY 2017 PFS for the proposed new HCPCS code for AMI, CABG, and SHFFT home visits will be included in the EPM Final Rule. In addition, we propose to update the values each year to correspond to final values established under the PFS.

The waiver would not apply with respect to an AMI, CABG, or SHFFT beneficiary who has qualified, or would qualify, for home health services when the visit was furnished. We expect that the visits by licensed clinical staff could include patient assessment, monitoring, assessment of functional status and fall risk, review of medications, assessment of adherence with treatment recommendations, patient education, communication and coordination with other treating clinicians, care management to improve beneficiary connections to community and other services, etc. These post-discharge home visits would remove barriers to follow-up care outside of the home with providers and suppliers and allow the beneficiary to be treated in his or her home environment or place of residence, where potential safety concerns, such as tripping hazards, could quickly be identified and remediated. Given these occasions for further patient assessment and intervention, we believe that where such post-discharge home visits are furnished, there are opportunities to increase patient-centered care coordination and decrease episode spending, potentially resulting in higher-quality care for beneficiaries and increased episode efficiency which may benefit the beneficiaries, the Medicare Trust Fund, and EPM participants.

We also propose to waive current Medicare billing rules in order to allow the separate reporting of these post-discharge home visits during surgical global periods. The PFS payment for the surgical procedure includes 90 days of post-operative care furnished by the surgeon. Post-operative follow-up care is not separately billable by the surgeon or, unless there is a transfer of care, by another practitioner. The current construction of the global packages

included in PFS payments reflects a narrow view of surgical follow-up care that does not encompass broader, more comprehensive models of post-operative care, such as an episode payment model like the proposed AMI, CABG, and SHFFT models. As we have noted in the past, it is also difficult to determine the appropriate valuation of the various components of the current global packages (2015 Physician Fee Schedule 79 FR 67584). We do not believe that the AMI, CABG, and SHFFT post-discharge home visits, which can include nursing assessments for chronic conditions for which care may be affected by the surgery, would replace or substantially duplicate the kind of post-operative visits involved in furnishing post-operative follow-up care for the global surgery procedure under the PFS. Instead, we anticipate that the work of these post-discharge visits will be similar to the work furnished by the physician coordinating the patient's overall episode care. Therefore, we propose to waive the global surgery billing rules to allow the surgeon or other practitioners to furnish and bill for the post-discharge home visits during surgical global periods.

We plan to monitor utilization patterns of post-discharge home visits under EPMs to monitor for overutilization and significant reductions in medical home health services. We seek comments on the proposed waiver of the "incident to" rule to pay for a maximum number of post-discharge home visits to beneficiaries who do not qualify for home health services by licensed clinical staff under the general supervision of a physician.

5. Billing and Payment for Telehealth Services

As discussed in the previous section, we expect that the EPMs' design features will lead to greater interest on the part of hospitals and other providers and suppliers caring for EPM beneficiaries in furnishing services to beneficiaries in their homes or places of residence, including physicians' professional services. While physicians may furnish and be paid by

Medicare for home visits under the PFS, few visits actually are furnished to Medicare beneficiaries because of the significant physician resources required for such visits and the general structure of most office-based physician practices. For example, in 2014, only 2.6 million physician or nonphysician practitioner home visits were furnished to Medicare beneficiaries, in contrast to almost 250 million office or other outpatient evaluation and management visits furnished by physicians or nonphysician practitioners. EPMs would create new incentives for comprehensive episode care management for beneficiaries, including early identification and intervention regarding changes in health status following discharge from the anchor hospitalization. We understand that EPM participants may want to engage physicians in furnishing timely visits to homebound or non-homebound EPM beneficiaries in their homes or places of residence to address concerning symptoms or observations raised by beneficiaries themselves, clinicians furnishing home health services, or licensed clinical staff furnishing post-discharge home visits, while physicians committed to the proposed AMI, CABG, and SHFFT care redesign may not be able to revise their practice patterns to meet this home visit need for EPM beneficiaries.

Under section 1834(m) of the Act, Medicare pays for telehealth services furnished by a physician or practitioner under certain conditions even though the physician or practitioner is not in the same location as the beneficiary. The telehealth services must be furnished to a beneficiary located in one of the eight types of originating sites specified in section 1834(m)(4)(C)(ii) of the Act and the site must satisfy at least one of the requirements of sections 1834(m)(4)(C)(i)(I) through (III) of the Act. Generally, for Medicare payment to be made for telehealth services under the PFS several conditions must be met, as set forth under

§ 410.78(b). Specifically, for a service to be eligible for payment, the individual receiving the services must be in an eligible originating site, and the service must be --

- On the Medicare list of telehealth services;[103]
- Furnished via an interactive telecommunications system; and
- Furnished to a telehealth-eligible individual.

When all of these conditions are met, Medicare pays a facility fee to the originating site and provides separate payment to the distant-site practitioner for the service. Section 1834(m)(4)(F)(i) of the Act defines Medicare telehealth services to include professional consultations, office visits, office psychiatry services, and any additional service specified by the Secretary, when furnished via a telecommunications system.

Under section 1834(m)(4)(F)(ii) of the Act, CMS has an annual process to consider additions to and deletions from the list of telehealth services. We do not include any services as telehealth services when Medicare does not otherwise make a separate payment for them.

Some literature suggests that technologies that enable health care providers to deliver care to patients in locations remote from providers are being increasingly used to complement face-to-face patient-provider encounters in both urban and rural areas.[104] In these cases, the use of remote access technologies may improve the accessibility and timeliness of needed care, increase communication between providers and patients, enhance care coordination, and improve the efficiency of care. We note that certain professional services that are commonly furnished remotely using telecommunications technology are paid under the same conditions as in-person physicians' services, and thus do not require a waiver to be considered as telehealth services.

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[103] For the list of approved Medicare telehealth services, see the CMS website at http://www.cms.gov/Medicare/Medicare-General-information/telehealth/.

[104] Telehealth in an Evolving Health Care Environment: Workshop Summary (2012). Available at http://www.ic4n.org/wp-content/uploads/2014/06/IoM-Telehealth-2012-Workshop-Summary.pdf. Accessed on June 7, 2015.

Such services that do not require the patient to be present in person with the practitioner when they are furnished are covered and paid in the same way as services delivered without the use of telecommunications technology when the practitioner is in person at the medical facility furnishing care to the patient.

In other CMS episode-based payment models, such as BPCI Models 2 and 3 and the CJR model, we determined it was necessary to waive the geographic-site requirements of sections 1834(m)(4)(C)(i)(I) through (III) of the Act. This waiver allows telehealth services to be furnished to eligible telehealth individuals when they are located at one of the eight originating sites at the time the service is furnished via a telecommunications system but without regard to the site meeting one of the geographic site requirements. For the proposed EPMs – AMI, CABG, and SHFFT – we propose a waiver of this same provision as well as waiver of the requirement that the eligible telehealth individual be in an originating site when an otherwise-eligible individual is receiving telehealth services in his or her home or place of residence. This waiver would allow providers and suppliers furnishing services to EPM beneficiaries to utilize telemedicine for beneficiaries that are not classified as rural and to allow the greatest degree of efficiency and communication between providers and suppliers and beneficiaries by allowing beneficiaries to receive telehealth services at their home or place of residence. We believe that these waivers are essential to maximize the opportunity to improve the quality of care and efficiency for the proposed EPMs' episodes.

Specifically, like the telehealth waiver for the BPCI and CJR models, we propose to waive the geographic-site requirements of sections 1834(m)(4)(C)(i)(I) through (III) of the Act that limit telehealth payment to services furnished within specific types of geographic areas or in an entity participating in a federal telemedicine demonstration project approved as of

December 31, 2000. Waiver of this requirement would allow beneficiaries located in any region to receive services related to the episode to be furnished via telehealth, as long as all other Medicare requirements for telehealth services are met. Any service on the list of Medicare approved telehealth services and reported on a claim with an ICD-9 principal diagnosis code that is not excluded from the proposed EPMs episode definition (see section III.C. of this proposed rule) could be furnished to an EPM beneficiary, regardless of the beneficiary's geographic location. Under the proposed EPMs, this waiver would support care coordination and increasing timely access to high quality care for all EPM beneficiaries, regardless of geography.

Additionally, we propose, only for the purpose of testing the proposed EPMs, waiving the originating site requirements of section 1834(m)(4)(C)(ii)(I)-(VIII) of the Act that specify the particular sites at which the eligible telehealth individual must be located at the time the service is furnished via a telecommunications system. Specifically, we propose to waive the requirement only when telehealth services are being furnished in the EPM beneficiary's home or place of residence during the episode. Any service on the list of Medicare approved telehealth services and reported on a claim with an ICD-9 principal diagnosis code that is not excluded from the applicable EPM's episode definition (see section III.C. of this proposed rule) could be furnished to an EPM beneficiary in his or her home or place of residence, unless the service's HCPCS code descriptor precludes delivering the service in the home or place of residence. For example, subsequent hospital care services could not be furnished to beneficiaries in their home since those beneficiaries would not be inpatients of the hospital.

The existing set of codes used to report evaluation and management (E/M) visits are extensively categorized and defined by the setting of the service, and the codes describe the services furnished when both the patient and the practitioner are located in that setting. Section 1834(m)

of the Act provides for particular conditions under which Medicare can make payment for office visits when a patient is located in a health care setting (the originating sites authorized by statute) and the eligible practitioner is located elsewhere. However, we do not believe that the kinds of E/M services furnished to patients outside of health care settings via real-time, interactive communication technology are accurately described by any existing E/M codes. This would include circumstances when the patient is located in his or her home and the location of the practitioner is unspecified. Therefore, in order to create a mechanism to report E/M services accurately under the EPMs, we propose to create a specific set of HCPCS G-codes to describe the E/M services furnished to EPM beneficiaries in their homes via telehealth. Among the existing E/M visit services, we envision these services would be most similar to those described by the office and other outpatient E/M codes. Therefore, we propose to structure the new codes similarly to the office/outpatient E/M codes but adjusted to reflect the location as the beneficiary's residence and the virtual presence of the practitioner. Specifically, we propose to create a parallel structure and set of descriptors currently used to report office or other outpatient E/M services, (CPT codes 99201-99205 for new patient visits and CPT codes 99212-99215 for established patient visits). For example, the proposed G-code for a level 3 E/M visit for an established patient would be a remote in-home visit for the evaluation and management of an established patient, which requires at least two of the following three key components:

- An expanded problem focused history.
- An expanded problem focused examination.
- Medical decision making of low complexity, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the

problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent with the patient or family or both via real-time, audio and video intercommunications technology.

We note that we are not proposing a G-code to parallel the level 1 office/outpatient visit for an established patient, since that service does not require the presence of the physician or other qualified health professional. We also believe this would duplicate the home visits for non-homebound beneficiaries previously proposed in this section.

We propose to develop payment rates for these new telehealth G-codes for E/M services in the patient's home that are similar to the payment rates for the office/outpatient E/M services, since the codes will describe the work involved in furnishing similar services. Therefore, we propose to include the resource costs typically incurred when services are furnished via telehealth. In terms of the relative resource costs involved in furnishing these services, we believe that the efficiencies of virtual presentation generally limit resource costs other than those related to the professional time, intensity, and malpractice risk to marginal levels. Therefore, we propose to adopt work and malpractice (MP) RVUs associated with the corresponding level of office/outpatient codes as the typical service because the practitioner's time and intensity and malpractice liabilities when conducting a visit via telehealth are comparable to the office visit.

We will include final RVUs under the CY 2016 PFS when we finalize the rules for EPMs. Additionally, we propose to update these values each year to correspond to final values established under the PFS. We considered whether each level of visit typically would warrant support by auxiliary licensed clinical staff within the context of the proposed EPMs. The cost of such staff and any associated supplies, for example, would be incorporated in the practice expense (PE) RVUs under the PFS. For the lower-level visits (levels 1-3 for new visits and

levels 2 and 3 for established visits), we did not believe that visits necessarily would require auxiliary medical staff to be available in patients' homes. We anticipate these lower-level visits would be the most-commonly furnished and would serve as mechanisms for patients to consult quickly with practitioners for concerns that patients can easily describe and explain. We do not propose to include PE RVUs for these services, since we do not believe that virtual visits envisioned for EPMs typically incur the kinds of costs included in the PE RVUs under the PFS. For higher-level visits, we typically would anticipate some amount of support from auxiliary clinical staff. For example, wound examination and minor wound debridement would be considered included in an E/M visit and would require licensed clinical staff to be present in the beneficiary's home during the telehealth visit for the complete service to be furnished. We believe it would be rare for a practitioner to conduct as complex and detailed a service as a level 4 or 5 E/M home visit via telehealth for beneficiaries in the proposed EPMs' episodes without licensed clinical staff support in the home.

However, we also note that the proposed EPMs already include several avenues for licensed clinical staff to be in the patient's home, either through a separately paid home visit as proposed for the model or through home health services as discussed earlier in this section of this proposed rule. Therefore, although we consider support by auxiliary clinical staff to be typical for levels 4 or 5 E/M visits furnished to EPM beneficiaries in the home via telehealth, we do not propose to incorporate these costs through PE RVUs. Given the anticipated complexity of these visits, we would expect to observe levels 4 and 5 E/M visits to be reported on the same claim with the same date of service as a home visit or during a period of authorized home health care. If neither of these occurs, we propose to require the physician to document in the medical record that auxiliary licensed clinical staff were available on site in the patient's home during the visit

and if they were not, to document the reason that such a high-level visit would not require such personnel.

We note that because the services described by the proposed G-codes, by definition, are furnished remotely using telecommunications technology, they therefore are paid under the same conditions as in-person physicians' services and they do not require a waiver to the requirements of section 1834(m) of the Act. We also note that because these home telehealth services are E/M services, all other coverage and payment rules regarding E/M services would continue to apply.

Under the proposed EPMs, this proposal to waive the originating site requirements and create new home visit telehealth HCPCS codes would support the greatest efficiency and timely communication between providers and beneficiaries by allowing beneficiaries to receive telehealth services at their places of residence.

With respect to home health services paid under the home health prospective payment system (HH PPS), we emphasize that telehealth visits under this model cannot substitute for in-person home health visits per section 1895(e)(1)(A) of the Act. Furthermore, telehealth services by social workers cannot be furnished for EPM beneficiaries who are in a home health episode of care because medical social services are included as home health services per section 1861(m) of the Act and paid for under the Medicare HH PPS. However, telehealth services permitted under section 1834 of the Act and furnished by physicians or other practitioners, specifically physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, nurse anesthetists, psychologists, and dieticians, can be furnished for EPM beneficiaries who are in a home health episode of care. Finally, sections 1835(a) and 1814(a) of the Act require that the patient has a face-to-face encounter with the certifying physician or an allowed nonphysician practitioner working in collaboration with or under the

supervision of the certifying physician before the certifying physician certifies that the patient is eligible for home health services. Under § 424.22(a)(1)(v), the face-to-face encounter can be performed up to 90 days prior to the start of home health care or within 30 days after the start of home health care. Section 424.22(a)(1)(v)(A) also allows a physician, with privileges, who cared for the patient in an acute or post-acute care setting (from which the patient was directly admitted to home health) or an allowed nonphysician practitioner working in collaboration with or under the supervision of the acute or post-acute care physician to conduct the face-to-face encounter.

Although sections 1835(a) and 1814(a) of the Act allow the face-to-face encounter to be performed via telehealth, we are not proposing that the waiver of the telehealth geographic site requirement for telehealth services and the originating site requirement for telehealth services furnished in the EPM beneficiary's home or place of residence would apply to the face-to-face encounter required as part of the home health certification when that encounter is furnished via telehealth. In other words, when a face-to-face encounter furnished via telehealth is used to meet the requirement for home health certification, the usual Medicare telehealth rules apply with respect to geography and eligibility of the originating site. We expect that this policy will not limit EPM beneficiaries' access to medically-necessary home health services because beneficiaries receiving home health services during a proposed EPM episode will have had a face-to-face encounter with either the physician or an allowed nonphysician practitioner during their anchor hospitalization or a physician or allowed nonphysician practitioner during a post-acute facility stay prior to discharge directly to home health services.

Under the proposed waiver of the geographic site requirement and originating site requirement, all telehealth services would be required to be furnished in accordance with all

Medicare coverage and payment criteria, and no additional payment would be made to cover set-up costs, technology purchases, training and education, or other related costs. The facility fee paid by Medicare to an originating site for a telehealth service would be waived if there is no facility as an originating site (that is, the service was originated in the beneficiary's home).

Finally, providers and suppliers furnishing a telehealth service to a EPM beneficiary in his or her home or place of residence during the episode would not be permitted to bill for telehealth services that were not fully furnished when an inability to provide the intended telehealth service is due to technical issues with telecommunications equipment required for that service.

Beneficiaries would be able to receive services furnished pursuant to the telehealth waivers only during the proposed EPM episode.

We plan to monitor patterns of utilization of telehealth services under the proposed EPMs to monitor for overutilization or reductions in medically-necessary care, and significant reductions in face-to-face visits with physicians and nonphysician practitioners. We plan to specifically monitor the distribution of new telehealth home visits that we are proposing, as we anticipate greater use of lower level visits. Given our concern that auxiliary licensed clinical staff be present for level 4 and 5 visits, we will monitor our proposed requirement that these visits be billed on the same claim with the same date of service as a home nursing visit, during a period authorized home health care, or that the physician document the presence of auxiliary licensed clinical staff in the home or an explanation as to the specific circumstances precluding the need for auxiliary staff for the specific visit. We seek comments on the proposed waivers with respect to telehealth services, and the proposed creation of the home visit telehealth codes.

6. SNF 3-Day Rule

a. Waiver of SNF 3-Day Rule

Pursuant to section 1861(i) of the Act, a beneficiary must have a prior inpatient hospital stays of no fewer than 3 consecutive days in order to be eligible for Medicare coverage of inpatient SNF care. We refer to this as the SNF 3-day rule. We note that the SNF 3-day rule has been waived for Medicare SNF coverage under other episode payment models, including BPCI Model 2 and the CJR model. BPCI Model 2 awardees that request and are approved for the waiver can discharge Model 2 beneficiaries in fewer than 3 days from an anchor hospital stay to a SNF, where services are covered under Medicare Part A as long as all other coverage requirements for such services are satisfied. Under the CJR model, we adopted a waiver of the SNF 3-day rule that applies beginning in performance year 2 as hospitals are not bearing risk in their first year. As discussed in section V.N. of this proposed rule with comment period, we are proposing to revise the effective date of the waiver of the SNF 3-day rule for the CJR model, and we are proposing that participant hospitals may begin using the waiver for episodes that begin on or after January 1, 2017.

We are proposing EPM payment policies, similar to CJR payment policies, in section III.D. of this proposed rule, which would require participating EPM hospitals to repay Medicare for excess episode spending beginning in performance year 2. Episode payment models like BPCI, CJR and those being proposed in this proposed rule have the potential to mitigate the existing incentives under the Medicare program to overuse SNF benefits for beneficiaries, as well as to furnish many fragmented services that do not reflect significant coordinated attention to and management of complications following hospital discharge. The removal of these incentives in an EPM lays the groundwork for offering EPM participants greater flexibility around the parameters that determine SNF stay coverage. BPCI participants

considering the early discharge of a beneficiary pursuant to the waiver during a Model 2 episode must evaluate whether early discharge to a SNF is clinically-appropriate and SNF services are medically-necessary. Next, they must balance that determination and the potential benefits to the hospital in the form of internal cost savings due to greater financial efficiency with the understanding that a subsequent hospital readmission, attributable to premature discharge or low quality SNF care, could substantially increase episode spending while also resulting in poorer quality of care for the beneficiary. Furthermore, early hospital discharge for a beneficiary who would otherwise not require a SNF stay (that is, the beneficiary has no identified skilled nursing or rehabilitation need that cannot be provided on an outpatient basis) following a hospital stay of typical length does not improve episode efficiency under episode-based payment models such as BPCI, the CJR model, or the EPMs in this proposed rule.

Because of the potential benefits we see for participating EPM hospitals, their provider partners, and beneficiaries, we propose to waive in certain instances, where it is clinically-appropriate, the SNF 3-day rule for coverage of a SNF stay following the anchor hospitalization under EPM for episodes that begin on or after April 1, 2018. While our intent is to align the effective date of the availability of this program waiver with performance year 2 (DR) of the model, when repayment responsibility for actual episode spending that exceeds the target price begins, we believe that an effective date based on the start of the episode will be clearer to participant hospitals, SNFs, and others in determining whether the waiver is available for an EPM beneficiary. We believe that clarity regarding whether a waiver applies to SNF services furnished to a particular beneficiary is important to help ensure compliance with the conditions of the waiver and also improve our ability to monitor waivers for misuse. We propose to use our authority under section 1115A of the Act with respect to certain SNFs that

furnish Medicare Part A post-hospital extended care services to beneficiaries included in an EPM episode. We believe this waiver is necessary to the model test so that EPM participants can redesign care throughout the episode continuum of care extending to 90 days post-discharge from the anchor hospital stay in order to maximize quality and hospital financial efficiency, as well as reduce episode spending under Medicare. However, we are not proposing to waive this requirement in performance year 1, when EPM participants are not responsible for excess actual episode spending. We believe that there is some potential for early hospital discharge followed by a SNF stay to increase actual episode spending over historical patterns unless EPM participants are particularly mindful of this potential unintended consequence. Without participant repayment responsibility in performance year 1, we are concerned that Medicare would be at full risk under the model for increased episode spending because, without a financial incentive to closely manage care, hospitals might be more likely to discharge beneficiaries to SNFs early leading to increased episode spending for which the hospital would bear no responsibility. For EPM episodes beginning on or after April 1, 2018, we propose to waive the SNF 3-day rule, where clinically-appropriate, because participants will bear partial or full responsibility (capped at the proposed stop-loss limit described in section III.D.7.b. of this proposed rule) for excess episode actual spending, thereby providing a strong incentive in those years for participants to redesign care with both quality and efficiency outcomes as priorities. All other Medicare rules for coverage and payment of Part A-covered SNF services would continue to apply to EPM beneficiaries in all performance years of the model.

In addition, for those proposed EPMs in this proposed rule and for future EPMs where this waiver is clinically-appropriate and the average LOS for Medicare beneficiaries hospitalized for certain EPM procedures without major complications or comorbidities may be already

relatively short at 3 days we believe that we should protect immediate EPM beneficiary safety and optimizing health outcomes. Therefore, we propose to require that participants may only discharge an EPM beneficiary under this proposed waiver of the SNF 3-day rule to a SNF rated an overall of three stars or better by CMS based on information publicly available at the time of hospital discharge. Problem areas due to early hospital discharge may not be discovered through model monitoring and evaluation activities until well after the episode has concluded, and the potential for later negative findings alone may not afford sufficient beneficiary protections. CMS created a Five-Star Quality Rating System for SNFs to allow SNFs to be compared more easily and to help identify areas of concerning SNF performance. The Nursing Home Compare website gives each SNF an overall rating of between 1 and 5 stars.[105] Those SNFs with 5 stars are considered to have much above average quality, and SNFs with 1 star are considered to have quality much below average. Published SNF ratings include distinct ratings of health inspection, staffing, and quality measures, with ratings for each of the three sources combined to calculate an overall rating. These areas of assessment are all relevant to the quality of SNF care following discharge from the anchor hospitalization initiating an EPM episode, especially if that discharge occurs after fewer than 3 days in the hospital. Because of the potential greater risks following early inpatient hospital discharge, we believe it is appropriate that all EPM beneficiaries discharged from the EPM participant to a SNF in fewer than 3 days be admitted to a SNF that has demonstrated that it is capable of providing quality care to patients with significant unresolved post-surgical symptoms and problems. We believe such a SNF would need to provide care of at least average overall quality, which would be represented by an overall SNF 3-star or better rating.

[105] www.medicare.gov/NursingHomeCompare/

As discussed in the CJR final rule (80 FR 73457 through 73459), commenters expressed concern about the variation in the number of SNFs across the participating MSAs rated an overall 3 stars or better that would qualify for the SNF 3-day rule waiver under CJR. While we appreciate the variation in qualifying SNFs across the participating MSAs, we continue to believe that we need to balance the goal of improved efficiency under an episode payment model through additional access to a covered SNF stay after an anchor hospitalization of less than 3 days with protecting beneficiaries from the risks of care stinting and premature discharge from the hospital that may result from the financial incentives of episode payment. We note that all 294 MSAs that are eligible for selection for the AMI and CABG models under this proposed rule have at least one SNF that passed the 3 star requirement from June 2015 to May 2016 and would therefore qualify for the waiver under our proposal. Therefore, all EPM beneficiaries would have access to at least one SNF in the MSA of the participant hospital that meets the SNF overall star rating requirement for the proposed EPM waiver.

Thus, the participating hospital must discharge the beneficiary to a SNF that is qualified under the SNF 3-day rule waiver. We are proposing that to be qualified under the SNF 3-day rule waiver a SNF must be included in the most recent calendar year quarter Five-Star Quality Rating System listing for SNFs on the Nursing Home Compare web site for the date of the beneficiary's admission to the SNF. The qualified SNF must be rated an overall 3 stars or better for at least 7 of the 12 months based on a review of the most recent rolling 12 months of overall star ratings. We propose to post on the CMS web site the list of qualified SNFs in advance of the calendar quarter.

For the CJR model, we justified the waiver of the SNF 3-day rule by reviewing data specific to the characteristics of CJR beneficiaries, such as, the geometric mean hospital LOS for

the MS-DRGs associated with lower extremity joint replacement (3 to 7 days) and the frequency and length of SNF usage (typically 30 days) for CJR beneficiaries. We stated in the CJR Final Rule that we believe this waiver is necessary to the model test so that CJR participant hospitals could redesign care throughout the episode continuum of care extending to 90 days post-discharge from the anchor hospital stay in order to maximize quality and hospital financial efficiency, as well as reduce episode spending under Medicare. However, the waiver does not apply in performance year 1, when CJR participant hospitals are not responsible for excess actual episode spending.

Based on our analysis of data discussed in section III.J.3. of this proposed rule, we believe some program and patient outcome vulnerabilities may exist with proposing to adopt the waiver of the SNF 3-day rule for the proposed AMI, CABG, and SHFFT models or under future EPMs. To mitigate these possible vulnerabilities, we believe it will be necessary to determine if this waiver applies to EPMs on a model-specific basis as follows:

- AMI Model -- AMI beneficiaries have geometric mean hospital LOSs that are similar to CJR beneficiaries, 2.0-4.5 days (see Table 35). Most AMI beneficiaries, regardless of AMI medical treatment or PCI treatment for AMI, are not discharged to post-acute care. There is no research that shows increased mortality associated with the hospital LOS. Therefore, we believe that is may be clinically-appropriate to propose to waive the SNF 3-day rule for the AMI model for episodes beginning on or after April 1, 2018, as participant hospitals are not bearing risk in their first performance year or performance year 2 (NDR).

We propose that the waiver be available for the AMI beneficiary's care. The SNF would insert a Treatment Authorization Code on the claim for a beneficiary in the model where the SNF seeks to the use the waiver. This process would promote coordination between the SNF and the

AMI model participant, as the SNF would need to be in close communication with the EPM participant to ensure that the beneficiary is in the model at the time the waiver is used. We propose that where the beneficiary would be eligible for inclusion in an AMI episode of care at the time of hospital discharge, use of the waiver would be permitted where it is medically-necessary and appropriate to discharge the beneficiary to a SNF prior to a 3 day inpatient stay. A beneficiary would be eligible to receive services furnished under the 3-day rule waiver only during the AMI episode.

- CABG Model -- CABG beneficiaries have a geometric mean hospital LOS of 6.0 to 11.6 days (see Table 35), much longer than the CJR model's mean LOS. While most CABG beneficiaries are discharged to SNFs, a mean hospital LOS well above 3 days indicates that it would not be clinically-appropriate for early discharges provided with this waiver. Therefore, we are not proposing to waive the SNF 3-day rule for the CABG model.

- SHFFT Model -- SHFFT beneficiaries have a geometric mean hospital LOS of 3.7-6.7 days (see Table 35), somewhat close to the CJR model's mean LOS. However, studies show that shorter than average hospital LOSs for hip fracture are associated with higher mortality.[106] While most SHFFT beneficiaries are discharged to SNFs, a mean hospital LOS above 3 days along with a higher mortality rates associated with shorter than average hospital LOSs indicates that it would not be clinically-appropriate for early discharges provided with this waiver. Therefore, we are proposing not to waive the SNF 3-day rule for the SHFFT model.

We plan to monitor patterns of SNF utilization under the EPM, particularly with respect to hospital discharge in fewer than 3 days to a SNF, to ensure that beneficiaries are not being discharged prematurely to SNFs and that they are able to exercise their freedom of choice

[106] http://www.ncbi.nlm.nih.gov/pubmed/19817664

without patient steering. We seek comment on our proposal to waive the SNF 3-day stay rule for stays in SNFs rated overall as 3 stars or better following discharge from the anchor hospitalization in EPM episodes.

b. Additional Beneficiary Protections under the SNF 3-Day Stay Rule Waiver

For those specific proposed EPMs, where we propose to allow the SNF 3-day rule waiver, we believe that it will be necessary to propose beneficiary protections against financial liability in addition to the beneficiary protections discussed elsewhere in this proposed rule. In proposing additional beneficiary protections that may be necessary to ensure proper use of the SNF 3-day rule waiver under the proposed EPMs, we note that there are existing, well-established payment and coverage policies for SNF services based on sections 1861(i), 1862(a)(1), and 1879 of the Act that include protections for beneficiaries from liability for certain non-covered SNF charges. These existing payment and coverage policies for SNF services continue to apply under the EPMs, including SNF services furnished pursuant to the SNF 3-day waiver. (For example, see section 70 in the Medicare Claims Processing Manual, Chapter 30 – Financial Liability Protections on the CMS website at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c30.pdf; and Medicare Coverage of Skilled Nursing Facility Care at https://www.medicare.gov/Pubs/pdf/10153.pdf; Medicare Benefit Policy Manual, Chapter 8 – Coverage of Extended Care (SNF) Services Under Hospital Insurance at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c08.odf). In general, CMS requires that the SNF inform a beneficiary in writing about services and fees before the beneficiary is discharged to the SNF (§ 483.10(b)(6)); a beneficiary cannot be required to request extra services as a condition of continued stay (§483.10(c)(8)(iii)(B)); and the

SNF must inform a beneficiary that requests an item or service for which a charge will be made that there will be a charge for the item or service and what the charge will be (§483.10(c)(8)(iii)(C)). (See also Chapter 6 of Medicare Coverage of Skills Nursing Facility Care at https://www.medicare.gov/Pubs/pdf/10153.pdf.)

As discussed in the CJR final rule, commenters expressed concern regarding the lag between a CJR beneficiary's Medicare eligibility status change and a participant hospital's awareness of that change. There may be cases in which a SNF waiver is used by a participant hospital because the participant hospital believes that the beneficiary meets the criteria, based on the information available to the hospital and SNF at the time of the beneficiary's admission to the SNF, but in fact the beneficiary's Medicare eligibility status has changed and the hospital was unaware of it based on available information. We recognize that despite good faith efforts by participant hospitals and SNFs to determine a beneficiary's Medicare status for the model, it may occur that a beneficiary is not eligible to be included in the CJR model at the time the SNF waiver is used. In these cases, we will cover services furnished under the waiver when the information available to the provider at the time the services under the waiver were furnished indicated that the beneficiary was included in the model.

In addition, as discussed in the CJR final rule, we noted that we would continue to evaluate the waiver of the SNF 3-day rule, including further lessons learned from Innovation Center models in which a waiver of the SNF 3-day rule is being tested. We indicated that in the event we determine that additional safeguards or protections for beneficiaries or other changes were necessary, such as to incorporate additional protections for beneficiaries, we would propose the necessary changes through future rulemaking. In section V of this proposed rule, we are proposing to add certain beneficiary protection requirements under the CJR model in § 510.610.

We have continued to learn from implementation of the SNF 3-day rule waiver in the CJR model, other models, and the Shared Savings Program. Based on these experiences, we believe there are situations where it would be appropriate to require additional beneficiary financial protections under the SNF 3-day rule waiver for the applicable proposed EPMs. Specifically, we are concerned about potential beneficiary financial liability for non-covered Part A SNF services that might be directly related to use of the SNF 3-day waiver under the applicable EPMs. For instance, we are concerned that a beneficiary could be charged for non-covered SNF services if an EPM participant hospital discharges a beneficiary to a SNF that does not meet the quality requirement (3 stars or higher in 7 of the last 12 months), and the beneficiary is not provided a discharge planning notice, as described in proposed § 512.450(b). Another scenario would be where the EPM participant hospital applies the SNF 3-day rule waiver for episodes that begin prior to April 1, 2018, when this waiver is not applicable, and payment to the qualified SNF for furnishing Medicare covered SNF services is denied. A third scenario would be if an EPM participant hospital applies the SNF 3-day rule waiver for a specific proposed EPM where the waiver is not allowed, such as proposed for the CABG and SHFFT models in this proposed rule. In any of these circumstances, we assume the participant EPM hospital's intent was to rely upon the SNF 3-day rule waiver, but the waiver requirements were not met. When this occurs, we are concerned that once the claim is rejected, the beneficiary may not be protected from financial liability under existing Medicare rules because the waiver would not be available, and the beneficiary would not have had a qualifying inpatient hospital stay. Thus, the EPM beneficiary could be charged by the SNF for non-covered SNF services that were a result of an inappropriate attempt to use the waiver. In these cases, Medicare would deny payment of the SNF claim, and the beneficiary could potentially be charged by the SNF for these

non-covered SNF services, potentially subjecting such beneficiaries to significant financial liability. We believe that the rejection of the claim, in these cases, could easily have been avoided if the hospital had confirmed that the requirements for applying of the SNF 3-day waiver were satisfied.

Other models have addressed similar issues in which the beneficiary may be subject to financial liability for non-covered SNF services related to the waiver. The Next Generation ACO Model generally places the risk on the SNF, where the SNF did not qualify under the waiver or otherwise knew or reasonably could be expected to have known that payment would not be made for the non-covered SNF services. In such cases, CMS makes no payment for the services, and the SNF may not charge the beneficiary for the services and must return any monies collected from the beneficiary. Additionally, under the Next Generation ACO Model, the ACO must indemnify and hold the beneficiary harmless for the services. We believe it is appropriate to propose to adopt a similar policy under the EPMs. In contrast to the Next Generation ACO Model, however, we believe it is most appropriate to hold the EPM participant hospitals financially responsible for misusing the waiver in situations where waiver requirements are not met, because EPM participant hospitals are required to be aware of the 3-day waiver requirements. EPM participant hospitals are the entities financially responsible for episode spending under the proposed EPMs and will make the decision as to whether it is appropriate to discharge a beneficiary without a 3-day stay. In addition, we will clearly lay out the requirements for use of the SNF waiver in the EPM final rule. As we are proposing, EPM participant hospitals may begin using this waiver only for specific episodes beginning on or after April 1, 2018, and may only utilize the waiver to discharge a beneficiary to a SNF that meets the quality requirements. EPM participant hospitals are required to ensure the waiver requirements

of proposed § 512.610 (a) and (b) are met. Therefore, we believe it is reasonable that the ultimate responsibility and liability for a non-covered SNF stay should rest with the EPM participant hospital. We considered holding the SNF responsible but decided that since hospitals, not SNFs, are the EPM participants, they therefore should be held responsible for complying with the SNF 3-day rule waiver conditions for the reasons stated previously.

To protect EPM beneficiaries from being charged for non-covered SNF charges in instances when the waiver was used inappropriately, we are proposing to add certain beneficiary protection requirements in proposed §512.610. These requirements would apply for SNF services that would otherwise have been covered except for lack of a qualifying 3-day hospital stay. Specifically, we propose if, subsequent to an EPM participant hospital applying the SNF 3-day rule waiver, we determine that the following waiver requirements were not met then the EPM participant hospital will be financially liable for the SNF stay:

- The EPM participant hospital discharges a beneficiary that is in a specific EPM where the SNF 3-day rule waiver does not apply.
- The EPM participant hospital discharges a beneficiary prior to April 1, 2018, where the SNF 3-day rule waiver does not apply.
- The EPM participant hospital discharges a beneficiary to a SNF that does not meet the quality requirement (3 stars or higher in 7 of the last 12 months) and does not provide a discharge planning notice, as described in proposed § 512.450(b), to the beneficiary alerting them of potential financial liability.

In these preceding instances, we propose to apply the following rules:

- CMS shall make no payment to the SNF for such services.

- The SNF shall not charge the beneficiary for the expenses incurred for such services. and the SNF shall return to the beneficiary any monies collected for such services.
- The hospital shall be responsible for the cost of the uncovered SNF services furnished during the SNF stay.

In addition, if the EPM hospital discharges a beneficiary to a SNF that does not meet the quality requirement (3 stars or higher in 7 of the last 12 months) and a discharge planning notice, as described in proposed § 512.450(b), is provided to the beneficiary alerting them of potential financial liability then the hospital will not be financially liable for the cost of the SNF stay and the normal Medicare FFS rules for coverage of SNF services will apply.

The discharge notice absolves the hospital of liability. However, we are requiring hospitals to keep a record of discharge planning notice distribution to EPM beneficiaries. We will monitor participant hospitals' use of discharge notification letters to protect EPM beneficiaries from potential abuse of the waiver. Nevertheless, we recognize there are some situations in which a beneficiary may wish to be discharged before a qualifying 3-day stay and may accept financial liability for a non-qualifying stay, in which case the participant hospital will not be held financially liable for the SNF stay. Therefore, when the EPM participant hospital has discharged a beneficiary to a SNF that does not qualify under the conditions of the waiver, we believe it is reasonable that the ultimate responsibility and financial liability for a non-covered SNF stay should rest with the EPM participant hospital. We will communicate with hospitals and SNFs about how a hospital would pay SNFs for non-qualifying services provided.

We seek comment on these proposals. Specifically, we seek comment on whether it is reasonable to: (a) cover services furnished under the SNF waiver based on the EPM participant hospital's knowledge of beneficiary eligibility for the applicable proposed EPMs, as determined

by Medicare status, at the time the services under the waiver were furnished; and (b) to hold the EPM participant hospital financially responsible for rejected SNF claims as a result of lack of a qualifying inpatient hospital stay in cases where the EPM participant hospital discharge a beneficiary to a SNF that did not qualify for waiver use and did not provide the beneficiary with a discharge planning notice. We seek comment on whether SNFs instead of, or in addition to, the EPM participant hospital should be held liable for such claims and under what circumstances. Finally, we seek comment on any other related issues that we should consider in connection with these proposal to protect beneficiaries from significant financial liability for non-covered SNF services related to the waiver of the SNF 3-day rule under the proposed EPMs. We may address those issues through future notice and comment rulemaking.

7. Waivers of Medicare Program Rules to Allow Reconciliation Payment or Repayment Actions Resulting from the Net Payment Reconciliation Amount

In order to make a reconciliation payment to or carry out recoupment from a participant that results from the NPRA calculation for each performance year as discussed in section III.D.5. of this proposed rule, we believe we would need to waive certain Medicare program rules. Therefore, in accordance with the authority in section 1115A(d)(1) of the Act, we propose to waive requirements of the Act for all Medicare Part A and Part B payment systems only to the extent necessary to make reconciliation payments or receive repayments based on the NPRA that reflect the episode payment methodology under this proposed payment model for EPM participants selected in accordance with CMS's proposed selection methodology. In addition, our proposals on reconciliation payments or repayments would not change beneficiary cost-sharing from the regular Medicare program cost-sharing for the related Part A and Part B services that were paid for CJR beneficiaries and aggregated to determine actual episode

spending in the calculation of the NPRA. We therefore would waive the requirements of sections 1813 and 1833(a) of the Act to the extent that they would otherwise apply to reconciliation payments or repayments from an EPM participant. We seek comment on our proposed waivers related to repayment and recoupment actions as a result of the NRPA calculated.

8. New Waiver for Providers and Suppliers of Cardiac Rehabilitation and Intensive Cardiac Rehabilitation Services Furnished to EPM Beneficiaries During an AMI or CABG Episode

A cardiac rehabilitation (CR) program, as defined in § 410.49(a) of the regulations, means a physician-supervised program that furnishes physician prescribed exercise, cardiac risk factor modification, psychosocial assessment, and outcomes assessment. An intensive cardiac rehabilitation (ICR) program, as defined in § 410.49(a) of the regulations, means a physician-supervised program that furnishes cardiac rehabilitation and has shown, in peer-reviewed published research, that it improves patients' cardiovascular disease through specific outcome measurements described in § 410.49(c).

Services provided under CR and ICR programs may be furnished to EPM beneficiaries during the proposed AMI and CABG episodes. We note that all EPM beneficiaries in an AMI or CABG episode would meet CMS's coverage criteria for CR and ICR services.

Section 410.49(f) describes the limitations of coverage of cardiac rehabilitation programs. The coverage requirements of CR limits the number of cardiac rehabilitation program sessions to a maximum of 2 one-hour sessions per day for up to 36 sessions over a period up to 36 weeks with the option for an additional 36 sessions over an extended period of time if approved by the MAC under section 1862(a)(1)(A) of the Act. Intensive cardiac rehabilitation program sessions are limited to 72 one-hour sessions (as defined in section 1848(b)(5) of the

Act), up to 6 sessions per day, over a period of up to 18 weeks. In section VI of this proposed rule, we are proposing to make a payment adjustment under the AMI and CABG models to account for and possibly incentivize the provision of CR and ICR services beyond what has historically been provided during AMI and CABG episodes. In addition, we believe that waiving certain CR/ICR program requirements may also increase the use of these beneficial services under the AMI and CABG models.

We reviewed the following physician functions required under § 410.49 in furnishing CR/ICR services:

- Medical director – defined at § 410.49(a) as a physician that oversees or supervises the cardiac rehabilitation or intensive rehabilitation program at a particular site.
- Supervising physician – defined at § 410.49(a) as a physician that is immediately available and accessible for medical consultations and medical emergencies at all times items and services are being furnished to individuals under cardiac rehabilitation and intensive cardiac rehabilitation programs.
- Physician-prescribed exercise – defined at § 410.49(a) as aerobic exercise combined with other types of exercise (that is, strengthening, stretching) as determined to be appropriate for individual patients by a physician.
- Individualized treatment plan – defined at § 410.49(a) as a written plan tailored to each individual patient that, under § 410.49(b)(2)(v), must be established, reviewed, and signed by a physician every 30 days.

Under § 410.49(a), and § 1861(r)(1) of the Act, a physician is defined as a doctor of medicine or osteopathy. Section 410.49(b)(3) states that Medicare Part B pays for CR/ICR in a physician's office or in a hospital outpatient setting. All settings must have a physician

immediately available and accessible for medical consultations and emergencies at all times when items and services are being furnished under the program. This provision is satisfied if the physician meets the requirements for direct supervision for physician office services, at § 410.26 of this subpart; and for hospital outpatient services at § 410.27 of this subpart.

To provide greater program flexibility that might increase the availability of CR and ICR services furnished to EPM beneficiaries in AMI and CABG episodes, we are proposing to provide a waiver to the definition of a physician to include a nonphysician practitioner (defined for the purposes of this waiver as a physician assistant, nurse practitioner, or clinical nurse specialist as authorized under sections 1861(s)(2)(K)(i) and (ii) of the Act and defined in section 1861(aa)(5) of the Act, or in §§ 410.74, 410.75, and 410.76 of the regulations). Thus, this waiver will allow, in addition to a physician, a nonphysician practitioner to perform the functions of supervisory physician, prescribing exercise, and establishing, reviewing, and signing an individualized treatment plan for a provider or supplier of CR and ICR services furnished to an EPM beneficiary during an AMI or CABG episode. We do not believe a nonphysician practitioner is qualified to act in the capacity of a medical director. Thus, we are specifically excluding the medical director function from this proposed waiver. In addition, all other definitions and requirements related to a physician or supervising physician under § 410.49 continue to apply. This proposed waiver is codified at proposed § 512.630.

For an EPM beneficiary in an AMI or CABG episode, this proposed waiver will apply to any provider or supplier that furnishes CR and ICR services to that beneficiary. We anticipate monitoring outcomes of care for EPM beneficiaries that receive CR and ICR services under this proposed waiver during an AMI or CABG episode. The monitoring may involve an analysis of all or a sample of claims, medical records, or other clinical data for AMI and CABG EPM

beneficiaries and providers or suppliers of CR and ICR services. We are soliciting comments on approaches we may take to monitor this waiver to ensure this program flexibility does not have a negative effect on how beneficiaries receive CR and ICR services which then may affect the outcome of the EPM beneficiary's care.

We also reviewed other program requirements, such as waiving beneficiary cost-sharing, allowing home nursing visits/home monitoring, and allowing telehealth visits in the home under the AMI and CABG models. We did not find clinical data and literature that we believed sufficient to support proposing any additional waivers to the CR/ICR program requirements in this proposed rule. We are soliciting comments on the proposed CR/ICR waiver to allow nonphysician practitioners to perform the aforementioned physician functions specified for the provision of CR/ICR services, as well as comments on possible other CR/ICR program requirement waive

K. Data Sharing

1. Overview

In section III.D.2.of this proposed rule, we propose models similar to the CJR model, to financially incentivize EPM participants to engage in care redesign efforts to improve quality of care and reduce spending for the aggregate Part A and B FFS spending for beneficiaries included in the model during the inpatient hospitalization and 90 days post-discharge. Consistent with the CJR model, we are proposing retrospective bundled payment models that provide financial incentives for EPM participants to work with other health care providers and suppliers to improve the quality and efficiency of care for Medicare beneficiaries by paying EPM participants or holding them responsible for repaying Medicare based on EPM participants' performance with respect to the quality and spending for AMI, CABG, and SHFFT episodes.

In addition to the CJR model, we have experience with a range of efforts designed to improve care coordination for Medicare beneficiaries through financial incentives similar to those currently proposed, including the Shared Savings Program, the Pioneer ACO model and the BPCI initiative, all of which make certain data available to participants to better enable them to achieve their goals. For example, participants in the Shared Savings Program initially receive aggregate information on their historical financial performance as well as quarterly data throughout their tenure in the program. In addition, Shared Savings ACOs receive certain beneficiary-identifiable claims information in accordance with our regulations. As noted in the June 9, 2015 Medicare Shared Savings Program final rule (80 FR 32733), ACOs participating in the Shared Savings Program have reported that the beneficiary-identifiable claims data that they receive from CMS are being used effectively to better understand the FFS beneficiaries that are receiving services from their providers. As stated in that rule, these data give ACOs valuable

insight into patterns of care for their beneficiary population and enable them to improve care coordination among and across providers and suppliers and sites of care. Similarly, participants in the Pioneer ACO model can request historical claims data of beneficiaries aligned with the particular Pioneer ACO entity, and the entities continue to receive certain ongoing data regarding the services furnished to those beneficiaries. (For more information see the CMS Web site http://innovation.cms.gov/Files/fact-sheet/Pioneer-ACO-Model-Beneficiaries-Rights-Fact-Sheet.pdf). In addition, we provide BPCI participants with the opportunity to request beneficiary claims data regarding their own patients, both for the historical period used to set baseline prices for entities participating in BPCI as well as ongoing monthly claims feeds containing Medicare FFS claims for beneficiaries that could have initiated an episode of care for that particular BPCI participant. These monthly claims feeds provide BPCI participants with data for both acute and post-acute care spending for beneficiaries that could have initiated an episode of care at that BPCI participant.

Based on our experience with these efforts, we believe that making certain data available to EPM participants can have a salutary effect on their performance and is necessary for them to, among other things, adequately structure their care pathways, coordinate care for beneficiaries, make practice changes supported under the models, identify services furnished to beneficiaries receiving services under the models, and estimate spending across provider types within EPM episodes. Further, we believe that providing EPM participants with certain claims and summary information on beneficiaries in accordance with applicable privacy and security laws and established privacy and security protections would improve their ability to monitor their performance and understand the totality of care provided during an episode of care. With this greater awareness and understanding, we anticipate that EPM participants would be better equipped to evaluate and modify their practice patterns and actively manage care delivery so that

care for beneficiaries is better coordinated, quality and efficiency are improved, and payments are aligned more appropriately to the medically necessary services beneficiaries have a right to receive.

Accordingly, we propose to provide EPM participants in the proposed AMI, CABG, and SHFFT models with beneficiary-level claims data for the historical period used to calculate their episode benchmark and quality-adjusted target prices as well as with ongoing quarterly beneficiary-identifiable claims data in response to their request for such data in accordance with our regulations. Given that we are also proposing to incorporate regional pricing in the calculation of benchmark and quality-adjusted target prices, we also propose to provide EPM participants with aggregate regional data. Our proposal to make these data available to EPM participants is included in § 512.350. We note that, consistent with CJR, the EPM participant with whom we would share data is the acute care hospital that is held accountable for spending during the episode of care. We believe our proposal to share data as we do under the CJR model would be the most effective approach under the proposed AMI, CABG, and SHFFT models, and that proposing different processes for these models would increase administrative complexity for CMS and model participants as well as create confusion, especially given that we are proposing in section III.B. that some of the hospitals participating in CJR will also participate in the proposed EPMs. We request comments on these proposals, particularly regarding possible ways, if any, to further align our proposed policies with those finalized under the CJR model, as well as any appropriate bases for treating these models differently.

2. Beneficiary Claims Data

Based on our experience with BPCI and CJR participants, we recognize that EPM participants could vary with respect to the kinds of beneficiary claims information that would be

most helpful. For example, we believe that while many EPM participants might have the ability to analyze raw claims data, other EPM participants could find it more useful to have a summary of these data. Given this, we propose to make beneficiary claims information for AMI, CABG, and SHFFT episodes available through two formats both for the baseline period and on an ongoing basis during their participation in the model as we do for CJR.

First, for EPM participants that lack the capacity to analyze raw claims data, we propose to provide summary beneficiary claims data reports on beneficiaries' use of health care services during the baseline and performance periods upon request and in accordance with applicable privacy and security laws and established privacy and security protections. Such summary reports would provide tools to monitor, understand, and manage utilization and expenditure patterns as well as to develop, target, and implement quality improvement programs and initiatives. For example, if the data provided by CMS to a particular EPM participant reflects that, relative to their peers, a certain provider is associated with significantly higher rates of inpatient readmissions than the rates experienced by other beneficiaries with similar care needs, that may be evidence that the EPM participant could consider, among other things, the appropriateness of that provider, whether other alternatives might be more appropriate, and whether there exist certain care interventions that could be incorporated post-discharge to lower readmission rates.

Such reports would allow EPM participants to assess summary data on their relevant beneficiary population without requiring a more complicated analysis of raw claims data. Therefore, for both the baseline period and on a quarterly basis during an EPM participant's performance period, we propose to provide EPM participants with an opportunity to request summary claims data that would encompass the total expenditures and claims for episodes under

the proposed AMI, CABG, and SHFFT models in which they are participating, including the procedure, inpatient stay, and all related care covered under Medicare Parts A and B within the 90 days after discharge, including hospital care, post-acute care, and physician services for the EPM participant's beneficiaries with an anchor diagnosis at discharge that is included under one of the proposed AMI, CABG, or SHFFT models.

We also propose that these summary claims data reports, at a minimum, would also contain payment information, based upon the following categories for each episode initiated under the models:

- Inpatient.
- Outpatient.
- Skilled Nursing Facility.
- Home Health.
- Hospice.
- Carrier/Part-B.
- Durable Medical Equipment.

These files would provide summary spending data such as episode counts, total average spending for each episode, and a breakdown of the episode counts and spending averages by each of the most common categories listed previously (for example, Inpatient, Outpatient, etc.). These reports should allow participants to assess summary data on their relevant beneficiary population without requiring analysis of raw claims data.

Alternatively, for EPM participants with the capacity to analyze raw claims data, we propose to make more detailed beneficiary-level information available upon request and in accordance with applicable privacy and security laws and established privacy and security

protections. These files would be much more detailed and include all beneficiary-level raw claims for all of the categories listed for each episode payment model episode. In addition, they would include episode summaries, indicators for excluded episodes, diagnosis and procedure codes, and enrollment and dual eligibility information for beneficiaries that initiate AMI, CABG, and SHFFT episodes. Through analysis, these detailed claims data would provide EPM participants with information to improve their ability to coordinate and target care strategies as well to monitor, understand, and manage utilization and expenditure patterns. Such data would also aid them in developing, targeting, and implementing quality improvement programs and initiatives. We propose that the data files would be packaged and sent to a data portal (to which the EPM participants must request and be granted access) in a "flat" or binary format for the EPM participant to retrieve. We would also note that, for both the summary and more detailed claims data, information that is subject to the regulations governing the confidentiality of alcohol and drug abuse patient records (42 CFR part 2) would be excluded from the data shared with an EPM participant. Our proposal to make available to EPM participants, through the most appropriate means, data that CMS determines may be useful to EPM participants to determine appropriate ways to increase the coordination of care, improve quality, enhance efficiencies in the delivery system, and otherwise achieve the goals of the proposed episode payment models is included in § 512.350. Further, CMS will make beneficiary-identifiable data available to an EPM participant in accordance with applicable privacy and security laws and only in response to the EPM participant's request for such data for a beneficiary who has been furnished a billable service by the participant corresponding to the episode definitions for AMI, CABG, and SHFFT episodes.

We request comments on this proposal.

3. Aggregate Regional Data

As discussed in section III.D. of this proposed rule, we propose to incorporate regional pricing data when establishing target prices for EPM participants as we do in the CJR model pricing methodology. As indicated in the CJR final rule (80 FR 73510), we finalized our proposal to share regional pricing data with CJR participants because it was a factor affecting target prices. Given the similarities between the CJR model and the EPMs proposed in this proposed rule, particularly our proposal to incorporate regional pricing data when establishing target prices under the model, we propose to provide aggregate expenditure data available for all claims associated with AMI, CABG, and SHFFT episodes for the U.S. Census Division in which the EPM participant is located, as we similarly provide to hospitals participating in the CJR model.

Specifically, we propose to provide EPM participants with aggregate data on the total expenditures during an acute inpatient stay and 90-day post-discharge period for all Medicare FFS beneficiaries who would have initiated an episode under our proposed episode definitions in section III.C. of this proposed rule. This data will be provided at the regional level; that is, we propose that an EPM participant would receive, if requested from CMS, aggregate regional data for potential episode payment model AMI, CABG, and/or SHFFT episodes initiated in the U.S. Census Division where the EPM participant is located.

These regional data would be in a format similar to the proposed summary claims data reports and would provide summary information on the average episode spending for AMI, CABG, and SHFFT episodes in the U.S. Census Division in which the EPM participant is located. Our proposal to provide aggregate regional data is included in § 512.350. We seek comments on our proposal to provide these data to EPM participants.

4. Timing and Period of Baseline Data

We recognize that providing the ability to request certain baseline data will be important for EPM participants to be able to estimate episode spending, coordinate care, and identify areas for practice transformation, and that early release of this data can facilitate their efforts to do so. Also, as discussed in section III.D. of this proposed rule, episode benchmark and quality-adjusted target prices will be calculated using an EPM participant's historical episode spending during their baseline period. Further, we believe that EPM participants will view the episode payment model effort as one involving continuous improvement. As a result, changes initially contemplated by an EPM participant could be subsequently revised based on updated information and experiences.

Therefore, as with CJR and BPCI, we propose to make 3 years of baseline data available to EPM participants and intend to make these data available upon request prior to the start of the first episode payment model performance year and in accordance with applicable privacy and security laws and established privacy and security protections. We believe that 3 years of baseline data is sufficient to reflect both an EPM participant's most recent performance and recent performance trends. Moreover, making data available for a 3-year period aligns with our proposal to set a target price based on a 3-year period of baseline data in section III.D. of this proposed rule. We believe that if an EPM participant has access to baseline data for the 3-year period used to set its episode benchmark and quality-adjusted target prices, then it would be better able to assess its practice patterns, identify cost drivers, and ultimately redesign its care practices to improve efficiency and quality.

Therefore, we propose that the 3-year period utilized for the baseline period match the baseline data used to create EPM participants episode benchmark and quality-adjusted target

prices, as discussed in section III.D. Specifically, we propose that the baseline beneficiary-level and summary data (both EPM participant-level and regional summary data) would be available for episodes that began January 1, 2013 through December 31, 2015. We request comments on these proposals.

5. Frequency and Period of Claims Data Updates for Sharing Beneficiary-Identifiable Claims Data During the Performance Period

In addition to baseline data, we believe that the availability of periodically updated beneficiary-identifiable claims data (both summary and beneficiary-level) will assist EPM participants in the proposed AMI, CABG, and SHFFT models to identify areas where they might wish to change their care practice patterns, as well as monitor the effects of any such changes. With respect to these purposes, we have considered what would be the most appropriate period and frequency for making updated claims information available to EPM participants, while complying with the HIPAA Privacy Rule's "minimum necessary" standard.

We believe that, as is the case with CJR, making claims data available that would represent up to 6 quarters of information upon receipt of a request for such information that meets the requirements of the HIPAA Privacy Rule, would be representative of total spending and useful to hospitals as they consider long-term practice changes. We note that we intend for the data for this model to be consistent with our proposed performance year of January 1 through December 31 (July 1 through December 31 for performance year 1). To accomplish this for the first year of the models (2017), we propose to provide, upon request and in accordance with the HIPAA Privacy Rule, claims data from July 1, 2017 to June 30, 2018 on as frequently as a running quarterly basis, as claims were available. For each quarter and extending through June 30, 2018, we propose that participants during that first year would

receive data for up to the current quarter and all of the previous quarters going back to July 1, 2017. These data sets would contain all claims for all potential episodes that were initiated on or after July 1, 2017 and capture a sufficient amount of time for relevant claims to have been processed. We note that we would limit the content of this data set to the minimum data necessary for the participating hospital to conduct quality assessment and improvement activities and effectively coordinate care of its patient population.

Accordingly, we propose to make updated claims data available to EPM participants, representing up to 6 quarters of data, upon receipt of a request for such information that meets CMS's requirements to ensure the applicable HIPAA conditions for disclosure have been met. Also, consistent with our procedures for CJR, we propose to make these data available as frequently as on a quarterly basis. Given that we have received requests in other initiatives to make data available on a more frequent basis, we also propose to eventually make these data available on as frequently as a monthly basis if practicable. In addition, we propose that for an EPM participant to receive data on episode spending, they will only need to make a single initial request rather than multiple periodic requests for data. CMS would make data available to the EPM participant for the duration of their participation or until they notify CMS that they no longer wish to receive these data.

Our proposal to make the minimum data necessary for EPM participants to conduct quality assessment and improvement activities and effectively coordinate care of its patient population as frequently as on a quarterly basis throughout the EPM participant's participation or until they notify CMS that they no longer wish to receive these data is included at § 512.350(b)(2). We seek comments on this proposal.

6. Legal Permission to Share Beneficiary-Identifiable Data

As we have stated previously (see 80 FR 73513), we recognize that there are a number of issues and sensitivities surrounding the disclosure of beneficiary-identifiable health information, and note that a number of laws place constraints on sharing individually identifiable health information. For example, section 1106 of the Act bars the disclosure of information collected under the Act without consent unless a law (statute or regulation) permits for the disclosure. Here, the HIPAA Privacy Rule allows for the proposed disclosure of individually identifiable health information by CMS.

In this proposed rule, we propose to make EPM participants financially responsible for services that may have occurred outside of the hospital during the 90-day post-discharge period. Although we expect EPM participants to be actively engaged in post-discharge planning and other care during the 90-day post-discharge period for beneficiaries receiving services under the proposed AMI, CABG, and SHFFT models, we believe that it is necessary for the purposes of these models to provide EPM participants with beneficiary-level claims data, either in summary or line-level claim formats for a 3-year historical period as well as on a quarterly basis during the performance period. We believe that these data constitute the minimum information necessary to enable the participant hospital to understand spending patterns during the episode, appropriately coordinate care, and target care strategies toward individual beneficiaries furnished care by the participant hospital and other providers and suppliers.

Under the HIPAA Privacy Rule, covered entities (defined as health care plans, providers that conduct covered transactions, including hospitals, and health care clearinghouses) are barred from using or disclosing individually identifiable health information (called "protected health information" or PHI) in a manner that is not explicitly permitted or required under the HIPAA Privacy Rule. The Medicare FFS program, a "health plan" function of the Department, is subject

to the HIPAA Privacy Rule limitations on the disclosure of PHI. The hospitals and other Medicare providers and suppliers are also covered entities, provided they are health care providers as defined by 45 CFR 160.103 and they conduct (or someone on their behalf conducts) one or more HIPAA standard transactions electronically, such as for claims transactions. In light of these relationships, we believe that the proposed disclosure of the beneficiary claims data for an acute inpatient stay plus 90-day post-discharge for episodes included under the proposed models would be permitted by the HIPAA Privacy Rule under the provisions that permit disclosures of PHI for "health care operations" purposes. Under those provisions, a covered entity is permitted to disclose PHI to another covered entity for the recipient's health care operations purposes if both covered entities have or had a relationship with the subject of the PHI to be disclosed, the PHI pertains to that relationship, and the recipient will use the PHI for a "health care operations" function that falls within the first two paragraphs of the definition of "health care operations" in the HIPAA Privacy Rule (45 CFR 164.506(c)(4)).

The first paragraph of the definition of health care operations includes "conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines," and "population-based activities relating to improving health or reducing health costs, protocol development, case management and care coordination" (45 CFR 164.501).

Under our proposal, EPM participants would be using the data on their patients to evaluate the performance of the participant hospital and other providers and suppliers that furnished services to the patient, conduct quality assessment and improvement activities, and conduct population-based activities relating to improved health for their patients. When done by or on behalf of a covered entity, these are covered functions and activities that would qualify as "health care operations" under the first and second paragraphs of the definition of health care

operations at 45 CFR 164.501. Hence, as previously discussed, we believe that this provision is extensive enough to cover the uses we would expect an EPM participant to make of the beneficiary-identifiable data and would be permissible under the HIPAA Privacy Rule. Moreover, our proposed disclosures would be made only to HIPAA covered entities that have (or had) a relationship with the subject of the information, the information we would disclose would pertain to such relationship, and those disclosures would be for purposes listed in the first two paragraphs of the definition of "health care operations."

When using or disclosing PHI, or when requesting this information from another covered entity, covered entities must make "reasonable efforts to limit" the information that is used, disclosed or requested to a "minimum necessary" to accomplish the intended purpose of the use, disclosure or request (45 CFR 164.502(b)). We believe that the provision of the proposed data elements listed previously would constitute the minimum data necessary to accomplish the EPM's goals of the participant hospital.

The Privacy Act of 1974 also places limits on agency data disclosures. The Privacy Act applies when the federal government maintains a system of records by which information about individuals is retrieved by use of the individual's personal identifiers (names, Social Security numbers, or any other codes or identifiers that are assigned to the individual). The Privacy Act prohibits disclosure of information from a system of records to any third party without the prior written consent of the individual to whom the records apply (5 U.S.C. 552a(b)).

"Routine uses" are an exception to this general principle. A routine use is a disclosure outside of the agency that is compatible with the purpose for which the data was collected. Routine uses are established by means of a publication in the **Federal Register** about the applicable system of records describing to whom the disclosure will be made and the purpose for

the disclosure. We believe that the proposed data disclosures are consistent with the purpose for which the data discussed in the proposed rule was collected and may be disclosed in accordance with the routine uses applicable to those records.

We note that, as is the case with CJR, in this proposed rule, we propose to disclose beneficiary-identifiable data to only the hospitals that are bearing risk for an AMI, CABG, or SHFFT episode and not with their collaborators. As stated in the final CJR rule (80 FR 73515), we believe that the hospitals that are specifically held financially responsible for an episode should make the determination as to which data are needed to manage care and care processes with their collaborators as well as which data they might want to re-disclose, if any, to their collaborators provided they are in compliance with the HIPAA Privacy Rule. We note that beneficiaries have the right to request restrictions on the use of their data in accordance with the HIPAA Privacy Rule, but covered entities are not required to agree to such requests.

We believe our data sharing proposals are permitted by and are consistent with the authorities and protections available under the aforementioned statutes and regulations. We seek comments on our proposals regarding the authority to share beneficiary-identifiable data.

7. Data Considerations with Respect to EPM and CJR Collaborators

As noted earlier in this section and as is the case with CJR (80 FR 73515), we propose to disclose beneficiary-identifiable data to only the EPM participants that are bearing risk for an AMI, CABG, or SHFFT episode and not with their collaborators because we believe that the EPM participants that are specifically held financially responsible for an episode should make the determination as to which data are needed to manage care and care processes with their collaborators as well as which data they might re-disclose in accordance with applicable privacy and security laws. Based on our experience in implementing the CJR, however, we understand

that some CJR collaborators under that model believe that not having comparable data poses challenges to their ability to assess their own performance in the context of the model and the region in which they operate. As such, these collaborators believe that it would helpful to have additional data with which they could better assess their own performance, including information about care patterns within their region.

We are considering ways in which to address the concerns raised by these CJR collaborators and potentially similar future concerns that could arise among EPM collaborators as well as what additional data might be helpful for these purposes and which could be disclosed in accordance with existing statutory and regulatory requirements. As previously discussed, EPM participants, like CJR participants, may share data with their EPM (or CJR) collaborators provided they are "business associates" in compliance with the HIPAA Privacy Rule, and we encourage them to make data available to their EPM collaborators to the extent they deem it appropriate and in compliance with these strictures.

In addition, given our view that the HIPAA Privacy Rule limits our ability to share beneficiary-identifiable data with non-EPM (or non-CJR) participants, we are considering whether it would be feasible and appropriate to make additional non-beneficiary-identifiable aggregate data publicly available through some means. For example, we are exploring whether it would be helpful to make available aggregate summary data organized by anchor MS-DRG, provider type, and region for care that would be included in episodes that would meet the criteria for inclusion in the regional component of EPM (or CJR) episode benchmark prices as described in section III.D.4.b. of this proposed rule (or 80 FR 73337 with respect to CJR), assuming all IPPS hospitals nationally were EPM (or CJR) participants. We will refer to these episodes as

simulated episodes later in this section. We are interested in whether information such as the following would be helpful to EPM (or CJR) collaborators:

- Number of simulated episodes and number of hospitals with each anchor MS-DRG at discharge in the simulated episodes.
- For AMI model anchor MS-DRGs, the number of simulated episodes with chained anchor admissions by the price MS-DRG that would have been assigned to the simulated episode.
- For AMI model anchor MS-DRGs, the number of simulated episodes with readmissions resulting in discharge under a CABG MS-DRG by the CABG MS-DRG.
- Average (mean and median) and standard deviation of total spending on those simulated episodes.
- Number of simulated episodes with and mean acute care payments for the anchor hospitalization and readmission.
- Number of simulated episodes with and mean Part B payments.
- Number of simulated episodes with and mean inpatient rehabilitation facility payments.
- Number of simulated episodes with and mean skilled nursing facility payments.
- Number of simulated episodes with and mean home health payments.
- Proportion of total simulated episode spending attributable to acute care payments for the anchor hospitalization and readmissions.
- Proportion of total simulated episode spending attributable to Part B payments.
- Proportion of total simulated episode spending attributable to inpatient rehabilitation facility payments.

- Proportion of total simulated episode spending attributable to skilled nursing facility payments.
- Proportion of total simulated episode spending attributable to home health payments.

To assist us as we consider future options for potentially increasing the availability of data to collaborators under the EPMs or similar models such as CJR, we seek comments on what kinds of actions and data would be most helpful to EPM, or similar model (such as CJR) collaborators, and which could be disclosed in accordance with the existing statutory and regulatory requirements for sharing data.

L. Coordination with Other Agencies

Impacts created by payment changes under this model are entirely internal to HHS operations; coordination with other agencies is not required outside of the usual coordination involved in the publication of all HHS regulatory changes.

IV. Evaluation Approach

A. Background

The proposed EPMs are intended to enable CMS to better understand the effects of episode payments approaches on a broader range of Medicare providers and suppliers than would choose to participate in a voluntary model such as is currently being tested under BPCI. Obtaining information that is representative of a wide and diverse group of episode initiators will best inform us on how such a payment model might function were it to be more fully integrated within the Medicare program. The proposed CR incentive model is intended to enable CMS to assess whether the proposed incentive improves patient quality and access to this covered benefit without increasing overall payments. All CMS models, which would include the proposed EPMs and CR incentive model, are rigorously evaluated on their ability to improve quality and reduce costs. In addition, we routinely monitor CMS models for potential unintended consequences of the model that run counter to the stated objective of lowering costs without adversely affecting quality of care. Outlined in the following section are the proposed design and evaluation methods, the data collection methods, key evaluation research questions, and the evaluation period and anticipated reports for the proposed EPMs.

B. Design and Evaluation Methods

Our evaluation methodology for the EPMs and CR incentive model would be consistent with the standard Innovation Center evaluation approaches we have taken in other projects such as the BPCI initiative, the Continuous Care for Joint Replacement (CJR) model[107], the Acute Care Episode (ACE) Demonstration, Pioneer ACO model, and other Innovation Center models. Specifically, the evaluation design and methodology would be designed to allow for a

[107] https://innovation.cms.gov/initiatives/cjr

comparison of historic patterns of care among the participant to any changes made in these patterns in response to the proposed models. In addition, the overall design would include a comparison of participants in EPM or CR areas with a matched comparison group in areas not participating in a specific episode to help us discern simultaneous and competing provider and market level forces that could influence our findings. Comparison group members for the EPMs would be selected based on how well they match the EPM participants along a variety of measurable dimensions, such as size, expenditures, and other provider characteristics and market characteristics. The random method of selection for participating MSAs will allow the evaluation to observe the operation of the model in a variety of circumstances and among providers and suppliers who may not otherwise choose to participate in a voluntary payment model.

We plan to use a range of analytic methods, including regression and other multivariate methods, and difference-in-differences methods to examine each of our measures of interest. Measures of interest could include, for example, quality of and access to care, utilization patterns, expenditures, and beneficiary experience. With these methodologies, we would be able to examine the experience over time relative to those in the comparison groups controlling for as many of the relevant confounding factors as is possible. The evaluation would also include rigorous qualitative analyses in order to capture the evolving nature of the care model interventions.

In our design, we plan to take into account the impact of the proposed models at the geographic unit level, the hospital level, and at the patient level. We are also considering various statistical methods to address factors that could confound or bias our results. For example, we would use statistical techniques to account for clustering of patients within hospitals and

markets. Clustering allows our evaluation to compensate for commonalities in beneficiary outcomes by hospitals and by markets. Thus, in our analysis, if a large hospital consistently has poor performance, clustering would allow us to still be able to detect improved performance in the other, smaller hospitals in a market rather than place too much weight on the results of one hospital and potentially lead to biased estimates and mistaken inferences. Finally, we plan to use various statistical techniques to examine the effects of the proposed models while also taking into account the effects of other ongoing interventions such as BPCI, Pioneer ACOs, and the Shared Savings Program. For example, we are considering additional regression techniques to help identify and evaluate the incremental effects of adding the EPMs in areas where patients and market areas are already subject to these other interventions as well as potential interactions among these efforts.

C. Data Collection Methods

We are considering multiple sources of data to evaluate the effects of the proposed EPM and CR Incentive models. We expect to base much of our analysis on secondary data sources such as the Medicare FFS claims. The beneficiary claims data would provide information such as use of CR, expenditures in total and by type of provider and service as well as whether or not there was an inpatient hospital readmission or a subsequent AMI. In conjunction with the secondary data sources mentioned previously, we are considering a CMS-administered survey of beneficiaries who received a qualifying procedure during the performance period in the EPM evaluation. This survey would be administered to beneficiaries who were in the EPM qualifying episode or similar patients selected as part of a control group. The primary focus of this survey would be to obtain information on the beneficiary's experience in EPMs' episodes relative to usual care. The administration of this beneficiary survey would be coordinated with

administration of the HCAHPS survey so as to not conflict with or compromise HCAHPS efforts. For the evaluation of both the EPMs and the CR incentive model, we are considering a survey administered by CMS and guided interviews conducted by CMS with providers and suppliers including, but not limited to, initiating and transfer hospitals, physicians, and post-acute care providers participating in the proposed models. These surveys would provide insight on providers' experience under the model and further information on the care redesign strategies undertaken.

In addition, we are considering CMS evaluation contractor administered site visits and focus groups with selected hospitals, physicians, and post-acute care providers in EPM and CR evaluation efforts. We believe that these qualitative methods would provide contextual information that would help us better understand the dynamics and interactions occurring among participants. For example, these data could help us better understand hospitals' intervention plans as well as how they were implemented and what they achieved. Moreover, in contrast to relying on quantitative methods alone, qualitative approaches would enable us to view program nuances as well as identify factors that are associated with successful interventions and distinguish the effects of multiple interventions that may be occurring, such as simultaneous ACO and bundled payment participation.

We anticipate that secondary data sources will be the source of most if not all data collection for the FFS-non CR control group; however, we may initiate some data collection from primary data sources for this group if warranted.

D. Key Evaluation Research Questions

Our evaluation would assess the impact of the proposed models on the aims of improved care quality and efficiency as well as reduced health care costs. This would include assessments of

patient experience of care, utilization, outcomes, Medicare expenditures, quality, and access. Our key evaluation questions would include, but would not be limited to, the following:

- PAYMENT. Is there a reduction in Medicare expenditures in absolute terms? By subcategories? Do the participants reduce or eliminate variations in utilization and/or expenditures that are not attributable to differences in health status? If so, how have they accomplished these changes?

- UTILIZATION. Are there changes in Medicare utilization patterns overall and for specific types of services? How do these patterns compare to matched comparators, historic patterns, regional variations, and national patterns of care? How are these patterns of changing utilization associated with Medicare payments, patient outcomes, and general clinical judgment of appropriate care? For example, in the AMI and CABG episodes, what changes to hospital transfer patterns, if any, could be seen under the models? Has there been any changes to utilization of cardiac rehabilitation services and does this appear to be associated with access to the cardiac rehabilitation incentive payment, participation in the cardiac EPMs or a combination of the two?

- REFERRAL PATTERNS AND MARKET IMPACT. How has the behavior in the selected MSAs changed under the models? Have the referral patterns of type and specific providers changed?

- OUTCOMES/QUALITY. Is there either a negative or positive impact on quality of care and/or better patient experiences of care? Did the incidence of relevant clinical outcomes including but not limited to complications, mortality, readmissions and other subsequent clinically relevant events, and beneficiary pain, functioning, and independence experiences remain constant or decrease? Were there changes in beneficiary outcomes under the models

compared to appropriate comparison groups? Was there an impact on quality during the episode/CR care period or in the period immediately preceding or following the episode/CR care period? Was there an impact on measures of relevant long term quality such as mortality at one year after the initiating event?

- UNINTENDED CONSEQUENCES. Did the proposed models result in any unintended consequences, including adverse selection of patients, access problems, cost shifting beyond the episode/CR care period, evidence of delay or stinting of appropriate care, anti-competitive effects on local health care markets, or evidence of inappropriate referrals practices? 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 proposed intervention;

++ The characteristics of the providers and suppliers serving patients during the entirety of the episode or CR care period and the nature of the interaction of these providers and suppliers with the EPM or CR participants;

++ The characteristics of the markets and MSAs, and

++ The clinical and socio-demographic characteristics associated with the patient populations served.

E. Evaluation Period and Anticipated Reports

As discussed in section III.B, the proposed models have a 5-year performance period. The evaluation periods would encompass this entire 5-year period and up to 2 years after. We plan to evaluate the proposed models on an annual basis. We recognize, however, that interim results are subject to issues such as sample size and random fluctuations in practice patterns. Hence, while CMS intends to have internal periodic summaries to offer useful insight during the course of the effort, a final analysis after the end of the 5-year performance period will be important for ultimately synthesizing and validating results.

We seek comments on our design, evaluation, data collection methods, and research questions.

V. Comprehensive Care for Joint Replacement Model

A. Participant Hospitals in the CJR Model

In the CJR proposed rule (80 FR 41207), we proposed to require that all hospitals paid under the IPPS that are physically located in a county in an MSA selected for participation in the CJR model would be required to participate. In the final rule (80 FR 73288), we finalized this proposal, noting that we would use the primary physical address associated with a hospital's CCN to identify whether or not a given hospital was physically located in an MSA selected for participation. In response to a commenter's inquiry as to whether all hospitals under a CCN would be required to participate in CJR if a CCN included multiple hospital campuses and some of these campuses were physically located in the MSA while others were not, we stated that since CMS tracks and identifies hospitals using the CCN, all hospital locations associated with that CCN would be required to participate in the model. In order to identify hospitals located in the MSAs selected to participate in the CJR model, we utilize the primary physical address associated with the CCN. In cases where a CCN is associated with multiple hospital campuses, if the primary CCN address is located in a selected MSAs, all hospital campuses associated with that CCN would be required to participate in CJR unless otherwise excluded. We also noted that our initial analysis of the acute care hospitals in the MSAs selected to participate in CJR indicated that none of the CCNs in the MSAs selected for CJR included multiple campuses crossing MSA boundaries. That is, none of the CCNs with a primary physical address in one of the selected MSAs had multiple campuses physically located in different MSAs that would result in inclusion of a hospital campus not physically located in a selected MSA.

We are not aware of any participant hospitals currently in the CJR model that are not physically located in one of the 67 MSAs chosen to participate in CJR. However, given the

comments we received from the public on the CJR proposed rule (80 FR 41207) and questions from stakeholders during our implementation of the CJR model, we note here that if a hospital that is not physically located in one of the 67 MSAs participating in CJR bills under a CCN with a primary address in one of the 67 CJR MSAs, whether through a merger or other organizational change, that hospital will be considered a CJR participant as of the date in which the hospital began to bill under the CCN address located within the 67 MSAs. This policy has been in effect since the start of the CJR model on April 1, 2016 and is laid out at 42 CFR §510.2 (definition of participant hospital).

B. Inclusion of Reconciliation and Repayment Amounts when Updating Data for Quality-Adjusted Target Prices

In response to the CJR proposed rule, commenters encouraged us to include reconciliation payments in updated historical episode spending totals when calculating quality-adjusted target prices for performance years 3 and 4 (based on spending for episodes beginning in years 2014 through 2016) and performance year 5 (based on spending for episodes beginning in 2016 through 2018). (Note that we propose to replace the term "target price" with the term "quality-adjusted target price," as described further in section V.C.) Commenters were concerned that if we excluded those payments, we would not account for care coordination services that are not paid for under Medicare FFS, but that participant hospitals paid for using reconciliation payments. As a result, we would underestimate hospital costs and prices by not accounting for care coordination services paid for with reconciliation payments. We finalized our proposal to exclude reconciliation payments from expenditure data, noting our view that including reconciliation payments would result in Medicare paying participant hospitals their quality-adjusted target price, regardless of whether the participant hospital's expenditures were

above or below that price. We also noted that we had not proposed an alternative in our proposed rule, and that we might consider including reconciliation payments in updating the set of historical years used to calculate quality-adjusted target prices through future rulemaking (80 FR 73332).

Based upon our further consideration, we propose to include both reconciliation payments and repayments in our calculations when updating quality-adjusted target prices for performance years 3 and 4 and performance year 5. We want to encourage hospitals to invest in novel ways of coordinating care and improving quality, and we recognize that such activities are not directly reimbursed by Medicare. We agree that including reconciliation payments would more fully recognize the total costs of care under an episode payment model than would excluding those payments. The number of comments we previously received on this topic indicates that excluding reconciliation payments could discourage such investment, due to concerns that quality-adjusted target prices would underestimate the true cost of care. Although including the entire reconciliation payment in our updated quality-adjusted target price calculations could result in overpaying for care coordination services, the impact of including these payments on quality-adjusted target prices will decrease as we move to regional pricing. In addition, we believe our proposal to also include repayment amounts when updating historical data used to calculate quality-adjusted target prices would mitigate any potential overpayment for care coordination services.

In addition, we propose to include in regional historical episode payments any reconciliation payments and repayment amounts from historical BPCI LEJR episodes initiated at regional hospitals in order to most fully capture the total costs of care under episode payment models. If we included reconciliation payments and repayment amounts for CJR episodes but

not BPCI LEJR episodes, we would likely underestimate the regional total costs of care to hospitals, which would result in artificially lowered quality-adjusted target prices for participant hospitals, in effect penalizing participant hospitals. By including these amounts from both initiatives we will avoid distorting the regional component of historical LEJR episode spending, which will be especially important once we move to setting prices based on 100 percent regional episode data in performance year 4 of the model. This policy mirrors our proposal to include these reconciliation payments and repayment amounts when updating the historical periods used for EPM quality-adjusted target prices; we refer readers to section III.D.3.e. of this proposed rule for further discussion of our rationale for proposing this approach.

We propose to amend our regulations to add a new subsection §510.3(b)(8) to reflect this proposal. We seek comment on our proposal.

C. Quality-Adjusted Target Price

We propose to change the term we use to refer to a CJR participant hospital's episode benchmark price incorporating the effective discount factor based on the participant hospital's quality category to "quality-adjusted target price." This term will replace our prior term, "episode target price," which referred to the episode benchmark price with a 3 percent discount applied. The term quality-adjusted target price would represent the price used at reconciliation to determine whether a CJR participant hospital is eligible for a reconciliation payment or repayment, and the amount of the reconciliation payment or repayment. To clarify, this change would be a change of terminology to more accurately reflect the impact of quality scores on the reconciliation process, and would not change the actual data that hospitals receive. In addition, our proposal to replace the term "episode target price" with "quality-adjusted target price"

mirrors the terminology for the proposed EPMs and would reduce confusion for hospitals participating in more than one model.

In accordance with 42 CFR §510.300(b)(7), CMS provides prospective prices to CJR participant hospitals prior to the performance period in which they apply, incorporating the 3 percent discount that would apply if the hospital is eligible for a reconciliation payment and achieves an "Acceptable" composite quality score category. As discussed in the CJR final rule, a hospital's effective discount percentage may be reduced at reconciliation to account for quality performance (80 FR 73378). At the conclusion of a performance year, CMS will calculate a composite quality score for each hospital, which determines the effective discount percentage at reconciliation. The CJR final rule outlines the relationship between the composite quality score and the effective discount percentage (80 FR 73365). That is, a participant hospital may be eligible to earn a greater reconciliation payment or have a lower repayment amount as a result of its quality performance under the model (80 FR 73378). Hospitals are therefore aware that a different effective discount factor, and thus different quality-adjusted target price, may be utilized at reconciliation to reflect their quality performance under the model, and they could easily estimate the range of potential quality-adjusted target prices that could apply at reconciliation.

We also wish to clarify the terminology we use to describe the discount factor included in the quality-adjusted target price. The discount factor included in the quality-adjusted target price based on the quality score is referred to as the "effective discount factor." In contrast, the discount factor used to determine repayment amounts in performance years 2 and 3, during which repayment responsibility is being phased in and a lower discount factor applies for purposes of calculating repayment amounts will be referred to as the "applicable discount

factor." In performance years 2 and 3, the effective discount factor would continue to apply for hospitals that qualify for and earn a reconciliation payment; the applicable discount factor would only be applied in those cases where a hospital exceeded expected episode spending and would be responsible for repayment.

We propose to implement these terminology changes in all communications with participant hospitals 60 days after the change is finalized. We propose to establish these definitions in the regulations at §510.2 and update our regulations at §510.300 and §510.315 to reflect our use of the term "quality-adjusted target price" in lieu of "episode target price" and our use of the term "applicable discount factor."

D. Reconciliation

1. Hospital Responsibility for Increased Post-Episode Payments

As discussed in the CJR final rule, participant hospitals will be responsible for repaying Medicare for post-episode spending that exceeds 3 standard deviations from the regional mean (80 FR 73408). We refer readers to the CJR final rule (80 FR 73407) for further discussion of our rationale for holding participant hospitals financially accountable for significant increases in Medicare Parts A and B spending during the 30 days after a CJR episode ends. We also finalized a policy to include the result of our post-episode spending calculation (the amount exceeding 3 standard deviations above the regional mean) in a participant hospital's NPRA for a given performance year; as a result, a hospital's financial responsibility for post-episode spending would be subject to the stop-loss and stop-gain limits we finalized for the CJR model (80 FR 73398).

We propose to modify our policy to hold hospitals responsible for post-episode payments that exceed 3 standard deviations from the regional mean. First, we propose to calculate

post-episode payments using the same timeframes we use for the subsequent reconciliation calculation, not when we conduct the initial reconciliation for a performance year (80 FR 73383). Given that we will begin reconciliation calculations 2 months after the conclusion of a performance year, we do not believe there would be sufficient time for claims run-out in order to set a reliable regional threshold for determining post-episode spending. Since in all cases any responsibility for post-episode payments would decrease a participant hospital's reconciliation payment or increase its repayment amount, our proposed change would more accurately and fairly hold hospitals accountable for increased post-episode spending. We believe instances in which a CJR participant hospital is responsible for post-episode spending repayment will be rare, given our belief that hospitals in the CJR model will focus on care redesign during the LEJR episode and our other monitoring efforts under the CJR model. Our intent is to prevent hospitals from delaying services or care until the conclusion of a CJR episode by monitoring for cases in which hospitals have significantly increased spending in the 30 days following the episode. Assessing post-episode spending when we have more complete claims information would allow a more accurate assessment of hospitals' behavior under the model and prevent potentially high fluctuations in results that may occur if we calculate regional thresholds and hold hospitals responsible for post-episode spending beginning 2 months after the conclusion of a performance year. We propose that this modified timeline would be applied to our reconciliation of the first CJR performance year and all performance years thereafter. That is, we would assess post-episode spending for the first performance year (episodes beginning and ending between April 1, 2016 and December 31, 2016) when we conduct the reconciliation for the second CJR performance year (2017) in early 2018.

We also propose that hospital responsibility for post-episode spending will not be subject to the stop-loss and stop-gain limits. Although we believe, as noted previously, that hospital responsibility for post-episode spending will be rare, we also believe that in those cases where a hospital has financial responsibility for post-episode spending, such hospitals should be responsible in full for these amounts. The CJR model includes stop-loss limits, including more generous limits for certain types of hospitals (80 FR 73403), which are designed to limit a participant hospital's responsibility for episode spending above the quality-adjusted target price during the anchor hospitalization and 90-day post-discharge period. The stop-loss limits are not intended to protect hospitals that engage in inappropriate behavior or shifting of care beyond the episode from financial responsibility for such actions.

We propose to implement this policy change when we conduct the subsequent reconciliation calculation for performance year 1 of the model in the first 2 quarters of 2018 and for all performance years thereafter. That is, when we conduct the reconciliation for performance year 1 in early 2017, we would not assess post-episode spending for performance year 1 at that time. Although hospitals would not have been aware of these proposed changes to our reconciliation process during performance year 1 of the model, the proposed changes will not impact the performance year 1 NPRA.

We propose to amend our regulations at §510.305(e), §510.305(h)(6), and add a new paragraph §510.305(j)(2) to reflect these proposals. We seek comment on our proposal.

2. ACO Overlap and Subsequent Reconciliation Calculation

In the CJR final rule, we finalized a policy to account for overlap in situations where a portion of the CJR discount percentage is paid out as savings to an ACO participating in the Shared Savings Program or specified ACO models. We refer readers to the CJR final rule for

further discussion of this policy and our rationale for this approach (80 FR 73395-73398). We propose a modification to how we will account for such cases of overlap in the CJR model at reconciliation. In the final CJR rule, we specified that the results of this overlap calculation would be included in the subsequent reconciliation calculation that occurs 14 months after the conclusion of a performance year (80 FR 73383). We propose that the subsequent reconciliation calculation not include the results of this ACO overlap calculation; that is, the subsequent reconciliation calculation will only include calculating the prior performance year's episode spending a second time with more complete claims data and comparing it to the quality-adjusted target price. The ACO overlap calculation will be a separate calculation from the subsequent reconciliation (although both calculations will occur concurrently) and added with the NPRA, subsequent reconciliation calculation, and post-episode spending calculation to determine the reconciliation payment or repayment amount at reconciliation. The effect of this proposal will be that these overlap amounts will not be subject to the stop-loss or stop-gain limits that apply to the calculation of the NPRA and subsequent reconciliation calculation. We believe this change is appropriate because the subsequent reconciliation calculation is intended to account for claims run-out and canceled episodes, and to reassess CJR episode spending during the model performance years. The stop-loss limit, therefore, is intended to ensure that participant hospitals that do not reduce actual episode payments below the quality-adjusted target price have a limit on the amount they must repay Medicare due to spending during CJR episodes. The stop-gain limit, conversely, is intended to place judicious limits on the degree to which hospitals can be rewarded based on responsible stewardship of CMS resources. In contrast, the ACO overlap calculation is intended to account for cases in which a portion of the CJR discount percentage is paid out to an ACO as shared savings, and does not hinge upon a participant hospital's

performance in the CJR model. If ACO overlap amounts are included in calculations of the stop-loss limit, CMS could in some cases pay twice for the same cost-reducing activities, thereby skewing the model results. We believe the stop-loss and stop-gains should provide limits on the amount a hospital could earn or lose due to episode spending, not limit CMS's ability to adjust for overlap between models. For these reasons, we do not believe our policy to avoid paying out savings twice for the same beneficiary during the same period should be subject to the stop-loss or stop-gain limits. More details on how this proposed modification will impact the steps involved in the reconciliation process are provided further in this section.

We propose to implement this proposed policy change when we conduct the subsequent reconciliation calculation for performance year 1 of the model in the first 2 quarters of 2018 and for all performance years thereafter. Although hospitals would not have been aware of these proposed changes to our reconciliation process during performance year 1 of the model, we believe this timeframe is reasonable for the following reasons. First, if CMS must recoup a portion of the CJR discount percentage paid out as shared savings, this calculation must occur during the same timeframe as the subsequent reconciliation calculation for a given performance year to ensure that the ACO models and program have already completed their financial reconciliation for a given performance year. Second, this policy change (that is, not including the ACO overlap calculation in assessing whether a hospital has met the stop-loss or stop-gain limit for a given year) will not impact the performance year 1 NPRA.

We propose to add a new paragraph to our regulations at §510.305(i). We seek comment on our proposal.

3. Stop-Loss and Stop-Gain Limits

In the CJR final rule, we finalized our proposal to limit the amount a CJR participant hospital will be required to repay Medicare or could earn as a reconciliation payment under the CJR model. Specifically, we stated that CJR participant hospitals would be subject to the following stop-loss limits: 5 percent in performance year 2, 10 percent in performance year 3, and 20 percent in performance years 4 and 5. Similarly, we finalized symmetrical stop-gain limits: 5 percent in performance years 1 and 2, 10 percent in performance year 3, and 20 percent in performance years 4 and 5 (80 FR 73401 through 73402). We finalized separate limits to provide additional financial protections for rural hospitals, Medicare-dependent hospitals, rural referral centers, and sole community hospitals (80 FR 73406). These limits are intended to provide financial protections for CJR participant hospitals, who may have varying levels of experience with episode payment models. We finalized symmetrical stop-gain limits to ensure hospitals do not have an incentive to excessively reduce services provided during episodes or shift services outside the CJR episode (80 FR 73398). As noted previously in this section, we are proposing a modification to our application of the stop-loss and stop-gain limits for the CJR model by excluding the post-episode spending amount and situations in which the CJR discount percentage is paid out to an ACO as shared savings.

In light of our proposal to exclude the ACO overlap and post-episode spending adjustments from the stop-loss and stop-gain limits, to calculate the stop-loss and stop-gain limits, we would use a hospital's quality-adjusted target price at reconciliation. For example, a hospital with benchmark episode spending of $30,000 and a composite quality score of "excellent," would have an effective discount percentage of 1.5 percent and a quality-adjusted target price of $29,550 at reconciliation. The hospital's stop-loss and stop-gain limits for year 2 (assuming for simplicity that the hospital has only 1 episode) would be 5 percent of the

quality-adjusted target price, or $1,477.50. This is consistent with our proposed calculation of stop-loss and stop-gain limits for the proposed EPMs described in section III.C. of this proposed rule. This approach is also consistent with our regulations at §510.305(e)(1)(v)(A) and §510.305(e)(1)(v)(B) to calculate stop-loss and stop-gain based on the effective discount factor at reconciliation.

In order to determine whether a participant hospital has reached the stop-loss or stop-gain limits, we would compare actual episode payments during the performance year to the quality-adjusted target price to calculate the NPRA. In the example previously noted, if the participant hospital had actual episode spending of $35,000 during performance year 2, this would be compared against its quality-adjusted target price of $29,550. The difference between the quality-adjusted target price and actual episode spending is $5,450, but since the applicable stop-loss limit is $1,477.50, the hospital would need to repay Medicare $1,477.50. In this example, any post-episode spending amount or adjustment for ACO overlap from the prior performance year (performance year 1 in this example) would not be included in determining whether a hospital has met the stop-loss or stop-gain limit for a performance year, but rather would be added, unadjusted, to the performance year 2 NPRA in order to calculate the reconciliation payment or repayment amount. Therefore, if the hospital in this example owed $1,000 due to post-episode spending in performance year 1, and we determined that $2000 represented the CJR discount percentage that was paid out as shared savings for performance year 1, the full $3000 would be added to the hospital's performance year 2 NPRA regardless of stop-loss, resulting in a repayment of $4,477.50. In addition, when performing the subsequent reconciliation calculation for performance year 2, which would be done simultaneously with the calculation of NPRA for performance year 3, we would apply the results of the performance year

2 subsequent reconciliation calculation to the year 2 stop-loss limit of $1,477.50 to ensure that, aggregated across all episodes in the performance year, the participant hospital is not responsible for repaying Medicare more for episode spending above the quality-adjusted target price than the stop-loss limit for that performance year. Thus, if the subsequent reconciliation calculation determined that the hospital in our example had actually spent $36,000 during performance year 2, resulting in a larger difference between actual spending and the quality-adjusted target price, the higher amount of $6,450 would still be subject to the stop-loss limit of $1,477.50, so the hospital would not be responsible for the additional $1,000 of episode spending beyond the quality-adjusted target price.

As discussed previously in this section, we are proposing to implement these changes to our reconciliation process beginning with the reconciliation for performance year 1.

We are proposing to amend our regulations at §510.305(e), §510.305(f), and add a new paragraph (j) to reflect these proposals. We also propose to streamline §510.305(i)(2) for clarity.

We seek comment on our proposal.

4. Proposed Modifications to Reconciliation Process

As previously discussed in this section, we are proposing several modifications to how we conduct the reconciliation process for participant hospitals in the CJR model for all performance years. We propose here how these steps would modify the CJR reconciliation process we finalized in the CJR final rule (80 FR 73383).

The following example illustrates our proposed modifications to the reconciliation process, reflecting our proposals to compare actual episode payments to the quality-adjusted target price; calculate post-episode spending beginning 14 months after the conclusion of a performance year; calculate post-episode spending amounts and the ACO overlap calculation

separately from the NPRA and subsequent reconciliation calculation; and apply the stop-loss and stop-gain limits only to calculations of NPRA and the subsequent reconciliation calculation (that is, exclude post-episode spending amounts and the ACO overlap calculation) for a given performance year:

Beginning 2 months after the conclusion of performance year 2, CMS would compare actual episode payments to the quality-adjusted target prices for the episodes at a CJR participant hospital. The quality-adjusted target price that applies at reconciliation would be based on a participant hospital's composite quality score for performance year 2. We would aggregate episodes at each CJR participant hospital and calculate the hospital's NPRA. The NPRA would be the difference between the quality-adjusted target price times the number of episodes and actual episode payments times the number of episodes during the performance year. We would apply the stop-gain and stop-loss limits of 5 percent of the quality-adjusted target price to determine if a hospital reached the limit.

We would simultaneously perform the subsequent reconciliation calculation for performance year 1, to account for claims run-out and canceled episodes from performance year 1. At this time, we would reapply the stop-gain limit for performance year 1, by summing the result of the subsequent reconciliation calculation for performance year 1 and the performance year 1 NPRA (which was calculated during the prior reconciliation). For example, if the participant hospital's NPRA for performance year 1 was greater than the stop-gain limit and the result of the subsequent reconciliation calculation for performance year 1 was positive, the subsequent reconciliation calculation would not be added to the reconciliation payment made to the participant hospital in the second quarter of 2018, because the stop-gain limit had already been reached for performance year 1.

Concurrently with our subsequent reconciliation calculation, we would also determine if a participant hospital is responsible for post-episode spending from performance year 1, as well as determine any potential amount of the CJR discount percentage that was paid out as savings to an ACO entity as previously described in this section during performance year 1. In this example, the results of all three calculations (the subsequent reconciliation calculation for performance year 1 -- subject to the stop-loss and stop-gain limits -- and the post-episode spending calculation and ACO overlap calculation) would be added to the NPRA calculated for performance year 2 in order to create the reconciliation payment or repayment amount. (The exception to this pattern will be performance year 5, as the subsequent reconciliation, post-episode spending, and ACO overlap calculations will occur in 2022 without a concurrent NPRA calculation.)

We note that this approach mirrors the reconciliation process we are proposing for the AMI, CABG, and SHFFT models at III.D.5. of this proposed rule. We refer readers to that section for additional discussion of our approach.

E. Use of Quality Measures and the Composite Quality Score

1. Hospitals included in quality performance distribution

As finalized in the CJR final rule, CMS computes quality performance points for each quality measure based on the participant hospital's performance percentile relative to the national distribution of all hospitals' performance on that measure. We propose to compute quality performance points for each quality measure based on the participant hospital's performance relative to the distribution of performance of all "subsection (d)" hospitals reporting the measure that are eligible for payment under IPPS and meet the minimum patient case or survey count for that measure. This approach is similar to the methodologies of other

CMS programs, such as the HVBP Program. In addition, comparing CJR participant hospitals' quality performance to IPPS-eligible subsection (d) hospitals' quality performance on the same measures is a fairer comparison of quality performance, as CJR participant hospitals are all IPPS-eligible subsection (d) hospitals. Defining and limiting the relative distribution in this way will minimize variability due to factors that are unrelated to quality, thereby increasing the validity of the quality performance score.

We propose to amend the regulations at §510.315(c) to reflect this change. We are also proposing a technical change to the regulations to renumber certain subparagraphs. We seek comment on our proposals.

2. Quality improvement points

As finalized in the CJR final rule, quality improvement points for each measure are added to the composite quality score if the hospital's score on that quality measure increases by at least 3 deciles on the performance percentile scale compared to the previous performance year. We propose to clarify that, for performance year 1, we will compare the hospital's performance percentile with the corresponding time period in the previous year, not the previous performance year. We are proposing this clarification because there is no performance year preceding performance year 1. For performance years 2 through 5, we will still compare the hospital's performance percentile with the previous performance year. We also propose to modify this policy to define quality measure improvement as an increase of at least 2 deciles on the performance percentile scale compared to the previous performance year. Reducing the threshold for improvement from 3 deciles to 2 deciles will increase the number of CJR participant hospitals eligible for quality improvement points and provide CJR participant hospitals at all current levels of quality performance, including those historically lagging, with

significant incentives to achieve improvement in the quality of care. Quality improvement points can contribute up to 1.8 points toward a CJR participant hospital's composite quality score, so increasing the number of CJR participant hospitals that are eligible for these points may also increase the number of CJR participant hospitals that are eligible for a reduced quality-adjusted target price. As defined in section V.C. of this proposed rule, the quality-adjusted target price is the price used at reconciliation to determine whether a CJR participant hospital is eligible for a reconciliation payment or repayment and the amount of the reconciliation payment or repayment. This mirrors the approach we are proposing for the proposed EPMs at III.E.3.c. of this proposed rule.

We propose to amend our regulations at § 510.315(d) to reflect these changes. We seek comment on our proposal.

3. Relationship of composite quality score to quality categories

As finalized in the CJR final rule, CMS will place participant hospitals into one of four quality categories to determine reconciliation payment eligibility and, if applicable, the value of the effective discount percentage at reconciliation. We refer readers to the CJR final rule for a full discussion of our approach (80 CFR 73363-73381). We describe here a technical correction to our composite quality scores that will determine reconciliation payment eligibility and the effective discount percentage at reconciliation. We note that this technical correction does not affect our estimation of savings due to the CJR model, because the measure distribution used for such calculations in the CJR final rule was the correct one we describe here.

Participant hospitals will be required to achieve a minimum composite quality score of greater than or equal to 5.0 to be eligible for a reconciliation payment if actual episode spending is less than the target price. Participant hospitals with a composite quality score less than 5.0

will be assigned to the "Below Acceptable" quality category and will not be eligible for a reconciliation payment if actual episode spending is less than the target price. Participant hospitals with a composite quality score greater than or equal to 5.0 and less than 6.9 will be assigned to the "Acceptable" quality category and will be eligible for a reconciliation payment if actual episode spending is less than the target price. Participant hospitals in the "Acceptable" quality category will not be eligible to receive a reduced effective discount percentage at reconciliation. Participant hospitals with a composite quality score greater than or equal to 6.9 and less or equal to 15.0 will be assigned to the "Good" quality category and will be eligible for a reconciliation payment if actual episode spending is less than the target price. Participant hospitals in the "Good" quality category will be eligible to receive a reduced effective discount percentage (80 FR 73378). Participant hospitals with a composite quality score greater than 15.0 will be assigned to the "Excellent" quality category and will be eligible for a reconciliation payment if actual episode spending is less than the target price. Participant hospitals in the "Excellent" quality category will be eligible to receive a reduced effective discount percentage (80 FR 73378).

4. Maximum Composite Quality Score

As finalized in the CJR final rule, a participant hospital could be awarded a maximum composite quality score of 21.8 if the hospital received maximum quality performance points for each quality measure, maximum quality improvement points for each quality measure, and successfully submitted voluntary patient-reported outcomes and limited risk variable data. We propose to award up to 10 percent of the maximum measure performance score on the THA/TKA Complications and HCAHPS Survey measures, and impose a cap on the CJR model composite quality score at 20 points. This change would bring calculation of the CJR composite

quality score into greater alignment with existing CMS programs, such as the HVBP Program, by reducing the number of participants who receive both the highest quality performance score on a measure and the maximum points for measure improvement.

We propose to amend our regulations at § 510.315(d) to reflect this change. We seek comment on our proposal.

5. Acknowledgement of Voluntary Data Submission

Our regulations at 42 CFR 510.400(c)(3) state that although we do not publicly report the voluntary patient-reported outcomes and limited risk variable data during the CJR model, we do indicate whether a hospital has voluntarily submitted such data. We propose to amend §510.400(c)(3) to clarify that we would acknowledge only CJR participant hospitals that successfully submit voluntary patient-reported outcomes and limited risk variable data, in accordance with § 510.400(b). We seek comment on our proposal.

6. Calculation of the HCAHPS Linear Mean Roll-up (HLMR) Score

We propose to calculate the HCAHPS Linear Mean Roll-up (HLMR) score by taking the average of the linear mean scores (LMS) for 10 of the 11 publicly reported HCAHPS measures for IPPS hospitals with 100 or more completed HCAHPS surveys in a 4-quarter period. The HLMR will summarize HCAHPS performance on all of the publicly reported measures, except for Pain Management. We propose this change because removal of Pain Management from the HVBP Program has been proposed in the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (81 FR 45603).

This mirrors the approach we are proposing for the proposed EPMs at III.E.4.d.(1)(f) of this proposed rule. Our regulations do not include the methods to calculate the HLMR, so we

refer readers to III.E.4.d.(1)(f) of this proposed rule for additional discussion of our approach.

We propose to implement the proposed changes to hospitals included in the quality performance distribution, the maximum number of points in the composite quality score, the change from 3 to 2 deciles for assessing quality improvement, and calculation of the HLMR score starting with the reconciliation for performance year 1 of the CJR model, when we calculate each participant hospital's composite quality score for year 1.

F. Accounting for Overlap with CMS ACO models and the Shared Savings Program

The CJR final rule details our policies to address cases of overlap in which beneficiaries that are aligned or attributed to an ACO model or Shared Savings Program participant are also included in a CJR episode. We recognize that there will be circumstances in which a Medicare beneficiary in a CJR episode is also aligned or attributed to an ACO participating in the Shared Savings Program or a CMS ACO model. In the CJR final rule, we finalized an approach to allow for such cases of overlap and minimize any double counting of savings through the following policies. We will conduct our annual reconciliation prior to the ACO reconciliation process, and make our reconciliation payments and repayment amounts available for the ACO models and program to take into account when performing their reconciliation, as their financial methodologies permit. In addition, in cases where a portion of the CJR discount percentage is paid out as shared savings to a participant hospital that participates in an ACO as a participant or provider/supplier, we would make an adjustment to the participant hospital's reconciliation results. We refer readers to the CJR final rule for a full discussion of our approach and the options we considered (80 FR 73387).

Given commenters' concerns about our approach, which are summarized in the final rule (80 FR 73387) we have continued to consider alternative options for accounting for overlap

between the ACO models and program and the CJR model. Specifically, we have considered, as some commenters suggested, attributing savings achieved during CJR episodes in which beneficiaries are also aligned or attributed to an ACO accepting downside risk to the ACO entity, not the participant hospital. We recognize that ACOs are engaged in care management activities for beneficiaries across the spectrum of care, which may also include care redesign during acute episodes. As a result, we are proposing to cancel (or never initiate) a CJR episode for beneficiaries that are prospectively aligned to a Next Generation ACO or ESRD Seamless Care Organization (ESCO) in the Comprehensive ESRD Care initiative in tracks with downside risk for financial losses. While the CJR model excludes beneficiaries whose eligibility for Medicare is on the basis of end stage renal disease, not all beneficiaries aligned to ESCOs meet this criterion. Thus, some beneficiaries aligned to ESCOs could be included in the CJR model.

We propose to implement this policy for episodes beginning on or after July 1, 2017, to align with the timeframe for implementation of the proposed AMI, CABG, and SHFFT models which propose the same exclusion of beneficiaries aligned to Next Generation ACOs and ESCOs in downside risk tracks. We propose this change to how we determine episodes included in CJR because these ACOs and ESCOs are accepting a high level of financial risk for the total cost of care for their aligned beneficiaries; for example, Next Generation ACOs are held to as much as 80 percent to 100 percent of first dollar losses. In addition, beneficiaries are prospectively aligned to ACOs in both initiatives. We believe that if we were to implement a policy where we would cancel CJR episodes based on a given beneficiary's ACO alignment status, we would do so only in those cases where the ACO alignment is prospective and does not change during a performance year. In such cases, CJR participant hospitals could be aware of a beneficiary's ACO alignment status, reducing uncertainty as to whether a given beneficiary is included in the

CJR model. We note that we are proposing elsewhere in this proposed rule to exclude beneficiaries prospectively aligned to a Next Generation ACO model participant or an ESCO in the Comprehensive ESRD Care Initiative in a downside risk track from the proposed AMI, CABG, and SHFFT model episodes because we wish to test this alternative approach to ACO overlap. We are not proposing to exclude beneficiaries assigned to Shared Savings Program Track 3 ACOs at this time, however, because we intend to test the approach of excluding prospectively-aligned ACO beneficiaries from the CJR model with the limited number of beneficiaries assigned to Next Generation ACOs and ESCOs in a downside risk track. We do not seek to disrupt the operations of our large, permanent ACO program at this time to test this novel approach for accounting for overlap. The Shared Savings Program is a national program; we do not believe that testing a new approach to addressing overlap in a national program would be appropriate at this time prior to testing such an approach with a smaller population. However, we seek comment on whether we should extend this proposed policy – that is, excluding from CJR beneficiaries who are prospectively assigned to an ACO – to beneficiaries who are assigned to a Track 3 Shared Savings Program ACO. We refer readers to section III.D.6.c. of this proposed rule for further discussion of our proposed approach and rationale, including details on how we would operationalize such an approach if finalized for CJR or the proposed EPMs.

In cases where a beneficiary is in a CJR episode and also aligned to a Pioneer ACO, Medicare Shared Savings Program ACO, or ESCO not participating in a downside risk track, we would not cancel the CJR episode. The policies we previously finalized for accounting for such overlap would continue to apply. We refer readers to the CJR final rule (80 FR 73391 through 73398) for additional discussion of our policies. Because the Pioneer ACO model ends on December 31, 2016, no adjustments are necessary to account for overlap between beneficiaries

in the proposed AMI, CABG, and SHFFT models and the Pioneer ACO model. However, since the first CJR performance year began in April 2016, we will make an adjustment for overlap between the two models during the first performance year of the CJR model.

Finally, we note that we are proposing elsewhere in this proposed rule to allow ACOs to be CJR collaborators. Our proposal, which is discussed in detail in section V.J.1.a. of this proposed rule, would allow for gainsharing arrangements between ACOs and CJR participant hospitals. This proposal would allow such partnerships in regions where such relationships could be mutually beneficial for ACOs and CJR participant hospitals. We believe these proposals will mitigate concerns about the limited opportunities for collaboration between ACOs and CJR participant hospitals that are often caring for the same beneficiaries. We refer readers to section V.J.1.a. of this proposed rule for additional detail on this proposed policy.

The proposal for addressing overlap between the CJR model and CMS's ACO models and program is included in §510.305(j)(1). We seek comment on our proposal to exclude beneficiaries aligned to a Next Generation ACO or ESCO downside risk track from the CJR model beginning with episodes that are initiated on or after July 1, 2017.

G. Appeals Process

The CJR final rule provides that participant hospitals may dispute a calculation that involves a matter related to payment, reconciliation amounts, repayment amounts, or determinations associated with quality measures affecting payment. The hospital is required to provide written notice of the error, in a form and manner specified by CMS, if the hospital wishes to dispute such calculation. Unless the participant hospital provides a written notice of the error, the CJR reconciliation report is deemed final 45 calendar days after it is issued, and CMS will then proceed with the payment or repayment process as applicable. In order to further

specify our timeline for this process, we propose that a timely notice of a calculation error means a notice received by CMS within 45 calendar days of CMS issuing a participant hospital's reconciliation report.

In continuing our efforts to be clear and concise, we propose to add language to our regulations highlighting the available appeals process for a participant hospital that receives a notice of termination from the CJR model. We previously described this appeals process for notice of termination in the CJR final rule at § 510.310(c), by using the notice of termination as an example of an exception to a participant hospital having to provide CMS with notice of calculation error. A notice of calculation error continues not to be required by participant hospitals that receive a notice of termination, as this matter does not involve an issue contained in, or a calculation that contributes to, a CJR reconciliation report. We propose that if a participant hospital receives notification that it has been terminated from the CJR model and wishes to appeal such termination, it must provide a written request for reconsideration to CMS requesting review of the termination within 10 calendar days of the notice. Following receipt of the participant hospital's timely written request, CMS would have 30 days to respond to the participant hospital's request for review. If the participant hospital fails to notify CMS, the termination would be deemed final.

We propose to amend the regulations at §510.310 to reflect these proposals, and to correct a technical error in paragraph (d)(6) (which would be renumbered (e)(6)). We also propose to delete §510.310(a)(3) in the current regulations as it is duplicative with §510.310(a)(1). We seek comment on our proposal.

H. Beneficiary Notification

Currently, CMS requires participant hospitals and CJR collaborators to provide written notice to any Medicare beneficiary that meets certain criteria in § 510.205 of his or inclusion in the CJR model detailing the structure of the model, existence of providers and suppliers with whom the participant hospital has a sharing arrangement, and that the beneficiary retains the freedom of choice. We refer readers to the CJR final rule (80 FR 73516-73521) for further discussion of this requirement. We propose to amend §510.405 to include all CJR collaborators in the requirements for delivery of beneficiary notices and streamline our current regulations. We seek comments on all aspects of this proposal.

1. Physician, Nonphysician Practitioner, and PGP Provision of Notice

We propose to amend §510.405(b)(2), which specifies that a physician who is a CJR collaborator must provide notices to CJR beneficiaries, to include PGPs. The CJR final rule included a requirement that physician collaborators provide notice to beneficiaries, but did not include a requirement that PGP collaborators or nonphysician practitioners also do so. Since PGPs and nonphysician practitioners may also be CJR collaborators, we believe it is important for PGPs and nonphysician practitioners to have a distinct notification requirement as well as physicians that are CJR collaborators. Requiring these collaborators to notify beneficiaries of the CJR model will help to ensure that beneficiaries are aware of the model and its potential effect on their care.

We propose to amend our regulations at §510.405(b)(2) to reflect this change. We seek comment on our proposal.

2. Other CJR Collaborators Provision of Notice

Given that we are proposing in V.J.1.a. of this proposed rule to add hospitals, ACOs, and CAHs to our definition of CJR collaborator (see section V.J.1 of this proposed rule), we also

propose to require that all CJR collaborators other than physicians and PGPs (ACOs, CAHs, hospitals, and post-acute care providers) provide notice of the model to CJR beneficiaries. We propose that in the case of ACOs, the ACO would require the ACO participants for which the ACO has an ACO distribution arrangement to provide the written notification. We propose that a participant hospital must require any CJR collaborator to provide written notice of the structure of the model and the existence of the hospital's sharing arrangement with the participant hospital to any Medicare beneficiary that meets the criteria specified in § 510.205. The notice must be provided no later than the time at which the beneficiary first receives services from the CJR collaborator or their collaboration agent during the CJR episode. We propose to amend our regulations at §510.405(b)(4) to reflect this change.

3. Beneficiary Notification Compliance and Records

We propose that participant hospitals and CJR collaborators must be able to, upon request by CMS, demonstrate compliance with the applicable beneficiary notification requirements. The participant hospital or CJR collaborator, as applicable, would be required to provide CMS or its designee with a list of beneficiaries that have received such notification, including the date the notification was given. We note that the method employed to document beneficiary notification may vary. For example, some hospitals and collaborators may retain a list of all beneficiaries that received the notification. Others may document in the medical record that the beneficiary received the beneficiary notification, add a barcode to the notification form to be scanned into the medical record, or employ another method of recordkeeping. Regardless of the method used by the individual hospital or collaborator for recordkeeping, the entity must be able to provide CMS or our designee with a list of all beneficiaries that received the notification materials within

the time period specified in the request. This requirement will aid CMS in monitoring participant hospitals for compliance with the CJR requirements.

We propose to amend our regulations at §510.405(b)(1) through §510.405(b)(5) and §510.405(b)(7) to reflect this change. We seek comment on our proposal.

4. Compliance with § 510.110

We propose elsewhere in this rule to consolidate and streamline our requirements for record retention (see section V.L. of this proposed rule for further details). As part of that proposed change, we also propose to require that participant hospitals and CJR collaborators, as applicable retain such records as are necessary to demonstrate the sufficiency of CJR beneficiary notifications.

I. Compliance Enforcement

We propose numerous amendments to the regulations in § 510.410. The amendments are largely to align terminology so that the CJR model regulations mirror the proposed EPM regulations at §512.460 in order to avoid confusion for hospitals that are participating in CJR and one or more of the proposed EPMs. Our proposed changes reflect that the requirements and rules regarding compliance enforcement under the CJR model would stay mostly the same. However, we are proposing the following changes in § 510.410 to adapt it to our proposal to amend the regulations at §510.500 and §510.505, as well as the addition of §510.506. We propose to replace the term 'collaborator agreement' with the term 'sharing arrangement' since we propose further in section V.J.1.b. of this proposed rule to consolidate the requirements of a collaborator agreement into requirements of a sharing arrangement, and to delete the term 'collaborator agreement' from part 510.

1. Failure to Comply

Currently, CMS may take remedial action against a participant hospital if a participant hospital or any of the hospital's CJR collaborators are noncompliant with CJR requirements in any of the ways listed in § 510.410(b)(1). As discussed in section V.J.1.a. of this proposed rule, the proposed addition of ACOs and hospitals, including CAHs, as CJR collaborators, and the proposed modification of the financial arrangements available under the CJR model, would require collaboration agents and downstream collaboration agents to comply with the CJR model requirements as well. We believe that because we are allowing additional entities and individuals to be CJR collaborators, collaboration agents, or downstream collaboration agent, we must ensure that all such entities and individuals comply with all requirements of the CJR model, such as notifying beneficiaries of the model and maintaining access to care. We believe that CJR participant hospitals should ensure that their sharing arrangements and the distribution arrangements and downstream distribution arrangements of their collaborators, collaboration agents, and downstream collaboration agents comply with the model requirements and safeguard program integrity. Therefore, we propose that CMS may take remedial actions against the participant hospital if any collaboration agent of such participant hospital's CJR collaborators, or any downstream collaboration agent of such CJR collaboration agent is not compliant with applicable requirements in any of the ways listed in of § 510.410(b)(1). Further, we propose that CMS may take remedial actions against a participant hospital if a participant hospital or any of the participant hospital's CJR collaborators, any collaboration agent of such CJR collaborators or any downstream collaboration agent has signed a sharing arrangement, distribution arrangement, or downstream distribution arrangement that is noncompliant with the requirements of part 510.

We propose to amend the regulations at §510.410 to include these requirements. We seek comment on our proposal.

J. Financial Arrangements under the CJR Model

Currently, participant hospitals may engage in financial arrangements under the CJR model. The arrangements published in the CJR final rule (80 FR 73412 through 73437) allow participant hospitals and providers and suppliers caring for CJR beneficiaries to share in the financial risks and rewards under the CJR model, to engage in care redesign and CJR beneficiary care management, and to establish close partnerships with these individuals and entities to promote accountability for the quality, cost, and overall care for CJR beneficiaries. In order to ensure that goals of the CJR model are met, and to ensure program integrity and protect from abuse, the CJR model has many requirements for financial arrangements. The sections further discuss and propose amendments to these requirements and safeguards, as well as amendments to align the CJR model with the proposed regulations of the EPMs. We propose a full replacement for the prior CJR regulations at § 510.500 and § 510.505 in order to streamline and consolidate our regulations in line with the proposed financial arrangements for the EPMs at § 512.500 and § 512.505. Our proposed changes are largely organizational in nature, not changes to policy or requirements. However, in several cases we are proposing new financial arrangements policies and/or requirements for the CJR model; we discuss these proposed policies in detail later in this section. We also refer readers to section III.J. of this proposed rule for further discussion and rationale behind our proposed approach.

We propose that all amendments to regulations discussed in this section would be effective beginning July 1, 2017, in order to align with the beginning of the first performance year of the proposed EPMs. We seek comment on all proposals discussed further in this section.

1. Definitions Related to Financial Arrangements

a. Addition to the Definition of CJR Collaborators

In order to align with the proposed financial arrangements for the EPMs and to provide further opportunity for coordination between participant hospitals and their partners in care redesign, we propose to allow the following entities to be CJR collaborators: ACOs (with the limitations discussed later in this section), hospitals, and CAHs. We believe this proposal would allow for increased care coordination opportunities across the spectrum of care for beneficiaries in CJR episodes. Given that our proposals in this section mirror those proposed for the EPMs in section III.I.3. of this proposed rule, we refer readers to that section for further discussion of our rationale for allowing ACOs, hospitals, and CAHs to be collaborators.

Many ACOs and other stakeholders have expressed strong interest in being collaborators in episode payment models such as CJR. In the CJR final rule, we did not include ACOs in the definition of CJR collaborators, responding that we decided to limit the testing of gainsharing relationships to solely those between hospitals and providers and suppliers enrolled in Medicare because we expected enrolled providers and suppliers to be most directly and specifically engaged with the CJR participant hospital in care redesign and episode care for beneficiaries who had surgery at the participant hospitals (80 FR 73417). We also noted that a number of scenarios discussed by commenters to support their request to allow ACOs to be CJR collaborators could be achieved outside of the context of gainsharing relationships between the participant hospital and ACOs. However, with the steady growth in the number of ACOs and ACO-attributed beneficiaries, we have further considered the potential for ACOs to be CJR collaborators, especially given ACO expertise in care coordination and accountability for the quality and expenditures for health care for ACO-attributed beneficiaries over an annual period. In addition, we note that the challenges of attributing savings and changes in the quality of care for

beneficiaries simultaneously in CJR and total cost-of-care models or programs, such as ACOs, remain not fully resolved, as discussed in section III.D.6. of this proposed rule.

We propose that "ACOs," meaning accountable care organizations, as defined at § 425.20 of regulations of this chapter, that participate in the Medicare Shared Savings Program, be permitted to be CJR collaborators. This proposal would allow locally variable financial arrangements that could account for the way CJR episode care is coordinated and managed in communities, and ensure that entities with appropriate skills and experience are permitted to share in the risks and rewards with participant hospitals. Our proposal would not allow any entities that are not providers or suppliers to be CJR collaborators other than ACOs. Medicare has a close relationship with these ACOs who are regulated by CMS, so we can verify that these ACOs meet current Shared Savings Program requirements that could make them suitable for a role as CJR collaborators.

We also propose to allow participant hospitals to enter into financial arrangements with other hospitals and CAHs that care for CJR beneficiaries. We believe it is important to allow participant hospitals to enter into financial arrangements with other hospitals and CAHs that care for CJR beneficiaries, in order to align the financial incentives of such other hospitals and CAHs with the CJR model's goals of improving the quality and efficiency of CJR episodes and to align with the proposed financial arrangements for the EPMs.

In summary, we propose that the following providers, suppliers, and other entities be added to the list of permissible CJR collaborators: ACOs, hospitals, and CAHs.

We seek comment on our proposal to include ACOs, hospitals, and CAHs in the definition of CJR collaborators.

b. Deletion of Term 'Collaborator Agreements'

In order to reduce duplicative language in § 510.500 and streamline the regulations for financial arrangements between CJR participant hospitals and CJR collaborators, we propose to delete the term "collaborator agreement" in § 510.2 and transition the requirements of collaborator agreements to requirements of sharing arrangements. Overall, this proposal would allow CMS to align the CJR financial arrangements with those of the proposed EPMs, and provide consistent regulations to potential parties that may participate in both the CJR model and the EPMs.

We recognize that current participant hospitals and CJR collaborators already have existing collaborator agreements. However, as noted further in this section, although we propose to change several terms, the proposed sharing arrangements policies are largely similar to the current policies regarding collaborator agreements.

We seek to amend the regulations at § 510.2 by deleting the term collaborator agreement in Part 510. We seek comment on our proposals.

c. Addition of CJR activities

We propose to use the term "CJR activities" to identify certain obligations of parties in a sharing arrangement that are currently described as "changes in care coordination or delivery" in the CJR regulations governing the contents of the written agreement memorializing the sharing arrangement. In addition to the quality of care provided during episodes, we believe the activities that would fall under this proposed definition of CJR activities would encompass the totality of activities upon which it would be appropriate for certain financial arrangements under the CJR model to be based in order to value the contributions of providers, suppliers, and other entities toward meeting the CJR model's goals of improving the quality and efficiency of episodes. Therefore, for purposes of financial arrangements under the CJR model, we propose to

define CJR activities as activities related to promoting accountability for the quality, cost, and overall care for CJR beneficiaries, including managing and coordinating care; encouraging investment in infrastructure, enabling technologies, and redesigned care processes for high quality and efficient service delivery; the provision of items and services during a CJR episode in a manner that reduces costs and improves quality; or carrying out any other obligation or duty under the CJR models. Sections V.J.2. through V.J.4. of this proposed rule further provide more detail as to how the addition of CJR activities affect other proposals in this part.

We propose to amend § 510.2 by adding the term 'CJR activities.' We seek comment on our proposal to add CJR activities as an inclusive and comprehensive framework for capturing direct care and care redesign for CJR episodes that contribute to improving the quality and efficiency of these episodes.

2. Sharing arrangements

As discussed previously in this section, we propose to delete the term 'collaborator agreement' and include all requirements of a financial arrangement between a participant hospital and a CJR collaborator under sharing arrangements. Given the magnitude of this terminology change, we propose a complete revision of § 510.500. We believe the proposed amendments to this section will provide participant hospitals and CJR collaborators with more revised, organized, and streamlined regulations.

a. General

With the exception of adding "past or anticipated" to the selection criteria for CJR collaborators, and replacing 'collaborator agreement' with 'sharing arrangement' the following proposed criteria are similar to the current requirements of the CJR model as finalized in prior regulations at § 510.500. We discuss here the proposed requirements for sharing arrangements,

including our continuation of policies we finalized in the CJR final rule, as well as several new proposals. We propose that participant hospitals must develop, maintain, and use a set of written policies for selecting individuals and entities to be CJR collaborators, and that the selection criteria must include the quality of care delivered by the potential CJR collaborator. The selection criteria cannot be based directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent. By adding "past or anticipated", all previous and future referrals between or among participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent would be encompassed. We do not believe it would be appropriate for sharing arrangements to be based on criteria that include the volume or value of past or anticipated referrals because the sole purpose of sharing arrangements is to create financial alignment between participant hospitals and CJR collaborators toward the CJR model's goals of improving the quality and efficiency of episode care. Thus, we continue to require that CJR participant hospitals select CJR collaborators based on criteria that include the quality of care furnished by the potential CJR collaborator to ensure that the selection of CJR collaborators takes into consideration the likelihood of their future performance in improving the quality of episode care.

In summary, we propose to amend § 510.500(a) as follows:

- A participant hospital may enter into a sharing arrangement with a CJR collaborator to make a gainsharing payment, or to receive an alignment payment, or both.

- A participant hospital must not make a gainsharing payment or receive an alignment payment except in accordance with a sharing arrangement.
- A sharing arrangement must comply with the provisions of this section and all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.
- Participant hospitals must develop, maintain, and use a set of written policies for selecting individuals and entities to be CJR collaborators. These policies must contain criteria related to, and inclusive of, the quality of care delivered by the potential CJR collaborator. The selection criteria cannot be based directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent.
- If a participant hospital enters into a sharing arrangement, its compliance program must include oversight of sharing arrangements and compliance with the applicable requirements of the CJR model.

We propose to amend the regulations at § 510.500(a). We seek comment on our proposal.

b. Requirements

Currently, there are a number of specific requirements for sharing arrangements under the CJR model. However, with our proposal to delete the term 'collaborator agreement,' the existing requirements under collaborator agreements would now be streamlined under sharing arrangements. Though many of the proposed requirements under sharing arrangements are largely similar to the current requirements under collaborator agreements, we discuss these

requirements in detail further in this section in order to ensure current and future participant hospitals and CJR collaborators are aware of all requirements.

We propose that the sharing arrangement must be in writing, signed by the parties, and entered into before care is furnished to CJR beneficiaries under the sharing arrangement. In addition, participation in a sharing arrangement must be voluntary and without penalty for nonparticipation. We propose that the sharing arrangement must require the CJR collaborator and its employees, contractors, and subcontractors to comply with certain requirements that are important for program integrity protections under the arrangement. We note that the terms contractors and subcontractors, respectively, include collaboration agents and downstream collaboration agents as defined later in this section.

The sharing arrangement must require all of the individuals and entities in this group to comply with the applicable provisions of Part 510, including requirements regarding beneficiary notifications, access to records, record retention, and participation in any evaluation, monitoring, compliance, and enforcement activities performed by CMS or its designees, because these individuals and entities all would play a role in CJR care redesign and be part of financial arrangements under the CJR model. The sharing arrangement must also require all individuals and entities in the group to comply with the applicable Medicare provider enrollment requirement at § 424.500, including having a valid and active TIN or NPI, during the term of the sharing arrangement. This is to ensure that the individuals and entities have the required enrollment relationship with CMS under the Medicare program, although we note that they are not responsible for complying with requirements that do not apply to them. Finally, the sharing arrangement must require individuals and entities to comply with all other applicable laws and regulations.

We propose that the sharing arrangement must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care so that financial relationships between participant hospitals and CJR collaborators do not negatively impact beneficiary protections under the CJR.

Further we propose that sharing arrangements must require the CJR collaborator to have a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the CJR, just as we would require participant hospitals to have a compliance plan for this purpose as a program integrity safeguard. We note that the CJR compliance program requirement does not mandate that a CJR collaborator's compliance program take a particular form or include particular components.

It is necessary that participant hospitals have adequate oversight over sharing arrangements to ensure that all arrangements meet the requirements of this section and provide program integrity protections. Therefore, we propose that the board or other governing body of the CJR participant hospital have responsibility for overseeing the participant hospital's participation in the CJR model, its arrangements with CJR collaborators, its payment of gainsharing payments, its receipt of alignment payments, and its use of beneficiary incentives in the CJR. We propose that the written agreement memorializing a sharing arrangement must specify a number of parameters of the arrangement, including the following:

- The purpose and scope of the sharing arrangement.
- The identities and obligations of the parties, including specified CJR activities and other services to be performed by the parties under the sharing arrangement.;
- Management and staffing information, including type of personnel or contractors that will be primarily responsible for carrying out CJR activities.

- The date of the sharing arrangement.
- The financial or economic terms for payment, including –

++ Eligibility criteria for a gainsharing payment;

++ Eligibility criteria for an alignment payment;

++ Frequency of gainsharing or alignment payment;

++ Methodology and accounting formula for determining the amount of a gainsharing payment that is substantially based on quality of care and the provision of CJR activities; and

++ Methodology and accounting formula for determining the amount of an alignment payment.

Finally, we propose to require that the terms of the sharing arrangement must not induce the participant hospital, CJR collaborator, or any employees, contractors, or subcontractors of the participant hospital or CJR collaborator to reduce or limit medically necessary services to any Medicare beneficiary or restrict the ability of a CJR collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies, and treatments. These requirements are to ensure that the quality of care for CJR beneficiaries is not negatively affected by sharing arrangements under the CJR.

In summary, we propose the following requirements for sharing arrangements:

- A sharing arrangement must be in writing and signed by the parties, and entered into before care is furnished to CJR beneficiaries under the sharing arrangement.
- Participation in a sharing arrangement must be voluntary and without penalty for nonparticipation.

- The sharing arrangement must require the CJR collaborator and its employees, contractors (including collaboration agents), and subcontractors (including downstream collaboration agents) to comply with the following:

++ The applicable provisions of this part (including requirements regarding beneficiary notifications, access to records, record retention, and participation in any evaluation, monitoring, compliance, and enforcement activities performed by CMS or its designees).

++ All applicable Medicare provider enrollment requirements at § 424.500 of this chapter, including having a valid and active TIN or NPI, during the term of the sharing arrangement.

++ All other applicable laws and regulations.

- The sharing arrangement must require the CJR collaborator to have a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the CJR model.

- The sharing arrangement must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care.

- The board or other governing body of the participant hospital must have responsibility for overseeing the participant hospital's participation in the CJR model, its arrangements with CJR collaborators, its payment of gainsharing payments, its receipt of alignment payments, and its use of beneficiary incentives in the CJR model.

- The written agreement memorializing a sharing arrangement must specify the following:

++ The purpose and scope of the sharing arrangement.

++ The obligations of the parties, including specified CJR activities and other services to be performed by the parties under the sharing arrangement.

++ Management and staffing information, including type of personnel or contractors that will be primarily responsible for carrying out CJR activities.

++ The financial or economic terms for payment, including --

-- Eligibility criteria for a gainsharing payment;

-- Eligibility criteria for an alignment payment;

-- Frequency of gainsharing or alignment payment;

-- Methodology and accounting formula for determining the amount of a gainsharing payment or alignment payment.

● The sharing arrangement must not --

++ Induce the participant hospital, CJR collaborator, or any employees, contractors, or subcontractors of the participant hospital or CJR collaborator to reduce or limit medically necessary services to any Medicare beneficiary; or

++ Restrict the ability of a CJR collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies, and treatments.

We propose to amend the requirements for sharing arrangements at § 510.500(b). We seek comment on our proposals.

c. Gainsharing Payment, Alignment Payment, and Internal Cost Savings Conditions and Restrictions.

Under the CJR model, we place a number of conditions and limitations on gainsharing payments, alignment payments, and internal cost savings. Our proposal to amend these limitations and conditions would allow us to reorganize and clarify current policies, account for

the addition of ACOs, CAHs, and hospitals as CJR collaborators, and align the CJR model with the proposed financial arrangements for the EPMs. Though many of the proposed requirements under sharing arrangements are largely similar to the current requirements under gainsharing payments, alignment payments, and internal cost savings conditions and restrictions, we discuss these requirements in detail further in this section in order to ensure current and future participant hospitals and CJR collaborators are aware of such requirements, in particular those that we are proposing to change.

We propose that to be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a CJR collaborator other than a PGP or an ACO must have directly furnished a billable item or service to an CJR beneficiary during an CJR episode that occurred in the same performance year for which the participant hospital has calculated a gainsharing payment or been assessed a repayment amount. For purposes of this requirement, we consider a hospital, CAH, or post-acute care provider to have "directly furnished" a billable service if one of these entities billed for an item or service for a CJR beneficiary during a CJR episode that occurred in the same performance year for which the CJR participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount. The phrase "performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount" does not mean the year in which the gainsharing payment was made. These requirements ensure that there is a required relationship between eligibility for a gainsharing payment and the quality of direct care for CJR beneficiaries during CJR episodes for these CJR collaborators. We believe the provision of direct care is essential to the implementation of effective care redesign, and the requirement

provides a safeguard against payments to CJR collaborators other than a PGP or an ACO that are unrelated to direct care for CJR beneficiaries during CJR episodes.

Further, we propose to establish similar requirements for PGPs and ACOs that vary because these entities do not themselves directly furnish billable services. To be eligible to receive a gainsharing payment or required to make an alignment payment, a PGP must have billed for an item or service that was rendered by one or more members of the PGP to a CJR beneficiary during an CJR episode that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount. Further, we propose that to be eligible to receive a gainsharing payment or required to make an alignment payment, an ACO must have had an ACO provider/supplier that directly furnished, or an ACO participant that billed for, an item or service that was rendered to an CJR beneficiary during a CJR episode that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount. With respect to ACOs, an "ACO participant" and "ACO provider/supplier" have the meaning set forth in § 425.20 of regulations. Like the proposal for CJR collaborators that are not PGPs or ACOs, these proposals also require a linkage between the CJR collaborator that is the PGP or ACO and the provision of items and services to CJR beneficiaries during CJR episodes by PGP members or ACO participants or ACO providers/suppliers, respectively.

Moreover, we further propose that because PGPs and ACOs do not directly furnish items and services to beneficiaries, in order to be eligible to receive a gainsharing payment or be required to make an alignment payment, the PGP or ACO must have contributed to CJR

activities and been clinically involved in the care of CJR beneficiaries during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount. For example, a PGP or ACO or might have been clinically involved in the care of CJR beneficiaries by providing care coordination services to CJR beneficiaries during and/or after inpatient admission; engaging with a participant hospital in care redesign strategies, and actually performing a role in implementing such strategies that are designed to improve the quality of care for CJR episodes and reduce CJR episode spending; or in coordination with providers and suppliers (such as members of the PGP, ACO participants, ACO providers/suppliers, the participant hospital, and post-acute care providers), implementing strategies designed to address and manage the comorbidities of CJR beneficiaries.

Because internal cost savings may be shared through gainsharing payments with CJR collaborators, we have certain requirements for their calculation as a safeguard against fraud and abuse. We propose that the internal cost savings reflect care redesign under the CJR in order to be eligible to be shared through gainsharing payments, the methodology used to calculate internal cost savings must reflect the actual, internal cost savings achieved by the participant hospital through the documented implementation of CJR activities identified by the participant hospital and must exclude any savings realized by any individual or entity that is not the participant hospital and "paper" savings from accounting conventions or past investment in fixed costs. Unlike the current CJR model policy where we require that sharing arrangements document the methodology for accruing, calculating, and verifying the internal cost savings generated by the participant hospital based on the care redesign elements specifically associated with the particular collaborator, we are proposing a revised policy to not require in the CJR

model that the calculation of internal cost savings be tied to the activities of any specific CJR collaborator. We believe this proposed change would recognize that multiple collaborators and collaboration agents contribute to internal cost savings and provide participant hospitals with flexibility to focus on overall internal cost savings due to model activities, rather than the activities of any specific collaborator or collaboration agent. Rather, we believe it is appropriate for participant hospitals to calculate internal cost savings based on the implementation of CJR activities and then provide gainsharing payments to CJR collaborators that may include internal cost savings, reconciliation payments, or both, based on a methodology that meets the requirements described later in this section.

We propose that the amount of any gainsharing payments must be determined in accordance with a methodology that is substantially based on quality of care and the provision of CJR activities. Further, we propose the methodology may take into account the amount of such CJR activities provided by a CJR collaborator relative to other CJR collaborators. While we emphasize that financial arrangements may not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent, so that their sole purpose is to align the financial incentives of the participant hospital and CJR collaborators toward the CJR goals of improved CJR episode care quality and efficiency, we believe that accounting for the relative amount of CJR activities by CJR collaborators in the determination of gainsharing payments does not undermine this objective. Rather, this proposed requirement allows flexibility in the determination of gainsharing payments where the amount of a CJR collaborator's provision

of CJR activities (including direct care) to CJR beneficiaries during CJR episodes may contribute to both the internal cost savings and participant hospital's reconciliation payment that may be available for making a gainsharing payment. We refer readers to section III.I.4. of this proposed rule for additional discussion of our rationale. We seek comment on this proposal for gainsharing payments, where the methodology could take into account the amount of CJR activities provided by a CJR collaborator relative to other CJR collaborators. In addition we invite comment on whether additional safeguards or a different standard is needed to allow for greater flexibility to provide certain performance-based payments consistent with the goals of program integrity, protecting against abuse and ensuring the goals of the model are met.

In the CJR model, we continue to have certain limitations on alignment payments. Currently for a performance year, the aggregate amount of all alignment payments received by the participant hospital must not exceed 50 percent of the participant hospital's repayment amount. In addition, the aggregate amount of all alignment payments from a CJR collaborator to the participant hospital may not be greater than 25 percent of the participant hospital's repayment amount for a CJR collaborator that is not an ACO and we propose 50 percent of the participant hospital's repayment amount for a CJR collaborator that is an ACO. We propose to allow a higher percentage of the participant hospital's repayment amount to be paid by an ACO than by CJR collaborators that are not ACOs in recognition that some ACOs are sizable organizations with significant financial and other resources. In addition, their expertise in managing the cost and quality of care for Medicare beneficiaries over a period of time may make some ACOs uniquely capable of sharing a higher percentage of downside risk under the CJR with the participant hospital under a sharing arrangement between the ACO and CJR participant hospital that meets all requirements for such arrangements, including that participation in the sharing

arrangement must be voluntary and without penalty for nonparticipation as discussed previously. We seek comment on the proposed limitation that would apply to ACOs that are CJR collaborators.

Additionally, we propose that all gainsharing payments and alignment payments must be made by check, electronic funds transfer, or another traceable cash transaction. This is different from the current CJR model policy which requires gainsharing payments and alignment payments to be made by electronic funds transfer. Here, we propose to revise this requirement this requirement in the CJR model in order to provide additional flexibility for entities making gainsharing payments and alignment payments. We believe our proposal would mitigate the administrative burden that the EFT requirement would place on the financial arrangements between certain participant hospitals and CJR collaborators, especially individual physicians and nonphysician practitioners and small PGPs, which could discourage participation of those suppliers as CJR collaborators. We seek comment on the effect of this proposal on reducing the administrative barriers to individual physician and nonphysician practitioner and small PGP participation in the CJR as CJR collaborators.

In summary, we propose the following conditions and restrictions on gainsharing payments, alignment payments, and internal cost savings:

- Gainsharing payments, if any, must —

++ Be derived solely from reconciliation payments, or internal cost savings, or both;

++ Be distributed on an annual basis (not more than once per calendar year);

++ Not be a loan, advance payment, or payment for referrals or other business; and

++ Be clearly identified as a gainsharing payment at the time it is paid.

● To be eligible to receive a gainsharing payment, a CJR collaborator must meet quality of care criteria for the performance year for which the CJR participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment. The quality of care criteria must be established by the participant hospital and directly related to the CJR episode.

● To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a CJR collaborator other than a PGP or an ACO must have directly furnished a billable item or service to a CJR beneficiary during a CJR episode that occurred in the same performance year for which the CJR participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount.

● To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a CJR collaborator that is a PGP must meet the following criteria:

++ The PGP must have billed for an item or service that was rendered by one or more members of the PGP to a CJR beneficiary during a CJR episode that occurred during the same performance year for which the participant hospital has calculated a gainsharing payment or been assessed a repayment amount.

++ The PGP must have contributed to CJR activities and been clinically involved in the care of CJR beneficiaries during the same performance year for which the participant hospital has calculated a gainsharing payment or been assessed a repayment amount. For example, a PGP might have been clinically involved in the care of CJR beneficiaries by --

-- Providing care coordination services to beneficiaries during and/or after inpatient admission;

-- Engaging with a participant hospital in care redesign strategies, and actually performing a role in implementing such strategies, that are designed to improve the quality of care for CJR episodes and reduce CJR episode spending; or

-- In coordination with other providers and suppliers (such as members of the PGP, the participant hospital, and post-acute care providers), implementing strategies designed to address and manage the comorbidities of CJR beneficiaries.

● To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a CJR collaborator that is an ACO must meet the following criteria:

++ The ACO must have had an ACO provider/supplier that directly furnished, or an ACO participant that billed for, an item or service that was rendered to a CJR beneficiary during a CJR episode that occurred during the same performance year for which the participant hospital has calculated a gainsharing payment or been assessed a repayment amount.

++ The ACO must have contributed to CJR activities and been clinically involved in the care of CJR beneficiaries. For example, an ACO might be have been clinically involved in the care of CJR beneficiaries by --

-- Providing care coordination services to CJR beneficiaries during and/or after inpatient admission;

-- Engaging with a participant hospital in care redesign strategies, and actually performing a role in implementing such strategies, that are designed to improve the quality of care and reduce spending for CJR episodes; or

-- In coordination with providers and suppliers (such as ACO participants, ACO providers/suppliers, the participant hospital, and post-acute care providers), implementing strategies designed to address and manage the comorbidities of CJR beneficiaries.

● The methodology for accruing, calculating and verifying internal cost savings must be transparent, measurable, and verifiable in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book).

● The methodology used to calculate internal cost savings must reflect the actual, internal cost savings achieved by the participant hospital through the documented implementation of CJR activities identified by the participant hospital and must exclude --

++ Any savings realized by any individual or entity that is not the participant hospital; and

++ "Paper" savings from accounting conventions or past investment in fixed costs.

● The total amount of a gainsharing payment for a performance year paid to a CJR collaborator must not exceed the following:

++ In the case of a CJR collaborator who is a physician or nonphysician practitioner, 50 percent of the Medicare-approved amounts under the PFS for items and services furnished by that physician or nonphysician practitioner to the participant hospital's CJR beneficiaries during CJR episodes that occurred during the same performance year in which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being made.

++ In the case of a CJR collaborator that is a PGP, 50 percent of the Medicare-approved amounts under the PFS for items and services billed by the PGP and furnished to the participant hospital's CJR beneficiaries by members of the PGP during CJR episodes that occurred during the same performance year in which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being made.

● The amount of any gainsharing payments must be determined in accordance with a methodology that is substantially based on quality of care and the provision of CJR activities. The methodology may take into account the amount of such CJR activities provided by a CJR collaborator relative to other CJR collaborators.

● For a performance year, the aggregate amount of all gainsharing payments that are derived from a reconciliation payment must not exceed the amount of the reconciliation payment the participant hospital receives from CMS.

● No entity or individual, whether a party to a sharing arrangement or not, may condition the opportunity to make or receive gainsharing payments or to make or receive alignment payments on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent.

● A participant hospital must not make a gainsharing payment to a CJR collaborator that is subject to any action for noncompliance with this part or the fraud and abuse laws, or for the provision of substandard care in CJR episodes or other integrity problems.

● The sharing arrangement must require the participant hospital to recoup any gainsharing payment that contained funds derived from a CMS overpayment on a reconciliation report or was based on the submission of false or fraudulent data.

● Alignment payments from a CJR collaborator to a participant hospital may be made at any interval that is agreed upon by both parties, and must not be—

++ Issued, distributed, or paid prior to the calculation by CMS of a repayment amount reflected in a reconciliation report;

++ Loans, advance payments, or payments for referrals or other business; or

++ Assessed by a participant hospital if it does not owe a repayment amount.

● The participant hospital must not receive any amounts from a CJR collaborator under a sharing arrangement that are not alignment payments.

● For a performance year, the aggregate amount of all alignment payments received by the participant hospital must not exceed 50 percent of the participant hospital's repayment amount.

● The aggregate amount of all alignment payments from a CJR collaborator to the participant hospital may not be greater than --

++ With respect to a CJR collaborator other than an ACO, 25 percent of the participant hospital's repayment amount; and

++ With respect to a CJR collaborator that is an ACO, 50 percent of the participant hospital's repayment amount.

● The methodology for determining alignment payments must not directly account for the volume or value of past or anticipated referrals or business otherwise generated by, between or among the participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent.

● All gainsharing payments and any alignment payments must be administered by the participant hospital in accordance with generally accepted accounting principles.

● All gainsharing payments and alignment payments must be made by check, electronic funds transfer, or another traceable cash transaction.

We propose to amend the regulations at § 510.500(c). We seek comment on our proposal, including the feasibility of implementing the proposed safeguards in the context of the current regulatory framework applicable to ACOs and whether additional or different safeguards are reasonable, necessary or appropriate to ensure the goals of program integrity, protecting against abuse and ensuring the goals of the model are met.

d. Documentation

We propose revisions to § 510.500(d) for organization and formatting purposes, and to align with the proposed regulations of the EPMs. Besides the proposed definitional changes and our proposal related to the determination of qualified practitioners under the Quality Payment Program, these revisions would not change any policies under the current documentation section of the CJR model.

In summary we propose the following requirements for documentation:

- Participant hospitals must --

++ Document the sharing arrangement contemporaneously with the establishment of the arrangement;

++ Maintain accurate current and historical lists of all CJR collaborators, including collaborator names and addresses; update such lists on at least a quarterly basis; and publicly report the current and historical lists of CJR collaborators on a webpage on the participant hospital's website as well as provide such lists to CMS; and

++ Maintain and require each CJR collaborator to maintain contemporaneous documentation with respect to the payment or receipt of any gainsharing payment or alignment payment that includes at a minimum the --

-- Nature of the payment (gainsharing payment or alignment payment);

-- Identity of the parties making and receiving the payment;

-- Date of the payment;

-- Amount of the payment; and

-- Date and amount of any recoupment of all or a portion of a CJR collaborator's gainsharing payment.

● The participant hospital must keep records of the following:

++ Its process for determining and verifying its potential and current CJR collaborators' eligibility to participate in Medicare.

++ Its plan to track internal cost savings.

++ Information on the accounting systems used to track internal cost savings.

++ A description of current health information technology, including systems to track reconciliation payments and internal cost savings.

++ Its plan to track gainsharing payments and alignment payments.

● The participant hospital must retain and provide access to, and must require each CJR collaborator to retain and provide access to, the required documentation in accordance with § 510.110.

In the proposed § 510.500(d)(3), we propose that participant hospitals must retain and provide access to the required documentation in accordance with § 510.110 and must obligate CJR collaborators to do the same. We propose to add a new section, § 510.110, to the CJR regulations, which would apply all records access and retention requirements under the CJR model, including those for financial arrangements as well as beneficiary notifications and beneficiary incentives. Because we propose to consolidate all records access and retention requirements in one place in the regulations, we propose to delete §510.500(e) from the current

CJR regulations. We discuss further our proposal to consolidate the requirements under the CJR model for access to records and record retention and apply them more broadly in the model. This approach mirrors our proposed records retention policies for the EPMs, which are discussed in detail in section III.H. of this proposed rule. We refer readers to that section for further discussion of our proposed policies and rationale.

We propose to amend these regulations at § 510.500(d). We seek comment on our proposals.

3. Distribution arrangements

Though we propose a complete revision of the regulations in § 510.505, these changes are mainly to accommodate our proposals to add ACOs as CJR collaborators, add the term 'collaboration agent,' consolidate the requirements under the previous term 'collaborator agreement' with sharing arrangements, and to mirror the proposed EPM regulations at §512.505 to avoid confusion for hospitals that are participating in CJR as well as one or more of the proposed EPMs. Our proposed changes to the regulations reflect that the requirements and rules regarding distribution arrangements under the CJR model would stay largely the same.

a. General

We propose that certain financial arrangements between CJR collaborators and other individuals or entities called "collaboration agents" be termed "distribution arrangements." A distribution arrangement is a financial arrangement between a CJR collaborator that is an ACO or PGP and a collaboration agent for the sole purpose of sharing a gainsharing payment received by the ACO or PGP. A collaboration agent is an individual or entity that is not a CJR collaborator and that is either a PGP member that has entered into a distribution arrangement with the same PGP in which he or she is an owner or employee or an ACO participant or ACO

provider/supplier that has entered into a distribution arrangement with the same ACO in which it is participating. Where a payment from a CJR collaborator to a collaboration agent is made pursuant to a distribution arrangement, we propose to define that payment as a "distribution payment." A collaboration agent may only make a distribution payment in accordance with a distribution arrangement which complies with the provisions of § 510.505 and all other applicable laws and regulations, including the fraud and abuse laws. We solicit comment on whether requirements for distribution payments by ACOs under this proposal are reasonable, necessary and appropriate to promote program integrity, prevent fraud and abuse, and achieve the goals of the model. In addition, we solicit comment on how the regulation of the financial arrangements this proposal may interact with how these or similar financial arrangements are regulated under the Medicare Shared Savings Program.

b. Requirements

We propose to amend the requirements for distribution payments in § 510.505 as discussed in this section.

We propose the opportunity to make or receive a distribution payment must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the participant hospital, any CJR collaborator, collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent. With the exception of adding "past or anticipated", this proposed requirement is similar to the existing requirement in the CJR model. By adding this language, all previous and future referrals between or among the participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity

affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent are encompassed.

Currently, methodologies for determining distribution payments must not directly account for volume or value of referrals, or business otherwise generated, by, between or among the participant hospital, PGP, other CJR collaborators, any collaboration agent, any downstream collaboration agent, and any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent. We propose to change this requirement as follows.

Like our proposal for gainsharing payments discussed previously, we propose a more flexible standard for the determination of the amount of distribution payments from ACOs and PGPs for the same reasons we propose this standard for the determination of gainsharing payments. Specifically, for ACOs we propose that the amount of any distribution payments must be determined in accordance with a methodology that is substantially based on quality of care and the provision of CJR activities and that may take into account the amount of such CJR activities provided by a collaboration agent relative to other collaboration agents. We believe that the amount of a collaboration agent's provision of CJR activities (including direct care) to CJR beneficiaries during a CJR episode may contribute to the participant hospital's internal cost savings and reconciliation payment that may be available for making a gainsharing payment to the CJR collaborator with which the collaboration agent has a distribution arrangement. Greater contributions of CJR activities by one collaboration agent versus another collaboration agent that result in different contributions to the gainsharing payment made to the CJR collaborator with which those collaboration agents both have a distribution arrangement may be appropriately valued in the methodology used to make distribution payments to those collaboration agents.

Accordingly, we believe this is the appropriate standard for determining the amount of distribution payments from an ACO to its collaboration agents.

We note that for distribution payments made by a PGP to PGP members, the requirement that the amount of any distribution payments must be determined in accordance with a methodology that is substantially based on quality of care and the provision of CJR activities may be more limiting in how a PGP pays its members than is allowed under existing law. Therefore, to retain existing flexibility for distribution payments by a PGP to PGP members, we propose that the amount of the distribution payment from a PGP to PGP members must be determined either using the methodology previously described for distribution payments from an ACO or in a manner that complies with §411.352(g). This proposal would allow a PGP the choice either to comply with the general standard that the amount of a distribution payment must be substantially based on quality of care and the provision of CJR activities or to provide its members a financial benefit through the CJR without consideration of the PGP member's individual quality of care. In the latter case, PGP members who are not collaboration agents (including those who furnished no services to CJR beneficiaries) would be able receive a share of the profits from their PGP that includes the monies contained in a gainsharing payment. We believe that our proposal to modify the current CJR regulations to allow the amount of the distribution payment from a PGP to a PGP member to be determined in a manner that complies with §411.352(g) is an appropriate exception to the general standard for determining the amount of distribution payment under the CJR model from a PGP to a PGP member. CMS has determined under the physician self-referral law that payments from a group practice as defined under §411.352 to its members that comply with §411.352(g) are appropriate. This proposal would allow a PGP the choice either to comply with the general standard that the amount of a

distribution payment must be substantially based on quality of care and the provision of CJR activities or to provide its members a financial benefit through the CJR model without consideration of the PGP member's individual quality of care. This approach mirrors our proposed policies for distribution arrangements for the EPMs, which are discussed in detail in section III.I.5. of this proposed rule.

We propose to amend the regulations at § 510.505(b)(4) and (b)(5). We seek comment on this proposal and specifically whether additional safeguards or a different standard is needed to allow for greater flexibility in calculating the amount of distribution payments consistent with the goals of promoting program integrity, protecting against abuse, and ensuring that the goals of the model are met. In addition, we solicit comment on the proposal to allow distribution payments by a PGP to its members that comply with §411.352(g) or whether additional/different safeguards are reasonable, necessary, and appropriate.

Except for a distribution payment from a PGP to a PGP member that complies with §411.352(g), we propose to continue the limits in the current CJR regulations on the total amount of distribution payments to physicians, nonphysician practitioners, and PGPs as we propose for gainsharing payments. Specifically, in the case of a collaboration agent that is a physician or nonphysician practitioner, absent the alternative safeguards afforded by compliance with §411.352(g), we would limit the total amount of distribution payments paid for a performance year to the collaboration agent to 50 percent of the total Medicare-approved amounts under the PFS for items and services furnished by the collaboration agent to the CJR participant hospital's CJR beneficiaries during CJR episodes that occurred during the same performance year for which the CJR participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed. In the case of a collaboration agent

that is a PGP, the limit would continue to be 50 percent of the total Medicare-approved amounts under the PFS for items and services billed by the PGP for items and services furnished by members of the PGP to the CJR participant hospital's CJR beneficiaries during CJR episodes that occurred during the same performance year for which the CJR participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed.

We propose that all distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction. This proposal would provide additional flexibility for entities making distribution payments as well as would mitigate the administrative burden that the EFT requirement previously placed on the financial arrangements between certain participant hospitals and CJR collaborators, especially individual physicians and nonphysician practitioners and small PGPs, which could discourage participation of those suppliers as CJR collaborators.

We propose to amend the regulations at § 510.505(b)(10). We seek comment on this proposal.

Finally, we propose that CJR collaborators must retain and provide access to the required documentation in accordance with § 510.110 and must require each collaboration agent to do so as well. We discuss further our proposal to consolidate the requirements under the CJR model for access to records and record retention and apply them more broadly in the model. This approach mirrors our proposed records retention policies for the EPMs, which are discussed in detail in section III.H. of this proposed rule. We refer readers to that section for further discussion of our proposed policies and rationale.

We propose to amend the regulations at § 510.505(b)(14). We seek comment on our proposals.

4. Downstream Distribution Arrangements Under the CJR Model

a. General

We propose that the CJR model allow for certain financial arrangements within an ACO between a PGP and its members. We discuss here our proposals for downstream distribution arrangements, which mirror our proposals for the proposed EPMs described in section III.I.6. of this proposed rule. Specifically, we propose that certain financial arrangements between a collaboration agent that is both a PGP and an ACO participant and other individuals termed "downstream collaboration agents" be termed a "downstream distribution arrangement." A downstream distribution arrangement is a financial arrangement between a collaboration agent that is a both a PGP and an ACO participant and a downstream collaboration agent for the sole purpose of sharing a distribution payment received by the PGP. A downstream collaboration agent is an individual who is not a CJR collaborator or a collaboration agent and who is a PGP member that has entered into a downstream distribution arrangement with the same PGP in which he or she is an owner or employee, and where the PGP is a collaboration agent. Where a payment from a collaboration agent to a downstream collaboration agent is made pursuant to a downstream distribution arrangement, we define that payment as a "downstream distribution payment." A CJR collaboration agent may only make a downstream distribution payment in accordance with a downstream distribution arrangement which complies with the requirements of this section and all other applicable laws and regulations, including the fraud and abuse laws.

The proposals for the general provisions for downstream distribution arrangements under the CJR model are included in § 510.506. These provisions mirror those proposed for the proposed

EPMs in § 512.510(a). We seek comment on our proposals for these general provisions, as well as any alternatives to this structure.

b. Requirements

We propose a number of specific requirements for downstream distribution arrangements to help ensure that their sole purpose is to create financial alignment between collaboration agents that are PGPs which are also ACO participants and downstream collaboration agents toward the goal of the CJR model to improve the quality and efficiency of CJR episodes. We refer readers to section III.I.6.(b) of this proposed rule for further discussion of our proposals regarding downstream distribution arrangements and our rationale for each proposal. Our proposed requirements largely parallel those proposed in § 510.510(b) and § 510.505(b) for sharing and distribution arrangements and gainsharing and distribution payments based on similar reasoning for these three types of arrangements and payments.

As listed in § 510.506 and described in detail in III.I.6(b) of this proposed rule, we propose requirements addressing the agreements governing downstream distribution arrangements, eligibility for receipt of downstream distribution payments, a cap on the amount of such payments, the methodologies used to determine the amount of downstream distribution payments, and documentation regarding downstream distribution arrangements. Specifically, we propose that all downstream distribution arrangements must be in writing and signed by the parties, contain the date of the agreement, and entered into before care is furnished to CJR beneficiaries under the distribution arrangement. We propose that participation must be voluntary and without penalty for nonparticipation, and the downstream distribution arrangement must require the downstream collaboration agent to comply with all applicable laws and regulations.

As with our proposals for gainsharing and distribution payments, we propose that the opportunity to make or receive a downstream distribution payment must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent. In determining the amount of downstream distribution payments we propose a more flexible approach, as we have with the proposed EPMs. We propose that the amount of any downstream distribution payments must be determined either in a manner that complies with § 411.352(g) or that is substantially based on quality of care and the provision of CJR activities and that may take into account the amount of CJR activities provided by a downstream collaboration agent relative to other downstream collaboration agents. Just as we propose an alternative to a methodology that is substantially based on quality of care and the provision of CJR activities for determining the amount of a distribution payment from a PGP to a PGP member, we similarly propose an alternative that the amount of a downstream distribution payment from a PGP to a PGP member may be determined in a manner that complies with §411.352(g)

Similar to our proposed requirements for distribution arrangements for those EPM collaborators that are PGPs, we propose that, except for a downstream distribution arrangement that complies with §411.352(g), a downstream collaboration agent is eligible to receive a downstream distribution payment only if the PGP billed for an item or service furnished by the downstream collaboration agent to a CJR beneficiary during a CJR episode that occurred during the same performance year for which the participant hospital accrued the internal cost savings

or earned the reconciliation payment that comprise the gainsharing payment from which the ACO made the distribution payment to the PGP that is an ACO participant. This approach mirrors our proposed requirements for distribution arrangements between collaborators and collaboration agents, as well as the proposed approach for the EPMs.

With regard to limitations on the amount of downstream distribution payments made to downstream collaboration agents, we propose the same limit as that proposed for distribution payments by CJR collaborators that are PGPs. With the exception of downstream distribution payments that comply with §411.352(g), we propose to limit the total amount of downstream distribution payments paid for a performance year to a downstream collaboration agent to 50 percent of the total Medicare-approved amounts under the PFS for services billed by the PGP and furnished by the downstream collaboration agent to the participant hospital's CJR beneficiaries during CJR episodes that occurred during the same performance year in which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment from which the ACO made the distribution payment to the PGP. We further propose that the total amount of all downstream distribution payments made to downstream collaboration agents must not exceed the amount of the distribution payment received by the collaboration agent (PGP that is an ACO participant) from the ACO that is a CJR collaborator. In addition, all downstream distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction, as with our proposed approach for gainsharing, alignment, and distribution payments. Finally, the distribution arrangement must not induce the downstream collaboration agent to reduce or limit medically necessary items and services to any Medicare beneficiary or reward the provision of items and services that are medically unnecessary.

We propose that the PGP must maintain contemporaneous documentation regarding downstream distribution arrangements in accordance with § 510.110, including:

- The relevant written agreements;
- The date and amount of any downstream distribution payment(s);
- The identity of each downstream collaboration agent that received a downstream distribution payment; and
- A description of the methodology and accounting formula for determining the amount of any downstream distribution payment.

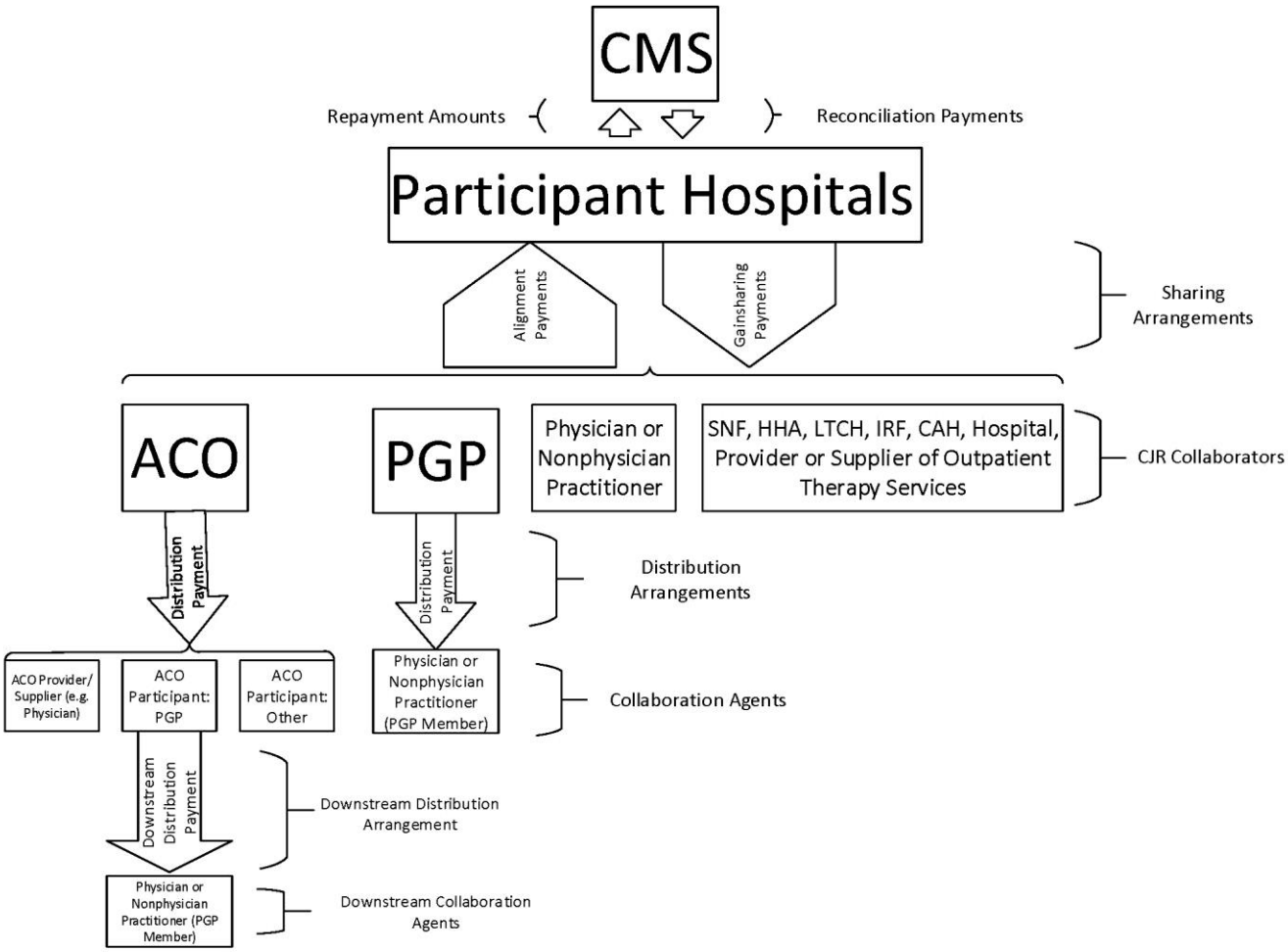
We propose that the PGP may not enter into a downstream distribution arrangement with any PGP member who has a sharing arrangement with a participant hospital or distribution arrangement with the ACO in which the PGP is a participant. Finally, we propose that the PGP must retain and provide access to, and must require downstream collaboration agents to retain and provide access to, the required documentation in accordance with § 510.110.

The proposals for downstream distribution arrangement requirements are included in § 510.506. We seek comment on our proposals.

5. Summary of Proposals for Sharing, Distribution, and Downstream Distribution Arrangements under the CJR model.

Figure 3 summarizes the proposals for the defined terms and financial arrangements discussed in section V.J. of this proposed rule.

Figure 3: PROPOSED CJR FINANCIAL ARRANGEMENTS



K. Beneficiary Incentives under the CJR Model

We propose numerous amendments to the regulations in § 510.515. These are mainly for organizational purposes, to more clearly specify our policies, and for the CJR model regulations to mirror the proposed EPM regulations at §512.525 to avoid confusion for hospitals that are participating in CJR as well as one or more of the proposed EPMs. Our proposed changes to the regulations reflect that the requirements and rules regarding the use of beneficiary incentives under the CJR model would stay largely the same. However, we are proposing several changes

in order to ensure adequate documentation of beneficiary incentives by participant hospitals and to align with our proposed requirements for the EPMs.

First, as a program safeguard against misuse of beneficiary incentives under the CJR model, we would clarify our existing requirements for documentation of beneficiary incentives. Documentation regarding items of technology exceeding $100 in retail value must also include contemporaneous documentation of any attempt to retrieve the technology at the end of a CJR episode. Documented, diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement.

We also propose to add as a requirement that participant hospitals retain and provide access to required documentation pertaining to beneficiary incentives as discussed throughout section V.L. of this proposed rule and proposed in §510.110 of the regulations. Participant hospitals retaining and providing access to documentation in accordance with §510.110 would promote parallel record retention for all CJR model requirements and further enable successful monitoring efforts by CMS. As discussed in section V.L., the proposed section §510.110 would apply to beneficiary incentives as well as financial arrangements and beneficiary notification requirements under the CJR model; therefore, we are proposing to delete §510.515(e) to avoid duplicative requirements and language and to align the applicable CJR model regulations with the proposed regulations of the EPMs.

We propose to include these requirements in the regulations at §510.515(d)(3) and §510.515(d)(4). We seek comment on our proposal. We also seek comment on the proposed additional requirements for compliance with proposed section § 510.110 and the deletion of §510.515(e).

L. Access to Records and Record Retention

We propose to consolidate the requirements under CJR for access to records and record retention and apply them more broadly in the model. This approach mirrors our proposed records retention policies for the EPMs, which are discussed in detail in section III.H. of this proposed rule. We refer readers to that section for further discussion of our proposed policies and rationale.

We propose to add §510.110 to the CJR regulations, which would apply to documentation regarding beneficiary notifications, financial arrangements, and beneficiary incentives. Because we propose to consolidate all of the existing records access and retention requirements in one place, we propose to delete §510.500(e) and §510.515(c). We further propose to require participant hospitals, CJR collaborators, collaboration agents, downstream collaboration agents and any other individuals or entities performing CJR activities to allow the Government, including CMS, OIG, HHS and the Comptroller General or their designees, scheduled and unscheduled access to all books, contracts, records, documents and other evidence sufficient to enable the audit, evaluation, inspection or investigation of the individual or entity's compliance with CJR model requirements, the calculation, distribution, receipt, or recoupment of gainsharing payments, alignment payments, distribution payments, and downstream distribution payments, the obligation to repay any reconciliation payments owed to CMS, the quality of the services furnished to a CJR beneficiary during a CJR episode, and the sufficiency of CJR beneficiary notifications.

In general, we propose that such documents be maintained for a period of 10 years from the last day of the participant hospital's participation in the CJR model or from the date of completion of any audit, evaluation, inspection, or investigation.

We believe these safeguards regarding access to records and record retention are necessary to ensure program integrity and protect against abuse, in view of the CJR model's design and requirements. We believe that by providing access to CJR records, we promote transparency of activities in the CJR model. Further, the proposed access to records and record retention requirements would ensure that the compliance of participant hospitals, CJR collaborators, collaboration agents, downstream collaboration agents, and any other individuals or entities performing CJR activities can be monitored and assessed. Also, these records may be necessary in the event that a participant hospital appeals any matter that is subject to dispute resolution through CMS. As such, CMS would have the resources necessary to prepare and respond to any such appeal. Finally, we propose to establish CEHRT use attestation for CJR participant hospitals so that a CJR participant hospital could be in Track 1 of the CJR model that meets the proposed requirements in the Quality Payment Program proposed rule to be an Advanced APM as discussed in section III.A.2. of this proposed rule. Thus, we propose to require access to records and record retention about the accuracy of each Track 1 CJR model participant hospital's submissions under CEHRT use requirements. Specifically, attestation to CEHRT use and submission of clinician financial arrangements lists are key requirements for Track 1 of the CJR model that is an Advanced APM, and the access to records and record retention requirements provide a program integrity safeguard by allowing us to assess the completeness and accuracy of the participant hospital's compliance with the requirements for those submissions.

In summary, we propose in § 510.110 that participant hospitals, CJR collaborators, collaboration agents, downstream collaboration agents, and any other individuals or entities performing providing CJR activities must allow the Government, including CMS, OIG, HHS and

the Comptroller General or their designees, scheduled and unscheduled access to all books, contracts, records, documents and other evidence (including data related to utilization and payments, quality criteria, billings, lists of CJR collaborators, sharing arrangements, distribution arrangements, downstream distribution arrangements and the documentation required under § 510.500(d) and § 510.525(c)) sufficient to enable the audit, evaluation, inspection or investigation of the following:

- Individual's or entity's compliance with CJR model requirements.
- The calculation, distribution, receipt, or recoupment of gainsharing payments, alignment payments, distribution payments, and downstream distribution payments
- The obligation to repay any reconciliation payments owed to CMS.
- The quality of the services furnished to a CJR beneficiary during a CJR episode.
- The sufficiency of CJR beneficiary notifications.
- The accuracy of the CJR participant hospital's submission under CEHRT use requirements.

Further, we propose that participant hospitals, CJR collaborators, collaboration agents, downstream collaboration agents, and any other individuals or entities performing providing CJR activities maintain all such books, contracts, records, documents, and other evidence for a period of 10 years from the last day of the participant hospital's participation in the CJR model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless CMS determines a particular record or group of records should be retained for a longer period and notifies the participant hospital at least 30 calendar days before the disposition date or there has been a dispute or allegation of fraud or similar fault against the participant hospital, CJR collaborator, collaboration agents, downstream collaboration agents, or any other individual

or entity performing CJR activities related to the CJR model. In this case, the records must be maintained for 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

We seek comment on our proposals, including whether additional or different requirements are appropriate to promote program integrity, prevent fraud and abuse and promote the goals of the model.

M. Waivers of Medicare Program Rules to Allow Reconciliation Payment or Repayment Actions Resulting From the Net Payment Reconciliation Amount.

In order to correct a technical error in the CJR final rule (42 CFR 510.620), we propose to waive the requirements of section 1833(a) of the Act to the extent that they would otherwise apply to reconciliation payments or repayments from a participant hospital under the CJR model. We proposed this policy in the CJR proposed rule (80 FR 41274) and received no comments from the public on our proposal; the proposal was finalized in the CJR final rule. We refer readers to the CJR final rule (80 FR 73460 and 73461) for further discussion.

We propose to amend our regulations at §510.620 to reflect this change.

N. SNF 3-day Waiver Beneficiary Protections

The Medicare SNF benefit is for beneficiaries who require a short-term intensive stay in a SNF, requiring skilled nursing, or skilled rehabilitation care, or both. Under section 1861(i) of the Act, beneficiaries must have a prior inpatient hospital stay of no fewer than 3 consecutive days in order to be eligible for Medicare coverage of inpatient SNF care. In the November 2015 final rule (80 FR 73454 through 73460), we provided hospitals in CJR with additional flexibility to attempt to increase quality and decrease costs by allowing a waiver of the SNF 3-day rule for beneficiaries in a CJR episode beginning on or after January 1, 2017. Program requirements for

this waiver are codified at §510.610. Specifically, under §510.610, for SNFs that meet all specified requirements, we waive the requirement in section 1861(i) of the Act for a 3-day inpatient hospital stay prior to a Medicare covered post-hospital extended care service for eligible beneficiaries in a CJR episode. The CJR SNF waiver will only be available to participant hospitals that are active participants in the CJR model. If a participant hospital no longer participates in the CJR model, due to a merger or other reason, it cannot continue to use the CJR SNF waiver. All other provisions of the statute and regulations regarding Medicare Part A post-hospital extended care services continue to apply.

We believe that clarity regarding whether a waiver applies to SNF services furnished to a particular beneficiary is important to help ensure compliance with the conditions of the waiver and also improve our ability to monitor waivers for misuse. Therefore, in the CJR final rule (80 FR 73454 through 73460), we discussed how the waiver can be utilized when a beneficiary is in a CJR episode at the time when the waiver is applied. In addition, at §510.405 we require participant hospitals to provide a discharge planning notice to beneficiaries in cases where there is potential beneficiary liability for the SNF stay (80 FR 73548 through 73549).

Based on our experiences under BPCI Model 2, the Pioneer ACO Model, and other initiatives, we established certain requirements under §510.610 for hospitals and SNFs with respect to the SNF 3-day rule waiver under the CJR model. As discussed in the CJR final rule, commenters expressed concern about beneficiary liability in cases whether the beneficiary's eligibility status has changed but the hospital is unaware of the change at the time it uses the waiver. We noted that we would continue to evaluate the waiver of the SNF 3-day rule, including further lessons learned from Innovation Center models in which a waiver of the SNF 3-day rule is being tested. We indicated that in the event we determine that additional safeguards or

protections for beneficiaries or other changes were necessary, such as to incorporate additional protections for beneficiaries, we would propose the necessary changes through future rulemaking.

In considering additional beneficiary protections that may be necessary to ensure proper use of the SNF 3-day waiver under the CJR model, we note that there are existing, well-established payment and coverage policies for SNF services based on sections 1861(i), 1862(a)(1), and 1879 of the Act that include protections for beneficiaries from liability for certain non-covered SNF charges. These existing payment and coverage policies for SNF services continue to apply under the model, including SNF services furnished pursuant to the SNF 3-day waiver. (For example, see section 70 in the Medicare Claims Processing Manual, Chapter 30 – Financial Liability Protections on the CMS website at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c30.pdf; and Medicare Coverage of Skilled Nursing Facility Care at https://www.medicare.gov/Pubs/pdf/10153.pdf; Medicare Benefit Policy Manual, Chapter 8 – Coverage of Extended Care (SNF) Services Under Hospital Insurance at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c08.odf). In general, CMS requires that the SNF inform a beneficiary in writing about services and fees before the beneficiary is discharged to the SNF (§483.10(b)(6)); the beneficiary cannot be charged by the SNF for items or services that were not requested (§483.10(c)(8)(iii)(A)); a beneficiary cannot be required to request extra services as a condition of continued stay (§483.10(c)(8)(iii)(B)); and the SNF must inform a beneficiary that requests an item or service for which a charge will be made that there will be a charge for the item or service and what the

charge will be (§483.10(c)(8)(iii)(C)). (See also section 6 of Medicare Coverage of Skilled Nursing Facility Care at https://www.medicare.gov/Pubs/pdf/10153.pdf.)

As we discussed in the CJR final rule (80 FR 73454 through 73460), commenters expressed concern regarding the lag between a CJR beneficiary's Medicare coverage or eligibility status change and a participant hospital's awareness of that change. There may be cases in which a SNF waiver is used by a participant hospital because the participant hospital believes that the beneficiary meets the inclusion criteria, based on the information available to the hospital and SNF at the time of the beneficiary's admission to the SNF, but in fact the beneficiary's Medicare coverage has changed and the hospital was unaware of it based on available information.. We recognize that despite good faith efforts by participant hospitals and SNFs to determine a beneficiary's Medicare status for the model, it may occur that a beneficiary is not eligible to be included in the CJR model at the time the SNF waiver is used. In these cases, we will cover services furnished under the waiver when the information available to the provider at the time the services under the waiver were furnished indicated that the beneficiary was included in the model.

Since publication of our final rule, we have continued to learn from implementation and refinement of the SNF 3-day waiver in other models and the Shared Savings Program. Based on these experiences, we believe there are situations where it would be appropriate to require additional beneficiary financial protections under the SNF 3-day waiver for the CJR model. Specifically, we are concerned about potential beneficiary financial liability for non-covered Part A SNF services that might be directly related to use of the SNF 3-day waiver under the CJR model. We are concerned that there could be scenarios where a beneficiary could be charged for non-covered SNF services that were a result of a participant hospital's inappropriate use of the

SNF waiver. Specifically, we are concerned that a beneficiary could be charged for non-covered SNF services if a participant hospital discharges a beneficiary to a SNF that does not meet the quality requirement (3 stars or higher in 7 of the last 12 months), and payment for SNF services is denied for lack of a qualifying inpatient hospital stay. We recognize that requiring a discharge planning notice (§510.405) will help mitigate concerns about beneficiaries' potential financial liability for non-covered services. Nevertheless, we are concerned that in this scenario, once the claim is rejected, the beneficiary may not be protected from financial liability under existing Medicare rules because the waiver would not be available, and the beneficiary would not have had a qualifying inpatient hospital stay. Thus, the CJR beneficiary could be charged by the SNF for non-covered SNF services that were a result of an inappropriate attempt to use the waiver. In this scenario, Medicare would deny payment of the SNF claim, and the beneficiary could potentially be charged by the SNF for these non-covered SNF services, potentially subjecting such beneficiaries to significant financial liability. In this circumstance, we assume the participant hospital's intent was to rely upon the SNF 3-day waiver, but the waiver requirements were not met. We believe that in this scenario, the rejection of the claim could easily have been avoided if the hospital had confirmed that the requirements for use of the SNF 3-day waiver were satisfied or if the beneficiary had been provided the discharge planning notice and elected to go to a SNF that met the quality requirement.

Other models have addressed similar issues in which the beneficiary may be subject to financial liability for non-covered SNF services related to the waiver. The Next Generation ACO Model generally places the risk on the SNF, where the SNF did not qualify under the waiver or otherwise knew or reasonably could be expected to have known that payment would not be made for the non-covered SNF services. In such cases, CMS makes no payment for the services, and

the SNF may not charge the beneficiary for the services and must return any monies collected from the beneficiary. Additionally, under the Next Generation ACO Model, the ACO must indemnify and hold the beneficiary harmless for the services. We believe it is appropriate to propose to adopt a similar policy under the CJR model. In contrast to the Next Generation ACO Model, however, we believe it is most appropriate to hold the participant hospitals financially responsible for misusing the waiver in situations where waiver requirements are not met, because participant hospitals are required to be aware of the 3-day waiver requirements. Participant hospitals are the entities financially responsible for episode spending under the model and will make the decision as to whether it is appropriate to discharge a beneficiary without a 3-day stay. In addition, we clearly laid out the requirements for use of the SNF waiver in the CJR final rule. Participant hospitals may begin using the waiver for episodes that begin on or after January 1, 2017, and may only utilize the waiver to discharge a beneficiary to a SNF that meets the quality requirements. CMS will post on the public website a list of qualifying SNFs (those with a 3-star or higher rating for 7 of the last 12 months). Participant hospitals are required to consult the published list of SNFs prior to utilizing the SNF waiver. As described later in this section, we propose that when the hospital provides the beneficiary with the discharge notice in accordance with the requirements of 510.405(b)(4), the hospital would not have financial liability for non-covered SNF services that result from inapplicability of the waiver. In other words, when the participant hospital has discharged a beneficiary to a SNF that does not qualify under the conditions of the waiver, and has not provided the required notice so that the beneficiary is aware that he or she is accepting financial liability for non-covered SNF services as a result of not having a qualifying inpatient stay, we believe it is reasonable that the ultimate responsibility and financial liability for the non-covered SNF stay should rest with the participant hospital. For this

reason, we are proposing to require hospitals to keep a record of discharge planning notice distribution to CJR beneficiaries. We will monitor participant hospitals' use of discharge planning notices to assess the potential for their misuse. We also considered holding the SNF responsible but decided that since hospitals, not SNFs, are the CJR model participants, they therefore should be held responsible for complying with the 3-day waiver conditions for the reasons stated previously in this section.

To protect CJR beneficiaries from being charged for non-covered SNF charges in instances when the waiver was used inappropriately, we are proposing to add certain beneficiary protection requirements in §510.610. These requirements would apply for SNF services that would otherwise have been covered except for lack of a qualifying hospital stay. Specifically, we propose that beginning with episodes that are initiated on or after January 1, 2017, when the SNF waiver is available, if a participant hospital discharges a beneficiary without a qualifying 3-day inpatient stay to a SNF that is not on the published list of SNFs that meet the CJR SNF waiver quality requirements as of the date of admission to the SNF, the hospital will be financially liable for the SNF stay if no discharge planning notice is provided to the beneficiary, alerting them of potential financial liability. If the participant hospital provides a discharge planning notice in compliance with the requirements of §510.405(b)(4), the participant hospital will not be financially liable for the cost of the SNF stay and the normal Medicare FFS rules for coverage of SNF services will apply. In cases where the participant hospital provides a discharge planning notice in compliance with the requirements of §510.405(b)(4) and the beneficiary chooses to obtain care from a non-qualified SNF without a qualifying inpatient stay, the beneficiary assumes financial liability for services furnished (except those that are covered by Medicare Part B during a non-covered inpatient SNF stay).

In the event a CJR beneficiary is discharged to a SNF without a qualifying 3-day inpatient stay, but the SNF is not on the qualified list as of the date of admission to the SNF, and the participant hospital has failed to provide a discharge planning notice, as specified in §510.405(b)(4), we propose that CMS apply the following rules:

- CMS shall make no payment to the SNF for such services.
- The SNF shall not charge the beneficiary for the expenses incurred for such services; and the SNF shall return to the beneficiary any monies collected for such services.
- The hospital shall be responsible for the cost of the uncovered SNF stay.

In addition, we propose to amend our regulations to clarify that the SNF 3-day waiver will be available in performance years 2 through 5 for those episodes beginning on or after January 1, 2017. In the CJR final rule, we discussed how the SNF 3-day waiver will be available beginning in performance year 2. We propose to clarify here that the waiver does begin in performance year 2, but only for those episodes that begin on or after January 1, 2017 when the waiver goes into effect.

We seek comment on these proposals. Specifically, we seek comment on whether it is reasonable to -- (1) cover services furnished under the SNF waiver based on participant hospital knowledge of beneficiary eligibility for the CJR model as determined by Medicare coverage status at the time the services under the waiver were furnished; and (2) to hold the participant hospital financially responsible for rejected SNF claims if a CJR beneficiary is discharged to a SNF without a qualifying 3-day inpatient stay, but the SNF is not on the qualified list as of the date of admission to the SNF, and the participant hospital has failed to provide a discharge planning notice as specified in §510.405(b)(4).. We seek comment on whether SNFs instead of, or in addition to, the participant hospital should be held liable for such claims and under what

circumstances. Finally, we seek comment on any other related issues that we should consider in connection with these proposal to protect beneficiaries from significant financial liability for non-covered SNF services related to the waiver of the SNF 3-day rule under the CJR model. We may address those issues through future notice and comment rulemaking.

We propose to amend our regulations at §510.610 to reflect this change. We also propose to clarify the language in §510.610 to reflect that the CJR SNF waiver will be available for use for episodes that begin on or after January 1, 2017.

O. Advanced Alternative Payment Model Considerations

1. Overview for CJR

The MACRA created two paths for eligible clinicians to link quality to payments: the MIPS and Advanced APMs. These two paths create a flexible payment system called the Quality Payment Program as proposed by CMS in the Quality Payment Program proposed rule (81 FR 28161 through 28586).

As proposed in the Quality Payment Program proposed rule, an APM must meet three criteria to be considered an Advanced APM (81 FR 28298). First, the APM must provide for payment for covered professional services based on quality measures comparable to measures described under the performance category described in section 1848(q)(2)(B)(i) of the Act, which is the MIPS quality performance category. Under the Quality Payment Program proposed rule, we proposed that the quality measures on which the Advanced APM bases payment for covered professional services (as that term is defined in section 1848(k)(3)(A) of the Act) must include at least one of the following types of measures, provided that they have an evidence-based focus and are reliable and valid (81 FR 28302):

- Any of the quality measures included on the proposed annual list of MIPS quality measures.
- Quality measures that are endorsed by a consensus-based entity.
- Quality measures developed under section 1848(s) of the Act.
- Quality measures submitted in response to the MIPS Call for Quality Measures under section 1848(q)(2)(D)(ii) of the Act.
- Any other quality measures that CMS determines to have an evidence-based focus and be reliable and valid.

As we discussed in the Quality Payment Program proposed rule, because the statute identifies outcome measures as a priority measure type and we wanted to encourage the use of outcome measures for quality performance assessment in APMs, we further proposed in that rule, that in addition to the general quality measure requirements, an Advanced APM must include at least one outcome measure if an appropriate measure is available on the MIPS list of measures for that specific QP Performance Period, determined at the time when the APM is first established (81 FR 28302 through 28303).

Second, the APM must either require that participating APM Entities bear risk for monetary losses of a more than nominal amount under the APM or be a Medical Home Model expanded under section 1115A(c) of the Act. Except for Medical Home Models, we proposed in the Quality Payment Program proposed rule that, for an Advanced APM to meet the nominal amount standard, the specific level of marginal risk must be at least 30 percent of losses in excess of expected expenditures; a minimum loss rate, to the extent applicable, must be no greater than 4 percent of expected expenditures; and total potential risk must be at least 4 percent of expected expenditures (81 FR 28306).

Third, the APM must require participants to use CEHRT (as defined in section 1848(o)(4) of the Act), as specified in section 1833(z)(3)(D)(i)(I) of the Act, to document and communicate clinical care with patients and other health care professionals. Specifically, where the APM participants are hospitals, the APM must require each hospital to use CEHRT (81 FR 28298 through 28299).

In this proposed rule, we propose to adopt two different tracks for CJR—Track 1 in which CJR and its participant hospitals would meet the criteria for Advanced APMs as proposed in the Quality Payment Program proposed rule, and Track 2 in which CJR and its participant hospitals would not meet those proposed criteria. The CJR model incorporates a pay-for-performance methodology including quality measures that we believe would meet the proposed Advanced APM quality measure requirements in the Quality Payment Program proposed rule. Both of the required quality measures in the CJR model are NQF-endorsed, have an evidence-based focus, and are reliable and valid. We believe they would meet the proposed Advanced APM general quality measure requirements.

The CJR pay-for-performance methodology includes one outcome measure that is NQF-endorsed, has an evidence-based focus, and is reliable and valid. The pay-for-performance methodology incorporates the Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550) (Hip/Knee Complications) outcome measure. Thus, we believe the CJR model would meet the requirement proposed for Advanced APMs in the Quality Payment Program proposed rule for use of an outcome measure that also meets the general quality measure requirements.

In terms of the proposed nominal risk criteria for Advanced APMs, beginning in performance year 2 for episodes ending between January 1, 2017 and December 31, 2017,

participant hospitals would begin to bear downside risk for excess actual CJR episode spending above the quality-adjusted target price. The marginal risk for excess actual CJR episode spending above the quality-adjusted target price would be 100 percent over the range of spending up to the stop-loss limit, which would exceed 30 percent marginal risk, and there would be no minimum loss rate. As a result, we believe the CJR model would meet the marginal risk and minimum loss rate elements of the nominal risk criteria for Advanced APMs proposed in the Quality Payment Program proposed rule. Total potential risk for most CJR participant hospitals is 5 percent of expected expenditures in performance year 2, and increasing in subsequent performance years. Therefore, we believe the total potential risk applicable to most participant hospitals, with the lowest total potential risk being 5 percent for CJR episodes ending on or after January 1, 2017 in performance year 2, would meet the total potential risk element of the nominal risk amount standard for Advanced APMs proposed in the Quality Payment Program proposed rule because it is greater than the value of at least 4 percent of expected expenditures.

We note that participant hospitals that are rural hospitals, sole community hospitals (SCHs), Medicare Dependent Hospitals (MDHs) and Rural Referral Centers (RRCs) will have a stop-loss limit of 3 percent in performance year 2. Because 3 percent is less than the proposed threshold of at least 4 percent of expected expenditures for total potential risk proposed for Advanced APMs in the Quality Payment Program proposed rule, those rural hospitals, SCHs, MDHs, and RRCs that are CJR participant hospitals subject to special protections would be in Track 2 of the CJR model and would not meet the proposed nominal risk standard for Advanced APMs for performance year 2. We recognize that this proposal might initially limit the ability of rural hospitals, SCHs, MDHs, and RRCs to be in an Advanced APM for performance year 2. We believe this potential limitation on rural hospitals, SCHs, MDHs, and RRCs is appropriate

for the following reasons: 1) greater risk protections for these hospitals under the CJR model beginning in performance year 2 and subsequent performance years compared to other participant hospitals are necessary, regardless of their implications regarding Advanced APMs based on the nominal risk standard proposed in the Quality Payment Program proposed rule, because these hospitals have unique challenges that do not exist for most other hospitals, such as being the only source of health care services for beneficiaries or certain beneficiaries living in rural areas or being located in areas with fewer providers, including fewer physicians and post-acute care facilities; and 2) under the CJR risk arrangements, these hospitals would not bear an amount of risk in performance year 2 that we determined to be more than nominal in the Quality Payment Program proposed rule. However, we seek comment on whether we should allow participant hospitals that are rural hospitals, SCHs, MDHs, or RRCs to elect a higher stop-loss limit performance year 2 where downside risk applies in order to permit these hospitals to be in Track 1 of the CJR model for performance year 2. We note that by performance year 3, the stop-loss limit for these hospitals with special protections under the CJR model would increase to 5 percent under our proposal, so these hospitals could be in Track 1 based on the nominal risk standard proposed in the Quality Payment Program proposed rule.

As addressed in the Quality Payment Program proposed rule, it is necessary for an APM to require the use of CEHRT in order to meet the criteria to be considered to be an Advanced APM. Therefore, according to the requirements proposed in the Quality Payment Program proposed rule, so that the CJR model may meet the proposed criteria to be an Advanced APM, we propose to require participant hospitals to use CEHRT (as defined in section 1848(o)(4) of the Act) to participate in Track 1 of the CJR model. We propose that Track 1 participant hospitals must use certified health IT functions, in accordance with the definition of CEHRT

under our regulation at 42 CFR 414.1305, to document and communicate clinical care with patients and other health care professionals as proposed in the Quality Payment Program proposed rule (81 FR 28299). We believe this proposal would allow Track 1 of CJR to be able to meet the proposed criteria to be an Advanced APM.

Without the collection of identifying information on eligible clinicians (physicians, nonphysician practitioners, physical and occupational therapists, and qualified speech-language pathologists) who would be considered affiliated practitioners as proposed in the Quality Payment program proposed rule under the CJR model, CMS would not be able to consider participation in the model in making determinations as to whom could be considered a QP (81 FR 28320). As detailed in the Quality Payment Proposed rule, these determinations are based on the whether the eligible clinician meets the QP threshold under either the Medicare Option starting in payment year 2019 or the All-Payer Combination Option, which is available starting in payment year 2021 (81 FR 28165). Thus, we make proposals in the following sections to specifically address these issues that might otherwise preclude the CJR model from being considered an Advanced APM, or prevent us from operationalizing it as an Advanced APM. Based on the proposals for Advanced APM criteria in the Quality Payment Program proposed rule, we seek to align the design of the CJR model with the proposed Advanced APM criteria and enable CMS to have the necessary information on eligible clinicians to make the requisite QP determinations.

2. CJR Participant Hospital Tracks

To be considered an Advanced APM, the APM must require participants to use CEHRT (as defined in section 1848(o)(4) of the Act), as specified in section 1833(z)(3)(D)(i)(I) of the Act. We propose that all participant hospitals must choose whether to meet the CEHRT use

requirement. Participant hospitals that do not meet and attest to the CEHRT use requirement would be in Track 2 of the CJR model. Participant hospitals selecting to meet the CEHRT use requirement would be in Track 1 of the CJR model and would be required to attest in a form and manner specified by CMS to their use of CEHRT that meets the definition in our regulation at section 414.1305 to document and communicate clinical care with patients and other health professionals, consistent with the proposal in the Quality Payment Program proposed rule for the CEHRT requirement for Advanced APMs (81 FR 28299). Participant hospitals choosing not to meet and attest to the CEHRT use requirement would not be required to submit an attestation.

We believe that the selection by the participant hospital to meet and attest to the CEHRT use requirement would create no significant additional administrative burden on participant hospitals. Moreover, the choice of whether to meet and attest to the CEHRT use requirement would not otherwise change any participant hospital's requirements or opportunity under the CJR model. However, to the extent the eligible clinicians who enter into financial arrangements related to Track 1 CJR participant hospitals are considered to furnish services through an Advanced APM, those services could be considered for purposes of determining whether the eligible clinicians are QPs.

The proposals for CEHRT use and attestation for participant hospitals are included in § 510.120(a). We seek comment on our proposals for CJR tracks and participant hospital requirements.

3. Clinician Financial Arrangements Lists under the CJR Model

In order for CMS to make determinations as to eligible clinicians who could be considered QPs based on services furnished under the CJR model (to the extent the model is determined to be an Advanced APM), we require accurate information about eligible clinicians

who enter into financial arrangements under Track 1 of CJR under which the Affiliated Practitioners support the participant hospitals' cost or quality goals as discussed in section V.J. of this proposed rule. We note that eligible clinicians could be CJR collaborators engaged in sharing arrangements with a CJR participant hospital; PGP members who are collaboration agents engaged in distribution arrangements with a PGP that is a CJR collaborator; or PGP members who are downstream collaboration agents engaged in downstream distribution arrangements with a PGP that is also an ACO participant in an ACO that is a CJR collaborator. These terms as they apply to individuals and entities with financial arrangements under CJR are discussed in section V.J. of this proposed rule. A list of physicians and nonphysician practitioners in one of these three types of arrangements could be considered an Affiliated Practitioner List of eligible clinicians who are affiliated with and support the Advanced APM Entity in its participation in the Advanced APM as proposed in the Quality Payment Program proposed rule. Therefore, this list could be used to make determinations of who would be considered for a QP determination based on services furnished under the CJR model (81 FR 28320).

Thus, we propose that each participant hospital that chooses to meet and attest to the CEHRT use requirement must submit to CMS a clinician financial arrangements list in a form and manner specified by CMS on a no more than quarterly basis. The list must include the following information for the period of the CJR performance year specified by CMS:

- For each CJR collaborator who is a physician, nonphysician practitioner, or provider of outpatient therapy services during the period of the CJR performance year specified by CMS --

++ The name, tax identification number (TIN), and national provider identifier (NPI) of the CJR collaborator; and

++ The start date and, if applicable, end date, for the sharing arrangement between the CJR participant hospital and the CJR collaborator.

- For each collaboration agent who is a physician or nonphysician practitioner of a PGP that is a CJR collaborator during the period of the CJR performance year specified by CMS --

++ The TIN of the PGP that is the CJR collaborator, and the name and NPI of the physician or nonphysician practitioner; and

++ The start date and, if applicable, end date, for the distribution arrangement between the CJR collaborator that is a PGP and the physician or nonphysician practitioner who is a PGP member.

- For each downstream collaboration agent who is a physician or nonphysician practitioner member of a PGP that is also an ACO participant in an ACO that is a CJR collaborator during the period of the CJR performance year specified by CMS --

++ The TIN of the PGP that is the ACO participant, and the name and NPI of the physician or nonphysician practitioner; and

++ The start date and, if applicable, end date, for the downstream distribution arrangement between the collaboration agent that is both PGP and an ACO participant and the physician or nonphysician practitioner who is a PGP member.

- If there are no individuals that meet the requirements to be reported as CJR collaborators, collaboration agents, or downstream collaboration agents, the participant hospital must attest in a form and manner required by CMS that there are no individuals to report on the clinician financial arrangements list.

As discussed in the Quality Payment program proposed rule, those physicians or nonphysician practitioners who are included on the Affiliated Practitioner List as of December 31 of a performance period would be assessed to determine whether they qualify for APM Incentive Payments (81 FR 28320).

While the submission of this required information may create some additional administrative requirements for certain participant hospitals, we expect that Track 1 participant hospitals could modify their contractual relationships with their CJR collaborators and, correspondingly, require those collaborators to include similar requirements in their contracts with collaboration agents and in the contracts of collaboration agents with downstream collaboration agents.

The proposal for the submission of a clinician financial arrangements list by participant hospitals that meet and attest to the CEHRT use requirements for the CJR model is included in § 510.120(b). We seek comments on the proposal for submission of this information. We are especially interested in comments about approaches to information submission, including the periodicity and method of submission to CMS that would minimize the reporting burden on participant hospitals while providing CMS with sufficient information about eligible clinicians in order to facilitate QP determinations to the extent the CJR model is considered to be an Advanced APM.

4. Documentation Requirements

For each participant hospital that chooses to meet and attest to CEHRT use, we propose that the participant hospital must maintain documentation of their attestation to CEHRT use and clinician financial arrangements lists submitted to CMS. These documents would be necessary to assess the completeness and accuracy of materials submitted by a participant hospital in Track

1 of CJR and to facilitate monitoring and audits. For the same reason, we further propose that the participant hospital must retain and provide access to the required documentation in accordance with § 510.110.

The proposal for documentation of attestation to CEHRT use and clinician financial arrangements lists submitted to CMS is included in § 510.120(c). We seek comment on this proposal for required documentation.

VI. Cardiac Rehabilitation Incentive Payment Model

A. Background

For patients with coronary and other atherosclerotic vascular disease, the American Heart Association and the American College of Cardiology Foundation's 2011 practice guideline for secondary prevention and risk reduction therapy specifically highlights health care treatment strategies following AMI or CABG.[108] These strategies include smoking cessation, close monitoring of blood pressure and cholesterol, and the use of certain medications.

The medical literature further indicates that cardiac rehabilitation (CR) and intensive cardiac rehabilitation (ICR) services, which incorporate the strategies discussed previously, are capable of achieving significant improvements in long-term patient outcomes. A January 2016 Cochrane Database of Systematic Reviews article reviewed 63 trials randomizing almost 15,000 patients and found that in long-term follow up (median 12 months), exercise-based CR services reduced cardiovascular mortality (but not total mortality), improved health-related quality of life, and reduced the risk of hospital admission.[109]

Despite the evidence from multiple studies that CR services improve health outcomes, the literature also indicates that these services are underutilized, estimating that only about 35 percent of AMI patients receive this indicated treatment.[110] Recent analysis confirms a similar pattern of underutilization for Medicare beneficiaries who are eligible for and could benefit from CR. This pattern is virtually unchanged over the past 2 decades, despite clinical

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[108] Smith SC et al. AHA/ACCF secondary prevention and risk reduction therapy for patients with coronary and other atherosclerotic vascular disease: 2011 update: a guideline from the American Heart Association and American College of Cardiology Foundation endorsed by the World Heart Federation and the Preventive Cardiovascular Nurses Association. J Am Coll Cardiol. 2011;58(23):2432-2446.

[109] Anderson L et al. Exercise-based cardiac rehabilitation for coronary heart disease. Cochrane Database Syst Rev. 2016 Jan 5;1:CD001800.

[110] Receipt of outpatient cardiac rehabilitation among heart attack survivors--United States, 2005. MMWR Morbidity and mortality weekly report. 2008 Feb 1;57(4):89–94.

practice guidelines for CR that were published in 1995 and subsequently endorsed by a number of professional associations and CMS.[111,112,113] Among beneficiaries hospitalized with a diagnosis of AMI in 2013, only about 15 percent had at least one claim for CR services, and of those who received CR services, slightly more than half received 25 or more CR sessions. Among beneficiaries hospitalized with an ICD-9-CM procedure code for percutaneous transluminal coronary angioplasty or coronary stenting in 2013, the findings on CR use were similar to those for AMI beneficiaries, with only about 23 percent having at least one claim for CR services, and of those who received CR services, slightly more than half received 25 or more CR sessions. Finally, among beneficiaries hospitalized in 2013 with ICD-9-CM procedure codes for coronary artery bypass surgery, about 45 percent had at least one claim for CR services, and slightly over 60 percent of those beneficiaries received 25 CR sessions or more, indicating slightly higher rates for utilization for these beneficiaries.[114] Barriers to CR utilization include low beneficiary referral rates (particularly of women, older adults, and ethnic minorities); lack of strong physician endorsement of CR to their patients; lack of awareness of CR; the financial burden on beneficiaries due to coinsurance and lost work; lack of accessibility of CR program

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[111] Suaya JA, Shepard DS, Normand SL, Ades PA, Prottas J, Stason WB. Use of cardiac rehabilitation by Medicare beneficiaries after myocardial infarction or coronary bypass surgery. Circulation. 2007;116:1653–1662

[112] Wenger N, Froelicher E, Smith L, Wenger N, Froelicher E, Smith L, Ades P, Berra K, Blumenthal J, Certo C, Dattilo A, Davis D, DeBusk R, DrozdaJ, 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: US Dept of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research and National Heart, Lung, and Blood Institute; 1995. Publication AHCPR 96-0673.

[113] Centers for Medicare and Medicaid Services (CMS). Cardiac rehabilitation programs. In: Medicare National Coverage Determinations Manual, chapter 1, part 1, section 20.10.

[114] Medicare Part A and B claims from 2013 through 12 month follow-up, Chronic Conditions Warehouse.

sites; the Medicare CR requirement for physician supervision; and inadequate insurance reimbursement.[115,116,117,118]

Moreover, beneficiaries with CAD often receive care in many different settings from multiple providers and suppliers over the long-term and subsequently commonly experience care that is fragmented and uncoordinated. For example, inpatient hospitals, physicians, and CR programs currently are paid separately for the services they provide, with limited financial incentives for providing care management and preventive services, limiting overuse of tests and procedures, and coordinating across care settings. Lack of coordination, of both care and financial incentives, across the continuum of CAD care, results in higher than necessary rates of adverse drug events, hospital readmissions, diagnostic errors, and other adverse outcomes, as well as lower than appropriate utilization of evidence-based treatments.

Medicare Part B generally covers CR/ICR services for all Medicare beneficiaries who are referred by their physician after having an AMI or CABG.[119] As specified in section 1861(eee) of the Act, CR/ICR programs must include all of the following: (1) physician-prescribed exercise; (2) cardiac risk factor modification, including education, counseling, and behavioral intervention, tailored to the patient's individual needs; (3) psychosocial assessment; (4) outcomes assessment; and (5) an individualized treatment plan established, reviewed, and signed by a

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[115] 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.

[116] Suaya JA, Shepard DS, Normand SL, Ades PA, Prottas J, Stason WB. Use of cardiac rehabilitation by Medicare beneficiaries after myocardial infarction or coronary bypass surgery. Circulation. 2007;116:1653–1662

[117] Wenger, NK. Current State of Cardiac Rehabilitation. J Am Coll Cardiol 2008;51:1619–31

[118] Arena, R, et al. Increasing Referral and Participation Rates to Outpatient Cardiac Rehabilitation: The Valuable Role of Healthcare Professionals in the Inpatient and Home Health Settings. AHA Scientific Advisory. 2012;125:1321-1329

[119] https://www.medicare.gov/coverage/cardiac-rehab-programs.html.

physician every 30 days that details how components are utilized for each patient. The CR/ICR services must be provided in a physician's office or a hospital outpatient setting, and a physician must be immediately available and accessible to furnish assistance and direction at all times when cardiac rehabilitation services are being furnished under the program.[120]

The number of CR program sessions are limited to a maximum of 2 one-hour sessions per day for up to 36 sessions over up to 36 weeks with the option for an additional 36 sessions over an extended period of time if approved by the Medicare Administrative Contractor under section 1862(a)(1)(A) of the Act.[121] ICR program sessions are limited to 72 one-hour sessions, up to 6 sessions per day, over a period of up to 18 weeks.[122] To be approved as an ICR program, a program must demonstrate through peer-reviewed published research that it has accomplished at least one of the following: (1) positively affecting the progression of coronary heart disease; (2) reducing the need for coronary bypass surgery; or (3) reducing the need for PCI.[123]

B. Overview of the CR Incentive Payment Model

1. Rationale for the CR Incentive Payment Model

Considering the evidence demonstrating that CR/ICR services improve long-term patient outcomes, the room for improvement in CR/ICR service utilization for beneficiaries eligible for this benefit, and the need for ongoing, chronic treatment for underlying CAD among beneficiaries that have had an AMI or a CABG, we believe that there is a need for improved long-term care management and care coordination for beneficiaries that have had an AMI or a CABG and that incentivizing the use of CR/ICR services is an important component of meeting

[120] Section 1861(eee)(1) of the Act.
[121] 42 CFR 410.49(b)(1)(vii)
[122] Section 1861(eee)(1) of the Act
[123] A list of ICR programs, approved through the national coverage determination process, is posted to the CMS website 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).

this need. We want to reduce barriers to high-value care by testing a financial incentive for hospitals that encourages the management of beneficiaries that have had an AMI or a CABG in ways that may contribute to long-term improvements in quality and reductions in Medicare spending.

We believe that there are important advantages to proposing such an incentive in conjunction with the EPMs that are also proposed in this rule. First, we wish to understand whether and how the effects of a financial incentive for the use of CR/ICR services differ depending upon whether a beneficiary's care is covered under an EPM or the Medicare FFS program. The proposed AMI and CABG models could be effective launching pads for beneficiaries to receive improved coordination, care management, and secondary risk reduction during the model episodes through greater use of medically necessary CR/ICR services, even if accountability for beneficiary care ultimately transitions to other entities, such as ACOs or PCMHs, after the AMI or CABG model episode ends. Therefore, the AMI and CABG models could make the proposed CR incentive payment more effective (if it is amplified by the broader care coordination infrastructure encouraged by the EPM in comparison with its effect in the Medicare FFS payment methodology) or less effective (if the care coordination infrastructure encouraged by the EPM is itself sufficient to ensure appropriate use of CR/ICR services such that the CR incentive payment itself has less effect than in the Medicare FFS payment methodology). Second, we wish to be able to examine each intervention's separate effects on the quality and efficiency of the care beneficiaries receive. We believe that coordinating the design, implementation, and evaluation of the EPMs and the CR incentive payment model is the best way to ensure that we accomplish both of these goals.

2. General Design of the CR Incentive Payment Model

We propose the CR incentive payment model to test the effects on quality of care and Medicare expenditures of providing explicit financial incentives to hospitals (hereinafter CR participants) for beneficiaries hospitalized for treatment of AMI or CABG to encourage care coordination and greater utilization of medically necessary CR/ICR services for 90 days post-hospital discharge where the beneficiary's overall care is paid under either an EPM or the Medicare FFS program. Under the EPM, we propose in general that the hospital where the anchor hospitalization for AMI or CABG treatment occurs that begins the AMI or CABG model episode as discussed in section III.C.4.a. of this proposed rule would be financially accountable for the AMI or CABG model episode. Thus, we expect that EPM participants would be highly engaged in care management of beneficiaries for the 90-day post-discharge duration included in the episode and may be able to capitalize on that engagement to encourage greater use of medically appropriate CR/ICR services if they are also selected for participation in the CR incentive payment model. Therefore, under the CR incentive payment model, we propose to provide a CR incentive payment specifically to selected hospitals with financial responsibility for AMI or CABG model episodes (hereinafter EPM-CR participants) because they are already engaged in managing the AMI or CABG model beneficiary's overall care for a period of time following hospital discharge.

Similarly, we believe there are opportunities to test the same financial incentives for hospitals where the beneficiary's overall care is paid under the Medicare FFS program. Thus, we also propose to provide a CR incentive payment specifically to selected hospitals that are not AMI or CABG model participants (hereinafter FFS-CR participants). This design of the CR incentive payment model would enable us to test and improve our understanding of the effects of the CR incentive payment within the context of an EPM and the Medicare FFS program, as well

as identify potential interactions between the proposed CR incentive payment and the underlying EPM and FFS payment methodologies. We understand that there may be providers and suppliers other than hospitals caring for beneficiaries with AMI or CABG whose care is paid under the Medicare FFS program and that could assume responsibility for encouraging greater utilization of CR/ICR services under the CR incentive payment model. However, for comparability to the roles and responsibilities of the hospitals that are the EPM participants selected for CR incentive payment model participation, we propose to identify hospitals as the participants in the CR incentive payment model for beneficiaries whose care is paid under the Medicare FFS program. Hospitals provide over 95 percent of CR/ICR services to Medicare beneficiaries and the beneficiaries in the CR incentive payment model are identified based on a hospitalization for AMI or CABG.[124] Thus, we believe that hospitals are an appropriate entity to take on care coordination responsibility for increasing the utilization of medically necessary CR/ICR services for those beneficiaries following AMI or CABG who are in the CR incentive payment model but that are not in an EPM.

To test strategies to encourage CR participants to prioritize referring beneficiaries following an AMI or CABG for important CR/ICR services, monitoring for beneficiary adherence to the treatment plan, and coordinating care, we propose to establish a per-service CR incentive amount for beneficiary CR use at two levels that would initially incentivize the use of any CR/ICR services and that would increase once a beneficiary meets or exceeds the proposed CR/ICR service utilization benchmark. We believe that encouraging timely referral of beneficiaries that have had an AMI or a CABG to CR/ICR programs would promote better

[124] Analysis of cardiac rehabilitation utilization in care periods for AMI and CABG beneficiaries initiated by all U.S. IPPS hospitals not in Maryland and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule, that began in CYs 2012-2014.

adherence to CR/ICR service protocols, an expectation that is supported by data showing that patients who are referred early to CR were more likely to enroll.[125]

Historical claims data show that more than half of beneficiaries who receive one CR session go on to complete at least 25 sessions.[126] Thus, providing a CR incentive payment to reward increased referrals to CR/ICR programs, as well as monitoring for beneficiary adherence with the referral and participation in the sessions, may encourage better CAD-specific care management and care coordination for beneficiaries that have had an AMI or a CABG and, ultimately, improve quality and reduce spending long-term for these beneficiaries with CAD. CR participants that would be eligible for these CR incentive payments could further reduce potential beneficiary barriers to CR/ICR services by utilizing other flexibilities we propose for the AMI and CABG models and the CR incentive payment model, such as beneficiary engagement incentives as discussed in sections III.I.9. and VI.F.6. of this proposed rule for EPM-CR participants and FFS-CR participants, respectively. Furthermore, we refer to section III.J.8. of this proposed rule for our proposal to provide greater CR/ICR program flexibility that may increase the availability of CR/ICR services for AMI and CABG model beneficiaries by providing a waiver of the definition of a physician to include a physician or nonphysician practitioner (defined for the purposes of this waiver as a physician assistant, nurse practitioner, or clinical nurse specialist) in performing specific physician functions. We also refer to section VI.F.7. of this proposed rule for discussion of our proposal for a similar waiver of the physician definition to provide greater CR/ICR program flexibility to increase the availability of these services for beneficiaries in a FFS-CR participant, as defined later in this section.

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[125] Grace SL et al. Effectiveness of inpatient and outpatient strategies in increasing referral and utilization of cardiac rehabilitation: a prospective, multi-site study. Implement Sci. 2012: 7:120.
[126] Analysis of CR/ICR services utilization in 2013 Medicare FFS Parts A and B claims.

While we recognize there are other services focused on secondary prevention for beneficiaries with CAD such as diabetes self-management training, as well as treatments including drugs for blood pressure and cholesterol control, we believe that CR/ICR services are unique as an underutilized Medicare benefit with a strong evidence-base of improved health outcomes for beneficiaries who have had an AMI or a CABG. Therefore, we believe that CR/ICR services are uniquely worthy of CR incentive payments to selected AMI and CABG model participants as well as selected hospitals that would not be participating in these models in order to reward their efforts where we observe increased CR/ICR service utilization for CR incentive payment model beneficiaries. By proposing to provide CR incentive payments to encourage CR/ICR service utilization, we maximize our opportunity to positively affect the quality of care and reduce the cost-of-care for beneficiaries that have had an AMI or a CABG both within the short- and long-term. Like under other Innovation Center models, beneficiaries in the CR incentive payment model would retain freedom of choice to choose providers and services, although the proposed model provides financial incentives to CR participants to specifically encourage and support beneficiaries in adhering to a prescribed CR treatment plan following AMI or CABG.

By making CR incentive payments available to selected EPM-CR and FFS-CR participants and comparing them to EPM participants and hospitals paid under the Medicare FFS program for AMI and CABG care who are not CR participants, we would be able to observe the effects of these proposed CR incentive payments on utilization of CR/ICR services and short-term (within the episode or care period) and longer-term outcomes, including mortality, hospitalizations, complications, and other clinically relevant events, as well as on Medicare expenditures. In testing the effects of a CR incentive payment, we want to account for a range of

factors and interactions that could potentially affect the outcomes we observe. We believe our proposed methodology would enable us to test and improve our understanding of the effects of the CR incentive payment within the context of an EPM and the Medicare FFS program, as well as examine potential interactions between the proposed CR incentive payment and the underlying EPM and FFS payment methodologies.

C. CR Incentive Payment Model Participants

The selection of MSAs for participation in the CABG and AMI EPMs is described in section III.B.5. of this proposed rule. This selection process would identify the 98 EPM MSAs from the 294 MSAs eligible for selection for the AMI and CABG models under the proposed rules. We propose that 45 MSAs be selected from within the pool of the 98 EPM MSAs for the CR incentive payment model (hereinafter EPM-CR MSAs). An additional 45 MSAs would be selected for the CR incentive payment model from the pool of MSAs who were eligible but not selected for EPM (hereinafter FFS-CR MSAs). The approach for both selections in the following paragraphs.

We are interested in identifying control group MSAs that are similar to the treatment MSAs in ways that might impact the nature of their response to the CR incentive payment model. Having well-matched MSAs in the four types of MSAs (FFS-CR, FFS-non CR, EPM-CR and EPM-non CR) is important to our ability to assess the specific impact of the CR incentive payment while holding other considerations constant. We are concerned that a simple random selection of FFS-CR and EPM-CR areas would have a large probability of selecting MSAs that are insufficiently similar to the EPM-non CR areas due to the small number of MSAs from which to choose. As such, CMS proposes the selection of the EPM-CR MSAs to balance

the incidence of key characteristics between the EPM-CR and EPM-non CR MSAs and the selection of FFS-CR MSAs to be based on similarity to the randomly selected EPM MSAs.

The 294 MSAs originally eligible for selection would be classified into groups based on combinations of several key dimensions related to CR or ICR service provision within the MSA in the reference year including --

- Percent Starting CR/ICR services: Percent of eligible cases in the MSA who received one or more CR or ICR services in the reference year. CMS is considering dividing MSAs through alternative cut points of this metric including 20 percent and 30 percent;
- Percent Completing CR/ICR services: Percent of eligible cases in the MSA who completed 25 or more CR or ICR services in the reference year. CMS is considering dividing MSAs through alternative cut points including 50 percent, 60 percent and 70 percent of this metric; and.
- Number of CR/ICR providers: The number of providers who billed for CR/ICR services in the MSA during the reference year. CMS is considering dividing MSAs according to whether they had one hospital who billed for CR services or more than one hospital.

MSAs would be assigned into a group based on combinations of these measures. An example of a possible group would be a group of MSAs that are "low starters, high users." Such a group might be defined as MSAs in which – (1) less than 20 percent of eligible patients start CR/ICR services; (2) more than 60 percent of individuals who start CR/ICR complete 25 or more sessions; and (3) more than one hospital bills for CR services.

We propose the selection of CR MSAs via a modified stratified random selection algorithm in which these groups serve as the selection strata. Specifically, we propose that the number of EPM-CR and FFS-CR MSAs selected from each group equals the number of EPM

MSAs in the group multiplied by 0.46. This rate was chosen with the goal of selecting 45 EPM-CR MSAs out of 98 EPM MSAs (45/98 is approximately equal to 0.46). As an example of this approach to selection, consider a hypothetical group with 16 EPM MSAs and 28 FFS MSAs. We would randomly select 7 EPM-CR MSAs from the 16 EPM MSAs (7 is equal to 0.46 x 16 with rounding). The remaining 9 would be EPM-non CR. We would also randomly select 7 FFS-CR MSAs from the 28 FFS MSAs. The remaining 21 MSAs would be FFS-non CR MSAs. This approach would ensure balance with respect to group membership between EPM-CR MSAs and EPM-non-CR MSAs, as well as between EPM-CR MSAs and FFS-CR MSAs; it would not necessarily achieve balance with respect to group membership for other comparisons among model arms.

We also considered other approaches to selection. Under one alternative approach, we would select a number of EPM-CR MSAs from each group equal to the number of EPM MSAs in the group multiplied by 0.46 and a number of FFS-CR MSAs from each group equal to the number of FFS MSAs in the group multiplied by 0.23. As previously discussed, the rate 0.46 was chosen with the goal of selecting 45 EPM-CR MSAs out of 98 EPM MSAs. The rate 0.23 is based on the goal of selecting 45 FFS-CR MSAs out of 196 FFS MSAs (45/196 is approximately equal to 0.23). As in our proposed approach, the calculated number of MSAs to be selected from each group would be rounded to the nearest integer as necessary. This approach would ensure balance with respect to group membership between EPM-CR MSAs and EPM-non-CR MSAs, as well as between FFS-CR MSAs and FFS-non-CR MSAs; it would not necessarily achieve balance with respect to group membership for other comparisons among model arms.

Under another alternative approach, we would use a stratified random assignment approach to determine both EPM participation and CR participation. Specifically, under this

approach, the number of EPM-CRs and FFS-CR MSAs selected from each group would each be equal to the total number of MSAs in that group multiplied by 0.15, the number of EPM-non-CR MSAs selected from each group would be equal to the total number of MSAs in the group multiplied by 0.18, and the remaining MSAs in each group would be assigned to be FFS-non-CR MSAs. The rate 0.15 was chosen with the goal of selecting 45 EPM-CR MSAs and 45 FFS-CR MSAs out of 294 total MSAs (45/294 is approximately equal to 0.15), and the rate 0.18 was chosen with the goal of selecting 53 EPM-non-CR MSAs out of 294 total MSAs (53/294 is approximately equal to 0.18). As in our proposed approach, the calculated number of MSAs to be selected into each arm would be rounded to the nearest integer as necessary. This approach would ensure balance with respect to group membership for all comparisons across the four arms—EPM-CR, FFS-CR, EPM-non-CR, and FFS-non-CR—but would forgo the simplicity of simple random assignment for the selection of EPM MSAs.

For the purposes of being able to evaluate the CR incentive payment model as a whole, we propose to implement it in a consistent manner between the EPM-CR areas and the FFS-CR areas. As such, we propose to use similar approaches to identifying CR participants in each while also coordinating with the specifications and requirements of the AMI and CABG models. We propose that EPM-CR participants are hospitals that are AMI or CABG model participants located in the MSAs selected for the EPM-CR participation based on the methodology previously described in this section VI.C. of this proposed rule. We similarly propose that FFS-CR participants are hospitals located in the MSAs selected for FFS-CR participation based on the methodology previously described in section VI.C of this proposed rule and that meet all provisions in sections III.B.2. through III.B.4. of this proposed rule to be an EPM participant if the hospital were located in an MSA selected for the AMI or CABG model. We believe that

requiring FFS-CR participants to meet all provisions in sections III.B.2. through III.B.4. of this proposed rule would ensure that FFS-CR participants resemble EPM-CR participants as closely as possible, which would contribute to our ability to test and evaluate the effect of the CR incentive payment and specifically whether there are differential effects of the CR incentive payment in the underlying EPM and FFS payment methodologies.

The proposal to select MSAs for the CR incentive payment model and to identify CR participants is included in §512.703. We seek comments on our proposed approach to selecting MSAs and identifying CR participants.

D. CR/ICR Services that Count Towards CR Incentive Payments

We propose to identify CR/ICR services that count towards CR incentive payments on the basis of the presence of the HCPCS codes on PFS and OPPS claims that report CR/ICR services as displayed in Table 37. These HCPCS codes have been active since prior to 2013 through the present. We note that CMS specifies the CR/ICR service HCPCS codes in implementing the statutory coverage provisions for CR and ICR programs, and we would update this list of HCPCS codes for CR/ICR services for the CR incentive payment model in future CR performance years should CMS adopt different or additional HCPCS codes for reporting these services.[127,128]

[127] 42 CFR 410.49

[128] MLN Matters® Number: MM6850 Revised. Related Change Request #: 6850; Related CR Release Date: May 21, 2010. Effective Date: January 1, 2010. Related CR Transmittal #: R1974CP, R126BP, R339PI, and R170FM. Implementation Date: October 4, 2010.

TABLE 37: HCPCS CODES FOR CARDIAC REHABILITATION AND INTENSIVE CARDIAC REHABILITATION SERVICES

HCPCS Code	Descriptor
93797	Physician services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)
93798	Physician services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per session)
G0422	Intensive cardiac rehabilitation; with or without continuous ECG monitoring with exercise, per session
G0423	Intensive cardiac rehabilitation; with or without continuous ECG monitoring; without exercise, per session

We propose that within the AMI and CABG models, CR/ICR services paid by Medicare to any provider or supplier for AMI and CABG model beneficiaries during AMI and CABG model episodes would result in EPM-CR participant eligibility for CR incentive payments. For FFS-CR participants, we propose to use the terms "AMI care period" and "CABG care period" to refer to a period of AMI or CABG care, respectively, that would meet the requirements to be an AMI or CABG model episode in accordance with all provisions in subpart B if the FFS-CR participant were an AMI or CABG model participant. CR/ICR services paid by Medicare to any provider or supplier for beneficiaries during AMI care periods and CABG care periods would result in FFS-CR participant eligibility for CR incentive payments. Defining AMI care periods and CABG care periods using the AMI and CABG model episode definitions ensures that the care covered under AMI care periods and CABG care periods is comparable to AMI and CABG model episodes in terms of the criteria that must be met to start an AMI care period or CABG care period or an AMI or CABG model episode, as well as the duration of AMI care periods and CABG care periods and AMI and CABG model episodes. This comparability would contribute to our ability to test and evaluate the effects of the CR incentive payment and specifically to

assess whether there are differential effects of the CR incentive payment in the underlying EPM and FFS payment methodologies.

We also propose that AMI and CABG model episodes take precedence over AMI care periods and CABG care periods. That is, an AMI care period or CABG care period would not begin if the beneficiary is in an AMI or CABG model episode when the AMI care period or CABG care period would otherwise begin. Similarly, an AMI care period or CABG care period would be canceled if at any time during the AMI care period or CABG care period the beneficiary initiates an AMI or CABG model episode. We believe that this is appropriate because AMI and CABG model participants would have ultimate responsibility for care coordination and the quality and cost of a beneficiary's care during an AMI or CABG model episode. Giving precedence to AMI and CABG model episodes would also ensure that Medicare does not make duplicative CR incentive payments for a beneficiary and that a single beneficiary is not in an AMI or CABG model episode and an AMI care period or CABG care period at the same time.

We propose that for the purposes of the CR incentive payment, all AMI and CABG model episodes and all AMI care periods and CABG care periods must begin on or after July 1, 2017 and end on or before December 31, 2021. Thus, the CR performance years would be the same as the performance years proposed for the EPMs in section III.D.2.a. of this proposed rule. Given that the CR incentive payment model seeks to determine whether there are differential effects of the CR incentive payment in the underlying EPM and FFS payment methodologies, it is important the EPM and CR performance years be aligned for EPM-CR participants.

The proposal to establish which CR/ICR services count towards CR incentive payments is included in §512.705. We seek comments on our proposal to establish which CR/ICR services count towards CR incentive payments.

E. Determination of CR Incentive Payments

1. Determination of CR Amounts that Sum to Determine a CR Incentive Payment

Given the potential benefits of CR/ICR services, in conjunction with the low adoption of these services, we seek to propose an incentive for CR participants that is sufficient to encourage them to increase clinically appropriate CR/ICR service referrals for beneficiaries; reduce barriers to beneficiary adherence a CR/ICR service treatment plan by making additional resources available for transportation to and from CR/ICR services; and incentivize CR participant monitoring and support of beneficiary adherence to all prescribed sessions of the CR/ICR program. As such, in addition to the usual payments that Medicare makes to providers and suppliers that furnish CR/ICR services, we propose to establish a two-level per-service CR incentive amount that would initially incentivize the use of any CR/ICR services and that would increase once a beneficiary meets or exceeds the proposed CR/ICR service utilization benchmark. The CR amount would be the dollar amount determined by the two-level per-service CR incentive amounts that apply to the number of CR/ICR services paid by Medicare to any provider or supplier for a beneficiary in an AMI or CABG model episode or AMI care period or CABG care period. CR amounts across all of a CR participant's beneficiaries that received CR/ICR services would be summed for the CR performance year to determine the CR incentive payment for a CR participant. CMS would pay the CR incentive payment from the Part B Trust Fund to the CR participant after the end of each CR performance year, and the

beneficiary-specific CR amounts would be submitted to the CMS Master Database Management (MDM) System.

For the purpose of determining the CR incentive payment, we propose to count the number of CR/ICR services for the relevant time periods under the OPPS and PFS on the basis of the presence on paid claims of the HCPCS codes that report CR/ICR services as displayed in Table 37 and the units of service billed.

The initial level of the per-service CR incentive amount that would count toward the CR amount would be $25 per CR/ICR service for each of the first 11 CR/ICR services paid for by Medicare during an AMI or CABG model episode or AMI care period or CABG care period. We believe that $25 is an appropriate amount to account for the additional resources that CR participants would expend to reduce beneficiary barriers to utilizing any CR/ICR services and to support beneficiary adherence to all prescribed services in the CR/ICR program.

After 11 CR/ICR services are paid for by Medicare for a beneficiary, the level of the per-service CR incentive amount would increase to $175 per CR/ICR service for each additional CR/ICR service paid for by Medicare during the AMI or CABG model episode or AMI care period or CABG care period. This higher payment would account for the additional resources that CR participants expend to reduce beneficiary barriers to CR/ICR service utilization and also would reward CR participants for AMI or CABG model episodes or AMI care periods or CABG care periods in which beneficiaries meet or exceed the service utilization benchmark of 12 CR/ICR services.

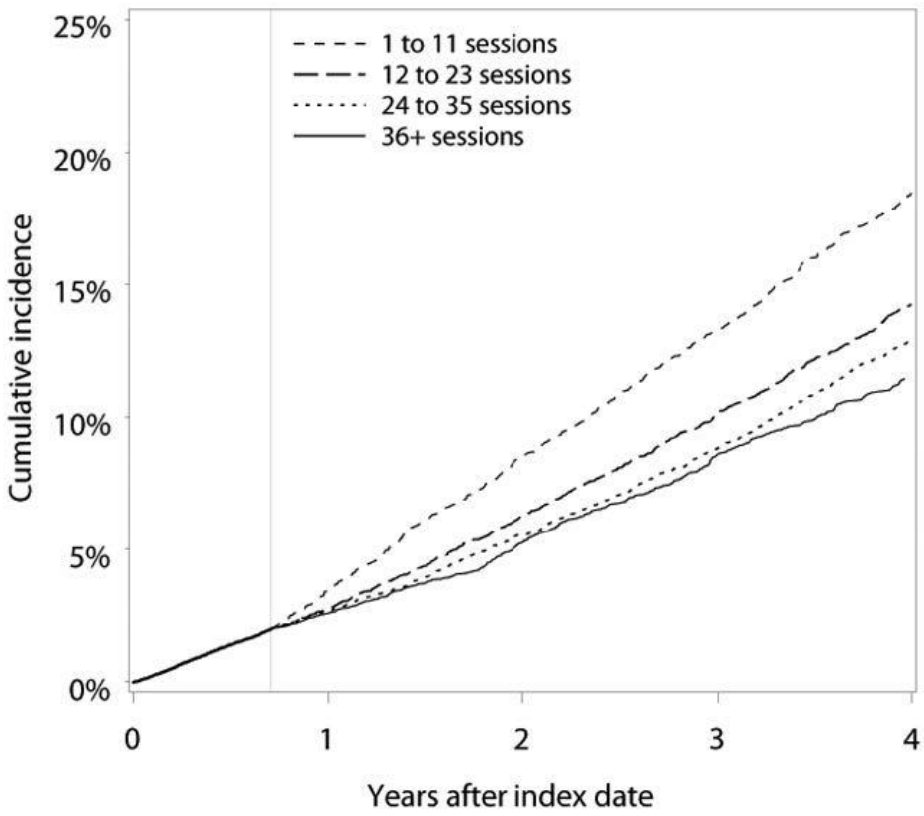
We set the proposed service utilization benchmark based on evidence from the literature that shows reduced mortality for Medicare beneficiaries that complete at least 12 CR sessions relative to Medicare beneficiaries who complete 1-11 CR sessions. A study by Hammill et al

found that over a 4-year follow-up period beneficiaries who completed 12-23 CR sessions had lower mortality compared to beneficiaries who completed 1-11 CR sessions and that beneficiaries who completed 24 or more CR sessions had lower mortality compared to beneficiaries that completed 12-23 sessions.[129] Figure 4 replicates Figure 2 from that study.

FIGURE 4: CUMULATIVE INCIDENCE OF MORTALITY BY NUMBER OF CARDIAC REHABILITATION SESSIONS ATTENDED[130]

[129] Hammill BG, Curtis LH, Schulman KA, Whellan DJ. Relationship between cardiac rehabilitation and long-term risks of mortality and myocardial infarction among elderly Medicare beneficiaries. Circulation. 2010; 121:63-70.

[130] Figure 2 of Hammill BG, Curtis LH, Schulman KA, Whellan DJ. Relationship between cardiac rehabilitation and long-term risks of mortality and myocardial infarction among elderly Medicare beneficiaries. Circulation. 2010; 121:63-70. Note that the 30,161 overall beneficiaries in the table contained in the figure refers to the number of Medicare beneficiaries that initiated cardiac rehabilitation services between January 1, 2000 and December 31, 2005 in the national 5 percent sample used by Hammill et al.

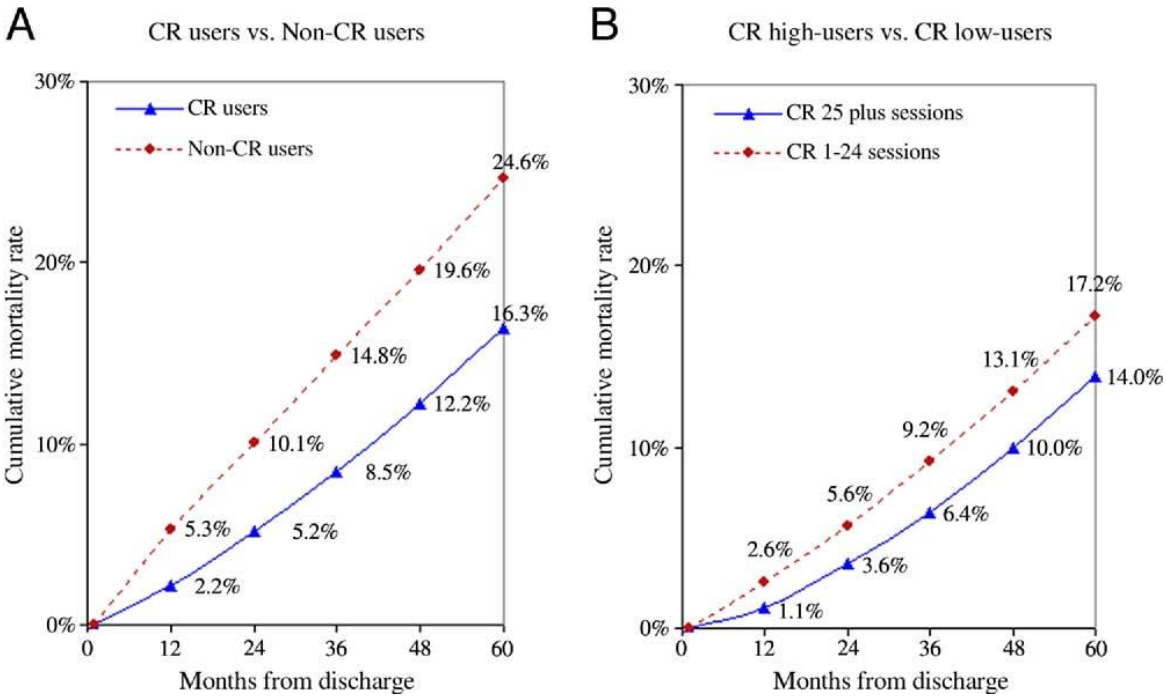


No. at risk					
Overall	30,161				
1 to 11 sessions		5937	4883	3865	2859
12 to 23 sessions		6933	5716	4427	3223
24 to 35 sessions		10,978	8955	6905	4885
36 sessions		5465	4513	3523	2481

Another study by Suaya et al showed that over a 5-year period beneficiaries who were hospitalized for coronary conditions or cardiac revascularization procedures and completed 1-24 CR sessions had lower mortality compared to beneficiaries who were probable candidates for CR but completed 0 CR sessions and that beneficiaries who completed 25 or more CR sessions had lower mortality compared to beneficiaries who completed 1-24 CR sessions.[131] Figure 5 replicates Figure 1 from that study.

[131] Suaya JA, Stason WB, Ades PA, Normand ST, Shephard DS. Cardiac rehabilitation and survival in older coronary patients. Journal of the American College of Cardiology 2009; 54:25-33.

FIGURE 5: ESTIMATES OF CUMULATIVE MORTALITY RATES FOR PROPENSITY-BASED MATCHED GROUPS OF CR USE[132]



We do not propose to set a cap on the number of CR/ICR services that would count toward the CR amount during an AMI or CABG model episode or AMI care period or CABG care period because the literature shows incremental improvements in outcomes associated with more CR/ICR services through 36 or more sessions. The duration of AMI and CABG model episodes and AMI care periods and CABG care periods is only 90 days post-discharge from the hospitalization that begins the episode or care period, or roughly 13 weeks, and Medicare already limits the number of covered CR/ICR services for a beneficiary. The number of CR program sessions are limited to a maximum of 2 one-hour sessions per day for up to 36 sessions over up to 36 weeks, with the option for an additional 36 sessions over an extended period of time if

[132]Figure 1 of Suaya JA, Stason WB, Ades PA, Normand ST, Shephard DS. Cardiac rehabilitation and survival in older coronary patients. Journal of the American College of Cardiology 2009; 54:25-33.

approved by the Medicare Administrative Contractor under section 1862(a)(1)(A) of the Act.[133] ICR program sessions are limited to 72 one-hour sessions, up to 6 sessions per day, over a period of up to 18 weeks.[134]

We believe that the higher per-service CR incentive amount that would count toward the CR amount when CR/ICR services paid by Medicare to any provider or supplier for a beneficiary in an AMI or CABG model episode or AMI care period or CABG care period meet or exceed the evidence-based service utilization benchmark would strengthen the financial incentive for CR participants to ensure beneficiary adherence to all prescribed CR/ICR services beyond the initial $25 per-service CR incentive amount for the first 11 CR/ICR services. Moreover, the higher level of the per-service CR incentive amount when a beneficiary completes at least 12 CR/ICR services provides a strong incentive for CR participants to expand CR referrals and to increase the likelihood that beneficiaries complete a clinically meaningful number of CR services. The proposal creates a continuous, significant incentive for increased CR/ICR service utilization that provides value beyond the service utilization benchmark of 12 CR/ICR services, consistent with the literature that shows a decrease in mortality for beneficiaries that complete more CR sessions relative to beneficiaries that complete fewer CR sessions.

The CR amount for a beneficiary in a CR participant's AMI and CABG model episodes or AMI care periods and CABG care periods in a CR performance year would be the sum of the $25 per-service CR incentive amount for each of the first 11 CR/ICR services and the $175 per-service CR incentive amount for each additional CR/ICR service paid by Medicare beyond

[133] 42 CFR 410.49(b)(1)(vii)
[134] Section 1861(eee)(1) of the Act

the first 11. The CR participant's CR incentive payment for a CR performance year would be determined based on the sum of the CR amounts across all of its beneficiaries for that CR performance year.

We believe that this comprehensive CR incentive payment methodology would be appropriate because it would create an explicit, strong incentive for CR participants to expand the utilization of CR/ICR services to achieve at least the evidence-based service utilization benchmark of 12 ICR/CR services and then significantly and continuously incentivize the provision of additional CR/ICR services that provide additional value, even if the full benefit of CR/ICR services for beneficiaries that have had an AMI or a CABG is not realized until after an episode or care period ends. Moreover, the CR incentive payment could offset resource costs incurred by CR participants that successfully increase utilization of CR/ICR services, such as FFS-CR participants providing transportation or EPM-CR participants providing beneficiary engagement incentives as discussed in sections III.I.9. and VI.F.6. of this proposed rule for EPM-CR and FFS-CR participants, respectively.

Because the CR incentive payment would be made to the CR participant retrospectively after the end of a CR performance year as discussed in section VI.E.4. of this proposed rule, the CR incentive payment would represent the totality of financial reward to the CR participant based on the proposed methodology for determining the payment based on CR/ICR service utilization during the CR performance year. The CR participant's resources required to support the increased utilization of CR/ICR services are likely to vary among beneficiaries. For example, it is possible that greater CR participant resources may be required to encourage and support the utilization of a beneficiary's first CR/ICR services during an AMI or CABG model episode or AMI care period or CABG care period, in comparison with promoting adherence to

additional prescribed CR/ICR services once the care pattern is well-established for that beneficiary. The proposed retrospective payment approach means CR participants would have the flexibility to redesign care to meet the needs of their beneficiaries regarding increased utilization of CR/ICR services, even though the CR incentive payment methodology only provides the higher level per-service CR incentive amount when CR/ICR service utilization achieves levels associated with improved outcomes. This approach is consistent with the model payment methodology that is designed to reward the value and not the volume of services by providing a higher total financial reward for utilization of services that has been shown to result in improved outcomes.

The proposals for determining the amount of the CR incentive payments are included in § 512.710(a) and (b). We would also note that we expect to revisit the levels of the CR incentive payment and the service utilization benchmark over the CR performance years as we observe the effects of the model policies on CR/ICR service utilization and the long-term outcomes and Medicare expenditures for CR incentive payment model beneficiaries under the EPM and Medicare FFS program payment methodologies for overall care. For example, it is possible that the proposed CR incentive payment methodology could lead to substantial increases in CR/ICR service utilization such that the proposed CR incentive payment model policies may no longer be necessary or appropriate once new care patterns are well-established.

2. Relation of CR Incentive Payments to EPM Pricing and Payment Policies and Sharing Arrangements for EPM-CR participants

We view the proposed CR incentive payments as separate and distinct from reconciliation payments and Medicare repayments for EPM-CR participants determined under § 512.305(d). The determination of these latter payments is based on an assessment of actual episode payments

and quality of the totality of episode services and coordination of those services during AMI and CABG model episodes within a performance year, consistent with the goals of improving quality and reducing costs within the model episode itself. In contrast, the proposed CR incentive payment under the CR incentive payment model is a more circumscribed and specific payment designed to financially incentivize increased utilization of CR/ICR services which may improve quality and reduce costs for AMI and CABG model beneficiaries in the long-term, after the episodes end. Thus, we propose to determine and apply the CR incentive payment separately from the determination and application of reconciliation payments and Medicare repayments for EPM-CR participants. Moreover, would also note that we propose to make CR incentive payments to EPM-CR participants without application of the limitation on gains as specified in § 512.305(c)(2)(iii)(B). This is because the limitation on gains is designed to mitigate potential excessive reductions in utilization under the proposed EPMs, and by construction, the CR incentive payment would only be made when an EPM-CR participant increases utilization of CR/ICR services. Therefore, the CR incentive payment is unrelated to the comparison of actual EPM episode payment to the quality-adjusted target price in calculating the NPRA, to which the limitation on gains applies and that may ultimately result in a reconciliation payment to an EPM-CR participant.

Consistent with the aforementioned proposal and for the aforementioned reasons, in contrast to reconciliation payments, we propose to not permit the inclusion of CR incentive payments in sharing arrangements for EPM-CR participants specified in § 512.500. As discussed in section III.I.1. of this proposed rule, we believe that EPM participants may wish to enter into financial arrangements with providers and suppliers caring for EPM beneficiaries to share financial risks and rewards under the EPM, in order to align the financial incentives of

those providers, suppliers, and Medicare ACOs with the EPM goals of improving quality and efficiency for EPM episodes. In contrast, the CR incentive payment for EPM-CR participants is specifically tied to increased utilization of CR/ICR services within AMI and CABG model episodes and, therefore, is designed to reward increased EPM-CR participant referral of AMI and CABG model beneficiaries to CR/ICR programs, as well as supporting beneficiary adherence to the referral and participation in CR/ICR services, rather than the quality and efficiency of EPM episodes themselves. Thus, we do not propose to allow CR incentive payments to be included in sharing arrangements, and the CR incentive payments may be shared with other individual and entities only under circumstances which comply with all existing laws and regulations, including fraud and abuse laws. Similarly, we do not propose that CR incentive payment be allowed to be shared by FFS-CR participants with other individuals and entities other than under circumstances which comply with all existing laws and regulations, including fraud and abuse laws. We refer to section VI.G. of this proposed rule for further discussion of considerations regarding financial arrangements under the CR incentive payment model.

Likewise, we propose to exclude CR incentive payments when updating quality-adjusted target prices for EPM-CR participants for performance years 3-5 of the EPM because payments for CR/ICR services already would be captured in the claims used to update those quality-adjusted target prices. Therefore, we believe that including the CR incentive payments would result in double counting expenditures for CR/ICR services when updating quality-adjusted target prices. We note that while the CR incentive payments would not be included in the calculation of actual EPM episode spending or when updating quality-adjusted target prices for EPM-CR participants, the claims for those CR /ICR services upon which the CR incentive payment was determined would be included in both calculations.

The proposals for keeping CR incentive payments, if any, separate from reconciliation payments and Medicare repayments as well as excluding them from sharing arrangements and updating quality adjusted target prices for EPM-CR participants are included in § 512.710(c) through (e). We seek comments on our proposals to keep CR incentive payments separate and exclusive.

3. CR Incentive Payment Report

For CR participants to receive timely and meaningful feedback on their performance with respect to the proposed CR incentive payments, we propose to annually issue to CR participants a report containing at a minimum --

- 1--The number of AMI and CABG model episodes or AMI care periods and CABG care periods attributed to the CR participant in which Medicare paid for 11 or fewer CR/ICR services for a beneficiary during the CR performance year, if any;
- 2--The total number of CR/ICR services Medicare paid for during AMI and CABG model episodes or AMI care periods and CABG care periods identified in (1);
- 3--The amount of the CR incentive payment attributable to the AMI and CABG model episodes or AMI care periods and CABG care periods identified in (1);
- 4--The number of AMI and CABG model episodes or AMI care periods and CABG care periods attributed to the CR participant in which Medicare paid for 12 or more CR/ICR services for a beneficiary during the CR performance year, if any;
- 5--The total number of CR/ICR services Medicare paid for during AMI and CABG model episodes or AMI care periods and CABG care periods identified in (4);
- 6--The amount of the CR incentive payment attributable to the AMI and CABG model episodes or AMI care periods and CABG care periods identified in (4); and

- 7--The total amount of the CR incentive payment.

We also considered including additional information in the CR incentive payment report, including information on the number of CR/ICR services paid for by Medicare during each AMI or CABG model episode or AMI care period or CABG care period attributed to the CR participant during the CR performance year. However, because EPM-CR participants and FFS-CR participants can request more specific beneficiary-level data that would contain information on CR/ICR services paid for by Medicare for each AMI or CABG model episode or AMI care period or CABG care period attributed to the CR participant during the CR performance year, as discussed in sections III.K.2. and VI.F.3. of this proposed rule, we do not propose to include such additional information in the CR incentive payment report.

For EPM-CR participants, we propose to issue this annual report at the same time we issue the reconciliation report specified in § 512.305(f). For FFS-CR participants, we propose to issue this report at the same time proposed for EPM-CR participants.

The proposal to issue a CR incentive payment report is included in § 512.710(f). We seek comments on our proposal to issue a CR incentive payment report to CR participants and what other information, if any, would be helpful to include in the CR incentive payment report.

4. Proposed Timing for Making CR Incentive Payments

We propose to make CR incentive payments on a retrospective basis. In the case of an EPM-CR participant, these payments would occur concurrently with EPM reconciliation payments or repayment amounts assessed for a specific CR performance year which is the same as the performance year for the EPM, subject to the relation of the CR incentive payment described in section VI.E.2. of this proposed rule and the appeals process for EPM participants described in section III.D.8. of this proposed rule. In the case of a FFS-CR participant, these

payments would occur at the same time as is proposed for EPM-CR participants, subject to the appeals process described in section VI.F.2. of this proposed rule.

The proposed timing for making CR incentive payments is included in §512.710(g). We seek comments on our proposed timing for making CR incentive payments.

F. Provisions for FFS-CR Participants

1. Access to Records and Retention for FFS-CR participants

In section III.H. of this proposed rule, we discuss our proposals for record access and retention under the EPM. The proposals describe the access to records and retention requirements for all EPM participants, including EPM-CR participants and other individuals and entities with respect to the EPM and CR incentive payment model, if the latter is applicable to the EPM participant. Two of the six categories of information subject to the requirements, specifically compliance with the requirements of the CR incentive payment model and the obligation to repay any CR incentive payments owed to CMS, are relevant only to the CR incentive payment model. Thus, we propose to establish CR incentive payment model access to records and retention requirements for FFS-CR participants and any other individuals or entities providing items or services to a FFS-CR beneficiary that are the same as we propose for EPM-CR participants and other individuals and entities but only for the two categories of information that are applicable to the CR incentive payment model. The other four categories of information proposed for records access and retention under the EPM, specifically the calculation, distribution, receipt, or recoupment of gainsharing payments, alignment payments, distribution payments, and downstream distribution payments; the quality of the services furnished; the sufficiency of beneficiary notifications; and the accuracy of the EPM participant's submissions under CEHRT use requirements, are not relevant to the CR incentive payment

model for FFS-CR participants and other individuals and entities providing items and services to FFS-CR beneficiaries because the CR incentive payment model includes no policies that relate directly to these categories of information.

The proposals for access to records and record retention for FFS-CR participants and other individuals and entities providing items and services to FFS-CR beneficiaries are included in § 512.715. We seek comment on our proposals, including whether it is necessary, reasonable and appropriate to impose these access and retention obligations on the FFS-CR participant and other individuals and entities providing items and services to FFS-CR beneficiaries for the proposed categories of information to be retained and made accessible. In addition, we seek comment on whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the CR incentive payment model are met.

2. Appeals Process for FFS-CR Participants

a. Overview

In section III.D.8. of this proposed rule, we discuss our proposals for the appeals process under the EPMs. The proposal outlines the appeals process requirements for all EPM participants, including EPM-CR participants, with respect to the EPM and CR incentive payment model, if the latter is applicable to the EPM participant. CR incentive payments as well as non-payment related issues, such as enforcement matters, are relevant only to the CR incentive payment model. Thus, we propose to establish CR incentive payment model appeals process for FFS-CR participants that have the same requirements as we propose for the EPM but based on only the CR incentive payment and non-payment related issues, such as enforcement matters. All other appealable items under the EPM, specifically related to payment, reconciliation

amounts, repayment amounts, determinations associated with quality measures affecting payment are not relevant to the CR incentive payment model for any FFS-CR participants because the CR incentive payment model includes no policies that relate directly to these categories of information.

b. Notice of Calculation Error (first level appeal).

We propose the following calculation error process for the CR incentive payment model to contest matters related to the calculation of the FFS-CR participant's CR incentive payment as reflected in the CR incentive payment report. FFS-CR participants would review their CR incentive payment report and be required to provide written notice of any error in a calculation error form that must be submitted in a form and manner specified by CMS. Unless the FFS-CR participant provides such notice, the CR incentive payment report would be deemed final within 45 calendar days after it is issued, and CMS would proceed with payment. If CMS receives a timely notice of an error in the calculation, CMS would respond in writing within 30 calendar days to either confirm or refute the calculation error, although CMS would reserve the right to an extension upon written notice to the participant. We propose that if a FFS-CR participant does not submit timely notice of a calculation error, which is notice within 45 calendar days of the issuance of the CR incentive payment report, the FFS-CR participant would be precluded from later contesting the CR incentive payment report for that CR performance year.

In summary, we propose the following requirements in § 512.720(a) for notice of calculation error:

- Subject to the limitations on review in subpart H of this part, if a FFS-CR participant wishes to dispute calculations involving a matter related to a CR incentive payment, the FFS-CR

participant is required to provide written notice of the error, in a form and manner specified by CMS.

- Unless the FFS-CR participant provides such notice, CMS deems final the applicable CR incentive payment report 45 calendar days after the applicable CR incentive payment report is issued and proceeds with the payment as applicable.

- If CMS receives a notice of a calculation error within 45 calendar days of the issuance of the applicable CR incentive payment report, CMS responds in writing within 30 calendar days to either confirm that there was an error in the calculation or verify that the calculation is correct, although CMS reserves the right to an extension upon written notice to the FFS-CR participant.

- Only FFS-CR participants may use the notice of calculation error process described in this subpart.

We seek comment on the proposed notice of calculation error requirements.

c. Dispute Resolution Process (second level of appeal)

We propose the following dispute resolution process. First, we propose that only a FFS-CR participant may utilize this dispute resolution process. Second, in order to access the dispute resolution process a FFS-CR participant must have timely submitted a calculation error form, as previously discussed, regarding the CR incentive payment. We propose these matters would include any amount or calculation indicated on a CR incentive payment report, including calculations not specifically reflected on a CR incentive payment report but which generated figures or amounts reflected on a CR incentive payment report. We propose calculation of CR incentive payment amounts would need to be first adjudicated by the calculation error process as previously detailed. If a FFS-CR participant wants to engage in the dispute resolution process with regard to the calculation of a CR incentive payment amount, we propose it would first need

to submit a calculation error form. Where the FFS-CR participant does not timely submit a calculation error form, we propose the dispute resolution process would not be available to the FFS-CR participant with regard to the CR incentive payment report for that CR performance year.

If the FFS-CR participant did timely submit a calculation error form and the FFS-CR participant is dissatisfied with CMS's response to the FFS-CR participant's notice of calculation error, the FFS-CR participant would be permitted to request reconsideration review by a CMS reconsideration official. The reconsideration review request would be submitted in a form and manner and to an individual or office specified by CMS. The reconsideration review request would provide a detailed explanation of the basis for the dispute and include supporting documentation for the FFS-CR participant's assertion that CMS or its representatives did not accurately calculate CR incentive payment in accordance with CR incentive payment model rules.

Where the matter is unrelated to payment, such as termination from the CR incentive payment model, the FFS-CR participant need not submit a calculation error form. We propose to require the FFS-CR participant to timely submit a request for reconsideration review, in a form and manner to be determined by CMS. Where such request is timely received, we propose CMS would process the request as discussed later in this section.

We propose that the reconsideration review would be an on-the-record review (a review of briefs and evidence only). The CMS reconsideration official would make reasonable efforts to notify the FFS-CR participant in writing within 15 calendar days of receiving the FFS-CR participant's reconsideration review request of the date and time of the review, the issues in dispute, the review procedures, and the procedures (including format and deadlines) for

submission of evidence (the "Scheduling Notice"). The CMS reconsideration official would make reasonable efforts to schedule the view to occur no later than 30 days after the date of the Scheduling Notice. The provisions at § 425.804(b), (c), and (e) (as in effect on the publication date of this proposed rule) would apply to reviews conducted pursuant to the reconsideration review process for the CR incentive payment model. The CMS reconsideration official would make reasonable efforts to issue a written determination within 30 days of the review. The determination would be final and binding.

In summary, we propose the following requirements in § 512.720 (b) for the reconsideration process:

- If the FFS-CR participant is dissatisfied with CMS's response to the notice of a calculation error, the FFS-CR participant may request a reconsideration review in a form and manner as specified by CMS.
- The reconsideration request must provide a detailed explanation of the basis for the dispute and include supporting documentation for the FFS-CR participant's assertion that CMS or its representatives did not accurately calculate the CR incentive payment in accordance with subpart H of this part.
- If CMS does not receive a request for reconsideration from the FFS-CR participant within 10 calendar days of the issue date of CMS's response to the FFS-CR participant's notice of calculation error, then CMS's response to the calculation error is deemed final and CMS proceeds with the applicable processes, as described in subpart H of this part.
- The CMS reconsideration official notifies the FFS-CR participant in writing within 15 calendar days of receiving the FFS-CR participant's review request of the following:

++ The date, time, and location of the review.

++ The issues in dispute.

++ The review procedures.

++ The procedures (including format and deadlines) for submission of evidence. The CMS reconsideration official takes all reasonable efforts to schedule the review to occur no later than 30 days after the date of receipt of notification.

● The provisions at § 425.804(b), (c), and (e) of this chapter are applicable to reviews conducted in accordance with the reconsideration review process for the FFS-CR participant.

● The CMS reconsideration official issues a written determination within 30 days of the review. The determination is final and binding.

● Only a FFS-CR participant may utilize the dispute resolution process described in this subpart. We seek comment on the proposed reconsideration process for the CR incentive payment model.

d. Exception to the Notice of Calculation Error Process and Notice of Termination.

If the FFS-CR participant contests a matter that does not involve an issue contained in, or a calculation which contributes to a CR incentive payment report, a notice of calculation error is not required. In instances where a notice of calculation error is not required, for example a FFS-CR participant's termination from the CR incentive payment model, we propose the FFS-CR participant provide a written notice to CMS requesting review within 10 calendar days of the notice. CMS has 30 days to respond to the FFS-CR participant's request for review. If the FFS-CR participant fails to notify CMS, the decision is deemed final.

In summary, we propose the following requirements in § 512.720 (c) for an exception to the notice of calculation error process:

● If the FFS-CR participant contests a matter that does not 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.

In summary, we propose the following requirements in § 512.720 (d) for notice of termination:

● If an FFS-CR participant receives notification that it has been terminated from the CR incentive payment model, it must provide a written request for reconsideration to CMS requesting review of the termination within 10 calendar days of the notice. CMS has 30 days to respond to the FFS-CR participant's request for review. If the FFS-CR participant fails to notify CMS, the termination is deemed final.

We seek comment on the proposed exception to the process and notice of termination.

e. Limitations on review.

In summary, we propose the following requirements in § 512.720 (e) for limitations on review:

● In accordance with section 1115A (d) (2) of the Act, there is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

++ The selection of models for testing or expansion under section 1115A of the Act.

++ The selection of organizations, sites, or participants to test those models selected.

++ The elements, parameters, scope, and duration of such models for testing or dissemination.

++ Determinations regarding budget neutrality under section 1115A (b) (3) of Act.

++ The termination or modification of the design and implementation of a model under section 1115A (b) (3)(B) of Act.

++ Decisions to expand the duration and scope of a model under section 1115A(c) of the Act, including the determination that a model is not expected to meet criteria described in paragraph (e)(1) or (2) of this section.

We seek comment on the proposed limitations on review.

The proposals for the appeals process for FFS-CR participants are included in § 512.720. We seek comment on our proposals for the appeals process as it related to FFS-CR participants. The two-step appeal process for payment matters — (1) calculation error form, and (2) reconsideration review—is used broadly in other CMS models. We seek comment on whether we should develop an alternative appeal process. In addition, we seek comment on whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the CR incentive payment model are met.

3. Data Sharing for FFS-CR Participants

a. Overview

Section III.K. of this proposed rule discusses our proposed policies for the types and formats of financial data that we would make available to EPM participants, frequency with which we would make these data available, and authority for making these data available to EPM participants. Specifically, in section III.K.2. of this proposed rule, we propose to provide certain financial data in two formats. First, we propose to make summary beneficiary claims data reports on beneficiaries' use of health care services during the baseline and performance periods upon request and in accordance with applicable privacy and security laws and established

privacy and security protections. These data would consist of summary claims data reports that would contain payment information such as episode counts, total average spending for each episode, based upon categories, including, inpatient services, outpatient services, skilled nursing facility services, and carrier/Part B services. Alternatively, for EPM participants with the capacity to analyze raw claims data, we propose to make more detailed beneficiary-level information available upon request and in accordance with applicable privacy and security laws and established privacy and security protections. In addition to these more detailed data, we would include episode summaries, indicators for excluded episodes, diagnosis and procedure codes, and enrollment and dual eligibility information for beneficiaries that initiate EPM episodes. In section III.K.2. of this proposed rule, we also noted our view that making this information available to EPM participants would provide tools to monitor, understand, and manage utilization and expenditure patterns as well as to develop, target, and implement quality improvement programs and initiatives.

In addition to the aforementioned data, we propose in section III.K.3. of this proposed rule to provide comparable aggregate regional data to EPM participants. Our proposal to make these regional data available is because regional pricing data would be used to determine benchmark and quality-adjusted target prices for EPM participants, and these aggregate regional data would assist participant in better understanding the basis of these prices. In section III.K.4. of this proposed rule, we propose to make 3 years of baseline data available to EPM participants prior to the models' start date, which we believe would help the participant assess its practice patterns, identify cost drivers, and ultimately redesign its care practices to improve efficiency and quality. In section III.K.5 of this proposed rule, we propose to provide to EPM participants, upon request and in accordance with the HIPAA Privacy Rule, up to 6 quarters of claims data as

frequently as on a quarterly basis throughout the EPM participant's participation or until they notify CMS that they no longer wish to receive these data.

As stated in section III.K.6 of this proposed rule, we believe our proposals are consistent with and authorized under the HIPAA Privacy Rule under the provisions that permit disclosures of PHI for "health care operations" purposes. Under those provisions, a covered entity is permitted to disclose PHI to another covered entity for the recipient's health care operations purposes if both covered entities have or had a relationship with the subject of the PHI to be disclosed, the PHI pertains to that relationship, and the recipient would use the PHI for a "health care operations" function that falls within the first two paragraphs of the definition of "health care operations" in the HIPAA Privacy Rule (45 CFR 164.506(c)(4)). The first paragraph of the definition of health care operations includes "conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines," and "population-based activities relating to improving health or reducing health costs, protocol development, case management and care coordination" (45 CFR 164.501). As we stated in section III.K.6. of this proposed rule, EPM participants would be using the data on their patients to evaluate the performance of the participant hospital and other providers and suppliers that furnished services to the patient, conduct quality assessment and improvement activities, and conduct population-based activities relating to improved health for their patients. When done by or on behalf of a covered entity, these are covered functions and activities that would qualify as "health care operations" under the first and second paragraphs of the definition of health care operations at 45 CFR 164.501. Hence, we noted our view that this provision covers the uses we would expect under the proposed EPMs. We also noted our view that, in proposing to make available the "minimum necessary" data to accomplish the intended purpose of the use, our

proposal was consistent with (45 CFR 164.502(b)). Last, we stated our belief that our proposed data disclosures are consistent with the purpose for which the data discussed in the proposed rule was collected and may be disclosed in accordance with the routine uses exception to the Privacy Act, which would otherwise prohibit disclosure of information from a system of records to any third party without the prior written consent of the individual to whom the records apply (5 U.S.C. 552a(b)). For a more detailed discussion of our proposals and authority for sharing data with EPM participants, please see section III.K. of this proposed rule.

b. Data Sharing with CR participants

As is the case with the proposed EPMs, we believe that making certain beneficiary-identifiable claims information available, upon request and in accordance with applicable privacy and security laws and established privacy and security protections, is necessary for CR participants to best improve their performance with respect to increasing utilization of CR/ICR services, which we believe should result in improved healthcare outcomes and reduced healthcare costs. However, we believe that a more limited set of data would be needed for purposes of testing the CR incentive payment model than would be made available under the proposed EPMs. This is because the purposes and processes related to the proposed CR incentive payment model are narrower in focus than under the proposed EPMs where hospitals must coordinate care across a broader array of providers and services to improve health care quality across a broader range of dimensions. Also, unlike the EPMs where a participant's performance each performance year is compared against historical spending, the CR incentive payments are based only on a CR participant's CR/ICR service utilization performance within a given CR performance year. Further, CR incentive payments are tied only to the CR participant's performance and are unrelated to performance within a region.

Thus, upon request and in accordance with applicable privacy and security laws and established privacy and security protections, we propose to make the following data available to FFS-CR participants:

- Inpatient claims - containing potential admissions for CABG and AMI MS-DRGs (and PCI DRGs with an AMI ICD-CM diagnosis code in the principal or any secondary diagnosis code position).
- Carrier and Outpatient claims – containing CR/ICR services that occurred in the 90- day period after discharge (called the AMI care period or CABG care period).

We would note that our proposal pertains only to FFS-CR participants and not to EPM-CR participants. This is because an EPM-CR participant that has requested data under the EPM would already have had the data previously described made available to them under their broader data sharing request. As such, we believe that also making these data separately available to EPM-CR participants would be duplicative and could create confusion for participants. We would also note that we do not propose to make historical payment or aggregate regional payment data available to FFS-CR participants. This is because, as previously discussed, neither historical nor regional CR/ICR service utilization performance would be factors considered when determining their eligibility for or the amount of a CR incentive payment.

As is the case for our proposed data sharing with EPM participants, we propose to make these data available in either summary or claims-level format, depending on the FFS-CR participant's request. Also, we propose to make these data available consistent with the same schedule we propose to use for making data available to EPM participants and to make available up to 6 quarters of claims data as frequently as on a quarterly basis throughout the FFS-CR

participant's participation or until they notify CMS that they no longer wish to receive these data. As is the case with the EPMs, we propose that the data files would be packaged and sent to a data portal (to which the FFS-CR participants must request and be granted access) in a "flat" or binary format for the FFS-CR participant to retrieve.

The proposal to share data with FFS-CR participants is included in §512.725. We seek comments on our data sharing proposals.

4. Compliance Enforcement for FFS-CR Participants and Termination of the CR Incentive Payment Model

In section III.F. of this proposed rule, we discuss our proposals for compliance enforcement under the EPM. The proposal outlines the non-compliance by EPM participants, including EPM-CR participants with respect to the EPM and CR incentive payment model, if the latter is applicable to the EPM participant that may trigger compliance enforcement by CMS and the enforcement mechanisms available to CMS. Four out of the seven remedial actions, specifically issuing a warning letter to the EPM participant, requiring the EPM participant to develop a corrective action plan, commonly referred to as a CAP, reducing or eliminating the EPM participant's CR incentive payment, and terminating the EPM participant from the CR incentive payment model, are relevant to the CR incentive payment model. Thus, we propose to establish compliance enforcement for the CR incentive payment model for FFS-CR participants that is substantively similar to the requirements as we propose for the EPM but that the CMS enforcement mechanisms may use with FFS-CR participants be the four remedial actions previously listed in this section. All other types of enforcement mechanisms under the EPM, specifically, reducing or eliminating the EPM participant's reconciliation payment, requiring the EPM participant to terminate a sharing arrangement with an EPM collaborator and prohibiting

the EPM collaborator from further engagement in sharing arrangements with the EPM participant, and allowing CMS to add 25 percent to a repayment amount on an EPM participant's reconciliation report under certain circumstances, are not relevant to the CR incentive payment model for any FFS-CR participants because the CR incentive payment model includes no policies that relate directly to these categories of activity.

Another distinction between the policies proposed under the EPMs and the CR incentive payment model is regarding prevention of EPM-CR participants from avoiding the high cost and high severity patients and targeting low cost and low severity patients. Under the EPMs, we prohibit EPM participants from avoiding both potentially high cost or high severity patients and targeting both potentially low cost or low severity patients. Under the CR incentive payment model we are only concerned with FFS-CR participants avoiding high severity patients and targeting low severity patients. The goal of EPM is to maintain or improve quality and coordination of care while reducing program expenditures. In contrast, the goals of the CR incentive payment model are to reduce cardiovascular mortality, improve health-related quality of life, and reduce the risk of hospital admission. The EPM explicit prohibition of avoiding high cost and targeting low cost patients is not included for the FFS-CR participants as cost savings are not a goal for participants under the CR incentive payment model.

We propose that CMS would have the remedial actions detailed in this section available for use against FFS-CR participants where such FFS-CR participant furnishing CR services to a beneficiary during the CR incentive payment model is not compliant in a matter listed in § 512.730(b)(1). These mechanisms would support CMS's goal for the CR incentive payment model to prevent overutilization of CR services that are not medically necessary, prevent FFS-CR participants from avoiding high severity patients and seeking out low severity patients,

safeguard program integrity, protect against fraud and abuse, and deter noncompliance with CR incentive payment model requirements.

Upon discovering an instance of noncompliance by a FFS-CR participant with the requirements of the CR incentive payment model, CMS, HHS, or a designee of such Agencies may take remedial action against such FFS-CR participant. Any information collected by CMS in relation to termination of a participant from the model would be shared with our program-integrity colleagues at HHS, the Department of Justice, and their respective designees. Should such participant, or one of its EPM collaborators, collaboration agents, or downstream collaboration agents, be noncompliant with the requirements of the EPMS or engage in unlawful behavior related to participation in the EPMS, we note that such information could be used in proceedings unrelated to the enforcement mechanisms in this section. FFS-CR participants also would be subject to all applicable requirements and conditions for Medicare participation not otherwise waived under section 1115A(d)(1) of the Act.

In summary, we propose in § 512.730 that FFS-CR participants must comply with all requirements outlined in subpart H. Except as specifically noted subpart H, the regulations under this part must not be construed to affect the payment, coverage, program integrity, or other requirements (such as those in parts 412 and 482 of this chapter) that apply to providers and suppliers under this chapter.

Further, we propose in § 512.730 that CMS may take the remedial actions later discussed in this section, if a FFS-CR participant -

- Fails to comply with any requirements of this subpart or is identified as noncompliant through monitoring by HHS (including CMS and OIG) of the CR incentive payment model, including but not limited to --

++ Avoiding potentially high severity patients;

++ Targeting potentially low severity patients;

++ Failing to provide medically appropriate services or systematically engaging in the over or under delivery of appropriate care;

++ Failing to provide beneficiaries with complete and accurate information; or

- Takes any action that threatens the health or safety of patients;
- Avoids at risk Medicare beneficiaries, as this term is defined in § 425.20;
- Avoids patients on the basis of payer status;
- Is subject to sanctions or final actions of an accrediting organization or federal, state, or local government agency that could lead to the inability to comply with the requirements of this subpart;
- Takes any action that CMS determines for program integrity reasons is not in the best interests of the CR incentive payment model, or fails to take any action that CMS determines for program integrity reasons should have been taken to further the best interests of the CR incentive payment model;
- Is subject to action by HHS (including OIG and CMS) or the Department of Justice to redress an allegation of fraud or significant misconduct, including intervening in a False Claims Act qui tam matter, issuing a pre demand or demand letter under a civil sanction authority, or similar actions; or
- Is subject to action involving violations of the physician self-referral law, civil monetary penalties law, federal anti-kickback statute, antitrust laws, or any other applicable Medicare laws, rules, or regulations that are relevant to the CR incentive payment model.

We propose the remedial actions to include the following:

- Issuing a warning letter to the FFS-CR participant.
- Requiring the FFS-CR participant to develop a corrective action plan, commonly referred to as a CAP.
- Reducing or eliminating the FFS-CR participant's CR incentive payment.
- Terminating the FFS-CR participant from the CR incentive payment model.

The proposals for compliance enforcement for FFS-CR participants are included in § 512.730. We seek comment on our proposals for compliance enforcement as it is related to FFS-CR participants. In addition, we seek comment on whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the CR incentive payment model are met.

We further propose under §512.905, CMS may terminate the CR incentive payment model for reasons including but not limited to --

- CMS no longer has the funds to support the CR incentive payment model; or
- CMS terminates the applicable model in accordance with section 1115A(b)(3)(B) of the Act. As provided by section 1115A(d)(2) of the Act, termination of the model is not subject to administrative or judicial review.

5. Enforcement Authority for FFS-CR Participants

OIG authority is not limited or restricted by the provisions of the CR incentive payment model, including the authority to audit, evaluate, investigate, or inspect the FFS-CR participants. Additionally, no CR incentive payment model provisions limit or restrict the authority of any other Government Agency to do the same.

The proposals for enforcement authority for FFS-CR participants in the CR incentive payment model are included in § 512.735. We seek comment about all of the requirements set

out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the CR incentive payment model are met.

6. Beneficiary Engagement Incentives for FFS-CR Participants

We propose to allow EPM participants to provide beneficiary engagement incentives under certain conditions as discussed in section III.I.9. of this proposed rule based on the goals of the EPM to improve EPM episode quality and efficiency. The goals of the CR incentive payment model in which some EPM participants also participate are to increase CR/ICR service care coordination and the medically necessary utilization of CR/ICR services in AMI and CABG model episodes for EPM-CR participants and in AMI care periods and CABG care periods for FFS-CR participants. We believe that one mechanism that may be useful to CR participants in achieving this goal is the provision of transportation to CR/ICR services as in-kind patient engagement incentives to AMI and CABG model beneficiaries and beneficiaries in AMI care periods and CABG care periods (hereinafter FFS-CR beneficiaries). As discussed earlier in this section, lack of accessibility of CR program sites can be a significant barrier to beneficiary adherence to a CR treatment plan. We do not believe there are beneficiary engagement incentives other than transportation that would be important for achieving the CR incentive payment model goals of increasing CR/ICR service care coordination and the medically necessary utilization of CR/ICR services. However, we believe that EPM-CR and FFS-CR participants should generally have the same regulatory flexibilities that are directly relevant to advancing the CR incentive payment model goals so that we can evaluate the CR incentive payment model under the two different underlying payment methodologies for AMI

and CABG care (episode or FFS) and draw conclusions about the relationship between the CR incentive payment model and the underlying payment methodology for care.

Under the proposed beneficiary engagement incentive policies for the EPM, EPM-CR participants would be able to provide beneficiary transportation to CR/ICR services in order to achieve the clinical goal of the EPM of beneficiary adherence to a care plan, subject to certain conditions on these incentives that are necessary to ensure that their provision is solely for the purpose of achieving the EPM goals of improvements in episode quality and efficiency. When transportation is provided by an EPM-CR participant as a beneficiary engagement incentive for CR/ICR services, its use would also be aligned with the CR incentive payment model goals of increasing CR/ICR service care coordination and the medically necessary utilization of CR/ICR services. Thus, our proposal for beneficiary engagement incentives under the EPM meets the potential need for transportation to CR/ICR services for AMI and CABG model beneficiaries under an EPM-CR participant.

We propose to allow FFS-CR participants to provide transportation to CR/ICR services as a beneficiary engagement incentive for FFS-CR beneficiaries during AMI care periods and CABG care periods to allow these participants similar use of beneficiary engagement incentives to achieve the CR incentive payment model goals as would be available to EPM-CR participants for that purpose. We propose the same conditions on beneficiary engagement incentives provided by FFS-CR participants as would be applicable to EPM beneficiary engagement incentives when those beneficiary incentives are transportation.

The proposed conditions for transportation when provided as a beneficiary engagement incentive by FFS-CR participants are --

- The incentive must be provided directly by the FFS-CR participant or by an agent of the FFS-CR participant under the FFS-CR participant's direction and control to the FFS-CR beneficiary during an AMI care period or CABG care period;
- Transportation must not be tied to the receipt of items or services other than CR/ICR services during AMI care periods or CABG care periods;.
- Transportation must not be tied to the receipt of items or services from a particular provider or supplier;
- The availability of transportation must not be advertised or promoted except that a beneficiary may be made aware of the availability of transportation at the time the beneficiary could reasonably benefit from it;
- The cost of transportation must not be shifted to another federal health care program, as defined at section 1128B(f) of the Act;.

In addition, as we would apply to transportation as a beneficiary engagement incentive under the EPM, we propose the same documentation requirements for beneficiary engagement incentives provided by FFS-CR participants;.

- FFS-CR participants must maintain documentation of transportation furnished as a beneficiary engagement incentive that exceeds $25 in retail value;
- The documentation established contemporaneously with the provision of transportation must include at least the following:

++ The date the transportation is provided.

++ The identity of the beneficiary to whom the transportation was provided.

- The FFS-CR participant must retain and provide access to the required documentation in accordance with § 512.715.

Our proposals for beneficiary engagement incentives provided by FFS-CR participants are included in § 512.740. We seek comment on our proposed provisions for beneficiary engagement incentives for FFS-CR participants and welcome comment on additional or alternative program integrity safeguards. We also seek comment about beneficiary engagement incentives other than transportation that could advance the CR incentive payment model goals of increased CR/ICR service care coordination and the medically necessary utilization of CR/ICR services in AMI care periods and CABG care periods.

7. Waiver of Physician Definition for Providers and Suppliers of CR/ICR Services Furnished to FFS-CR Beneficiaries During an AMI Care Period or CABG Care Period

a. Overview of Program Rule Waivers

In section III.J. of this proposed rule we discuss the proposed waivers of certain program rules that we believe offers providers and suppliers more flexibility so that they may increase coordination of care and management of beneficiaries in EPM episodes. These additional flexibilities are being proposed through our waiver authority under section 1115A of the Act, which affords broad authority for the Secretary to waive statutory Medicare program requirements as necessary to carry out the provisions of section 1115A. As discussed later in this section, we are using this authority to propose a waiver of the physician definition for providers and suppliers of CR/ICR services furnished to FFS-CR beneficiaries during an AMI care period or CABG care period. This proposed waiver is similar to the CR/ICR wavier for beneficiaries in the EPM episodes discussed in section III.J.8 of this proposed rule.

b. General Physician Requirements for Furnishing CR/ICR Services

A CR program, as defined in § 410.49(a) of regulations, means a physician-supervised program that furnishes physician prescribed exercise, cardiac risk factor modification,

psychosocial assessment, and outcomes assessment. An ICR program, as defined in § 410.49(a) of the regulations, means a physician-supervised program that furnishes cardiac rehabilitation and has shown, in peer-reviewed published research, that it improves patients' cardiovascular disease through specific outcome measurements described in § 410.49(c). A physician is defined under § 410.49(a), and under § 1861(r)(1) of the Act as a doctor of medicine or osteopathy.

In general, the following physician functions are required under § 410.49 in furnishing CR/ICR services;

- Medical director – defined at § 410.49(a) as a physician that oversees or supervises the cardiac rehabilitation or intensive rehabilitation program at a particular site;
- Supervising physician – defined at § 410.49(a) as a physician that is immediately available and accessible for medical consultations and medical emergencies at all times items and services are being furnished to individuals under cardiac rehabilitation and intensive cardiac rehabilitation programs;
- Physician-prescribed exercise – defined at § 410.49(a) as aerobic exercise combined with other types of exercise (that is, strengthening, stretching) as determined to be appropriate for individual patients by a physician; and
- Individualized treatment plan – defined at § 410.49(a) as a written plan tailored to each individual patient that, under § 410.49(b)(2)(v), must be established, reviewed, and signed by a physician every 30 days.

c. Proposed Waiver of Physician Definition For Providers and Suppliers of CR/ICR Services Furnished to EPM Beneficiaries During AMI or CABG Model Episodes

In section III.J.8. of this proposed rule, for providers or suppliers of CR/ICR services furnished to EPM beneficiaries during the proposed AMI or CABG model episodes, we

propose to waive the physician definition, under § 410.49, to allow a physician or a qualified nonphysician practitioner to perform the functions of supervising physician, prescribing exercise, and establishing, reviewing, and signing an individualized treatment plan every 30 days. A nonphysician practitioner, for the purposes of this proposed waiver is defined as a physician assistant, nurse practitioner, or clinical nurse specialist as authorized under sections 1861(s)(2)(K)(i) and (ii) of the Act and defined in section 1861(aa)(5) of the Act, or in §§ 410.74, 410.75, and 410.76 of the regulations. We do not believe a nonphysician practitioner is qualified to act in the capacity of a medical director. Thus, we are specifically excluding the medical director function from this proposed waiver. We propose this waiver to provide greater program flexibility that might increase the availability of CR/ICR services furnished to EPM beneficiaries during AMI or CABG model episodes. This proposed waiver is codified at proposed § 512.630.

d. Proposed Waiver of Physician Definition for Providers or Suppliers of CR/ICR Services Furnished to FFS-CR Beneficiaries during AMI Care Periods or CABG Care Periods

Providers and suppliers may furnish CR/ICR services to FFS-CR beneficiaries during AMI care periods or CABG care periods, as described in this section of this proposed rule. To provide greater program flexibility that might increase the availability of CR/ICR services to FFS-CR beneficiaries, we propose to provide a waiver to the definition of a physician to include a nonphysician practitioner (defined for the purposes of this waiver as a physician assistant, nurse practitioner, or clinical nurse specialist as authorized under sections 1861(s)(2)(K)(i) and (ii) of the Act and defined in section 1861(aa)(5) of the Act, or in §§ 410.74, 410.75, and 410.76 of the regulations). Thus, this proposed waiver would allow, in addition to a physician, a nonphysician practitioner to perform the functions of supervisory physician, prescribing exercise,

and establishing, reviewing, and signing an individualized treatment plan for providers or suppliers of CR/ICR services furnished to a FFS-CR beneficiary during an AMI care period or CABG care period. This proposed waiver for FFS-CR beneficiaries is similar to the proposed physician definition waiver for EPM beneficiaries during the proposed AMI or CABG model episodes as discussed in section III.J.8. of this proposed rule. All other definitions and requirements related to a physician or supervising physician under § 410.49 continue to apply. We solicit comments on this proposed waiver to allow nonphysician practitioners to perform the physician functions previously specified for the provision of CR/ICR services furnished to FFS-CR beneficiaries. This proposed waiver is codified at proposed § 512.745.

For a FFS-CR beneficiary, this waiver would apply to any provider or supplier that furnishes CR/ICR services to that beneficiary during an AMI care period or CABG care period. We anticipate monitoring the outcomes of care for beneficiaries that receive CR/ICR services under this waiver during an AMI care period or CABG care period. The monitoring may involve an analysis of all or a sample of claims, medical records, or other clinical data for beneficiaries and providers or suppliers of CR/ICR services. We solicit comments on approaches we may take to monitor this waiver to ensure this program flexibility does not have a negative effect on how beneficiaries receive CR/ICR services which then may affect the outcome of the beneficiary's care.

G. Considerations Regarding Financial Arrangements Under the CR Incentive Payment Model

As discussed in section VI.E.2. of this proposed rule, we propose to not permit the inclusion of CR incentive payments in sharing arrangements for EPM participants specified in § 512.500. Similarly, we do not propose to allow specific financial arrangements for FFS-CR participants. Thus, financial arrangements regarding CR incentive payments paid by CMS to CR

participants would be subject to all existing laws and regulations, including all fraud and abuse laws and applicable CR payment and coverage requirements. Given that more than 95 percent of CR/ICR services were historically furnished by hospital outpatient departments (HOPDs) to beneficiaries in the 90 days following discharge from a hospitalization for AMI or CABG, we expect that in many cases the CR participant that is accountable under the CR incentive payment model would itself carry out the model implementation activities, including coordination of CR/ICR services to CR beneficiaries, through the hospital's own CR program.[135] However, in other cases, depending on beneficiary choices and the availability of CR/ICR services and expertise in a CR participant's local community, CR participants may wish to engage other individuals and entities, including individuals and entities that are not providers and suppliers, in order to advance the CR incentive payment model goals of increased CR/ICR service care coordination and the medically necessary utilization of CR/ICR services in AMI and CABG model episodes and AMI care periods and CABG care periods. Thus, we expect that all financial relationships with other individuals and entities under the CR incentive payment model would be narrowly focused on certain activities related to the CR participant's specific plan to advance the goals of model.

For example, we expect that CR participants may choose to engage with providers, suppliers, and other organizations that are neither providers nor suppliers to assist with matters such as CR/ICR service utilization data analysis; beneficiary outreach; CR beneficiary care coordination and management for CR/ICR service referral and adherence to a treatment plan; CR participant compliance with the terms and conditions of the CR incentive payment model; or

[135] Analysis of cardiac rehabilitation utilization in care periods for AMI and CABG beneficiaries initiated by all U.S. IPPS hospitals not in Maryland and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that began in CYs 2012 through 2014.

other model activities. These individuals and entities may play important roles in a CR participant's plans to implement the CR incentive payment model based on their direct clinical care for beneficiaries in AMI or CABG model episodes or AMI care periods or CABG care periods; their prior experience with cardiovascular risk-factor reduction and management initiatives; their care coordination expertise; or their familiarity with the local community and access to resources that may reduce barriers to beneficiary utilization of CR/ICR services. We expect that all relationships established between CR participants and other individuals and entities for such purposes of the CR incentive payment model would only be those permitted under existing law and regulation. We would also expect that all of these relationships would solely be based on the level of engagement of the individual's or entity's resources to directly support the CR participant's CR incentive payment model implementation.

We recognize, however, that we do not have precedent with other CMS models and programs that have a similar design to the CR incentive payment model. Thus, we seek comment on whether there are other types of financial arrangements that CR participants would wish to pursue in advancing the model goals of increased CR/ICR service care coordination and the medically necessary utilization of CR/ICR services in AMI and CABG model episodes and AMI care periods and CABG care periods. We specifically request comments on which individuals and entities would be parties to the financial arrangements; what specific CR incentive payment model implementation activities would be included in the financial arrangements; and what methodologies would be used for sharing the CR incentive payment under such financial arrangements. In addition, we seek comment on what safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the CR incentive payment model would be met. Based on comments and our early implementation

experience with the CR incentive payment model, we may make specific proposals around CR incentive payment model financial arrangements in future rulemaking.

VII. Collection of Information Requirements

As stated in section1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of models under section 1115A of the Act. As a result, the information collection requirements contained in this final rule need not be reviewed by the Office of Management and Budget. We have, however, summarized the anticipated information collection requirements in the Regulatory Impact Analysis.

VIII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IX. Regulatory Impact Analysis

We have examined the impact of this rule as required by Executive Order 12866 and other laws and Executive Orders requiring economic analysis of the effects of proposed rules.

A. Statement of Need

1. Need for EPM proposed rule

This proposed rule is necessary in order to implement and test three new EPMs under the authority of section 1115A of the Act, which allows the Innovation Center to test innovative payment and service delivery models in order to "reduce program expenditures while preserving of enhancing the quality of care furnished to individuals." Under the FFS program, Medicare makes separate payments to providers and suppliers for the items and services furnished to a beneficiary over the course of treatment (an episode of care). With the amount of payments dependent on the volume of services delivered, providers may not have incentives to invest in quality-improvement and care-coordination activities. As a result, care may be fragmented, unnecessary, or duplicative. The goal for the proposed EPMs is to improve the quality of care provided to beneficiaries in an applicable episode while reducing episode spending through financial accountability.

Payment approaches that reward providers for assuming financial and performance accountability for a particular episode of care can create incentives for the implementation and coordination of care redesign between participants and other providers and suppliers such as physicians and post-acute care providers. Under the proposed EPMs, CMS will test whether an EPM for AMI, CABG, and SHFFT episodes of care will reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. We believe the proposed models have the potential to benefit Medicare beneficiaries by improving the coordination and

transition of care, improving the coordination of items and services paid for through FFS Medicare, encouraging more provider investment in infrastructure and redesigned care processes for higher-quality and more efficient service delivery, and incentivizing higher-value care across the inpatient and post-acute care spectrum. The goal for the proposed EPMs is to improve the quality of care provided to beneficiaries in an applicable episode while reducing episode spending.

The proposals for the AMI, CABG, and SHFFT models would require the participation of hospitals in multiple geographic areas that might not otherwise participate in testing episode payment for the proposed episodes of care. CMS is testing other episode payment models with the BPCI initiative and the CJR model. The BPCI initiative is voluntary; risk-bearing organizations applied to participate and chose from 48 clinical episodes. In the CJR model, acute care hospitals in selected geographic areas are required to participate in the CJR model for all eligible LEJR episodes that initiate at a CJR model participant hospital. Realizing the full potential of new EPMs will require the engagement of an even broader set of providers than have participated to date in our episode payment models such as the BPCI initiative and the CJR model. As such, we are interested in testing and evaluating the impact of episode payment for the three proposed EPMs in a variety of circumstances, including those hospitals that may not otherwise participate in such a test.

2. Need for CJR modifications

This proposed rule also includes proposed modifications to the CJR model. Acute care hospitals in selected geographic areas are required to participate in the CJR model for LEJR episodes that initiate at a CJR model participant hospital. The modifications proposed here clarify and update provisions of the CJR model and create alignment between CJR and the

proposed AMI, CABG, and SHFFT models. The primary impact of these changes will be related to: 1) incorporation of BPCI and EPM reconciliation payments and Medicare repayments in setting quality-adjusted target prices in performance years 3-5; and 2) updates to the calculation of composite quality scores.

3. Need for CR Incentive Payment Model

CR and intensive CR services are capable of achieving significant improvements in patient outcomes beyond the proposed AMI and CABG model 90-day post-discharge care period. Despite evidence from multiple studies that CR services improve health outcomes, these services remain underutilized. Beneficiaries with CAD often receive care in many different settings from multiple providers over the long-term and subsequently commonly experience care that is fragmented and uncoordinated. Lack of coordination, of both care and financial incentives, across the continuum of CAD care, results in higher than necessary rates of adverse drug events, hospital readmissions, diagnostic errors, and other adverse outcomes, as well as lower than appropriate utilization of evidence-based treatments. The CR incentive payment model will test whether a financial incentive for hospitals that encourages the management of beneficiaries that have had an AMI or a CABG in ways that may contribute to long-term improvements in quality and reductions in Medicare spending.

4. Aggregate impact of EPMs, CJR, and CR Incentive Payment Model

As detailed in Table 38, we estimate a total aggregate impact of $170 million in net Medicare savings over the proposed duration of the AMI, CABG, and SHFFT models, July 2017-December 2021. As detailed in Table 39, we estimate the proposed changes in the CJR model, along with the revised assumption that participating hospitals will report quality data, will increase estimated costs to the Medicare program by $35 million over the duration of the CJR

model (April 2016-December 2020) relative to the financial estimate published in the CJR final rule (80 FR 73288). These estimated impacts represent the net effect of federal transfers that incent hospitals for improving care while making it more efficient. Furthermore, the proposed models may benefit beneficiaries since the models require participants to be accountable for episodes extending 90 days post-hospital discharge, which may potentially improve the coordination of FFS items and services, and encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery that demonstrate a dedication and focus toward patient-centered care. Although it is possible that participating hospitals may respond to the demonstration through improvements in the efficiency of care that reduce FFS Medicare spending during these episodes, such reductions in Medicare spending will be largely offset through greater reconciliation payments paid by CMS to the participating hospital. As long as reductions in Medicare FFS spending for participating hospitals are equally offset through greater reconciliation payments from CMS to those participating hospitals, the financial impact to the Medicare program should not be significantly different from what we have currently estimated.

As detailed in Table 40, we estimate a total aggregate impact between $27 million in net Medicare costs and $32 million in net Medicare savings from July 2017-December 2024 through the cardiac rehabilitation incentive payment model. These estimated impacts represent the net effect of federal transfers to CR-EPM and CR-FFS participants and savings related to decreased future utilization in beneficiaries who receive CR/ICR services. A range of potential impacts is provided due to uncertainty in the likely increase in CR/ICR utilization based on the CR incentive provided.

We solicit comment on the assumptions and analysis presented throughout this regulatory impact section.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) (having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. This proposed rule triggers these criteria.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, pre-empts state law, or otherwise has federalism implications. We do not believe that there is anything in this proposed rule that either explicitly or implicitly pre-empts any state law, and furthermore we do not believe that this proposed rule will have a substantial direct effect on state or local governments, preempt states law, or otherwise have a federalism implication.

C. Anticipated Effects

1. Overall Magnitude of the Model and Its Effects on the Market

a. EPMs

Nationally, the total number of historical episodes ending in CY 2014 that began with IPPS hospitalizations and extended 90 days post-hospital discharge were approximately 168,000 for AMI; 48,000 for CABG; and 109,000 for SHFFT. The total Medicare spending for these historical episodes was approximately $4.1 billion, $2.3 billion, and $4.7 billion, respectively. Based on analysis of Medicare claims for historical episodes in 2012-2014, the mean estimated total payment for AMI episodes (defined based on ICD-CM diagnosis code and DRGs as described in section III.C of this proposed rule) is about $24,000, where approximately 61 percent of the spending is attributable to hospital inpatient services, 18 percent is attributable to post-acute care services and 21 percent to physician, outpatient hospital and other spending. For CABG episodes (defined based on DRGs as described in section III.C. of this proposed rule) the mean estimated total payment is about $47,000, where approximately 68 percent of the spending is attributable to hospital inpatient services, 12 percent is attributable to post-acute care services and 20 percent to physician, outpatient hospital and other spending. For SHFFT episodes

(defined based on DRGs as described in section III.C. of this proposed rule) the mean estimated total payment is about $43,000, where approximately 33 percent of the spending is attributable to hospital inpatient services, 50 percent is attributable to post-acute care services and 17 percent to physician, outpatient hospital and other spending.

We propose to test the AMI and CABG models in 98 MSAs out of 294 MSAs eligible for selection, as described in section III.B.5. of this proposed rule; we propose to test the SHFFT model in 67 MSAs in which CJR is currently operating as discussed in section III.B.4. of this proposed rule. In the 2014 calendar year there were 136,000 episodes for AMI, and 42,000 for CABG in the 294 MSAs eligible for selection, and 33,000 episodes for SHFFT in the 67 MSAs eligible for participation.

b. CJR

The overall magnitude of the CJR model is described in the CJR final rule (80 FR 73288). The modifications proposed in this rule are not related to episode definition or hospital selection and therefore do not affect the number of episodes included in the model or the mean episode payment. The primary impact of the changes proposed will be related to the calculation of quality-adjusted target prices, which will now incorporate reconciliation payments and Medicare repayments in years 3-5 of the model and include modifications to the calculation of composite quality scores. For the CJR final rule we assumed that hospitals will not report voluntarily submitted patient reported outcome measures data to CMS. Given prior experience in the Medicare program with voluntary reporting, we are revising our assumption to assume that all hospitals in CJR report this quality data. These modifications along with the revised assumptions regarding quality reporting will raise the costs estimated to the Medicare program

by $35 million from the estimate of $343 million in savings as published in the CJR final rule (80 FR 73288).

c. CR incentive payment model

We propose to test the CR incentive payment model in 45 of the 98 MSAs selected for the AMI and CABG EPMs, as well as 45 FFS MSAs selected through stratified random sampling, as described in section VI of this proposed rule. As discussed subsequently in this analysis and displayed in Table 40, this is likely to result in an impact between $27 million in net Medicare costs and $32 million in net Medicare savings from July 2017 through December 2024.

d. Aggregate Effects on the Market

There may also be spillover effects in the non-Medicare market, or even in the Medicare market in other areas as a result of this models. Changes in Medicare payment policy often have substantial implications for non-Medicare payers. As an example, non-Medicare patients may benefit if participating EPM hospitals introduce system wide changes that improve the coordination and quality of health care. Other payers may also be developing episode payment models and may align their payment structures with CMS or may be waiting to utilize results from CMS evaluations of episode payment models. Because it is unclear whether and how this evidence applies to a test of a new payment model (as opposed to a change in permanent policy), our analyses assume that spillovers effects on non-Medicare payers will not occur, although this assumption is subject to considerable uncertainty. We welcome comments on our assumptions and calculations.

2. Effects on the Medicare Program

a. EPMs

Under the proposed EPMs, the CMS will test whether an EPM for AMI, CABG, and SHFFT episodes of care will reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. Payment approaches that reward providers for assuming financial and performance accountability for a particular episode of care can potentially create incentives for the implementation and coordination of care redesign between participants and other providers and suppliers such as physicians and post-acute care providers. The proposed EPMs could enable hospitals to consider the most appropriate strategies for care redesign, including -- (1) increasing post-hospitalization follow-up and medical management for patients; (2) coordinating across the inpatient and post-acute care spectrum; (3) conducting appropriate discharge planning; (4) improving adherence to treatment or drug regimens; (5) reducing readmissions and complications during the post-discharge period; (6) managing chronic diseases and conditions that may be related to the proposed EPM episodes; (7) choosing the most appropriate post-acute care setting; and (8) coordinating between providers and suppliers such as hospitals, physicians, and post-acute care providers.

We are interested in testing and evaluating the impact of episode payment for the AMI, CABG, and SHFFT models in a variety of circumstances, including those hospitals that may not otherwise participate in such a test. The clinical circumstances of the episodes we are proposing differ in important ways from the LEJR episodes included in the CJR model. We expect the patient population included in these episodes would be substantially different from the patient population in CJR episodes, due to the clinical nature of the cardiac and SHFFT episodes. Beneficiaries in these episodes commonly have chronic conditions that contribute to the initiation of the episodes, and need both planned and unplanned care throughout the EPM episode following discharge from the initial hospitalization that begins the episode. Both AMI

and CABG model episodes primarily include beneficiaries with cardiovascular disease, a chronic condition which likely contributed to the acute events or procedures that initiate the episodes. About half the average AMI model historical episode spending was for the initial hospitalization, with the majority of spending following discharge from the initial hospitalization due to hospital readmissions, while there was relatively less spending on SNF services, Part B professional services, and hospital outpatient services. In CABG model historical episodes, about three-quarters of episode spending was for the initial hospitalization, with the remaining episode spending relatively evenly divided between Part B professional services and hospital readmissions, and a lesser percentage on SNF services. Similar to AMI episodes, post-acute care provider use was relatively uncommon in CABG model historical episodes, while hospital readmissions during CABG model historical episodes were relatively common. SHFFT model historical episodes also were accompanied by substantial spending for hospital readmissions, and post-acute care provider use in these episodes also was high.[136]

We believe that by requiring participation by a large number of hospitals with diverse characteristics, the proposed EPMs would result in a robust data set for evaluating this payment approach, and would stimulate the rapid development of new evidence-based knowledge. Testing the proposed EPMs in this manner would also allow us to learn more about patterns of inefficient utilization of health care services and how to possibly incentivize quality improvement for beneficiaries receiving services in AMI, CABG, and SHFFT episodes.

Under the proposed EPMs, as described further in section III.B.2. of this proposed rule, an AMI, CABG, or SHFFT model episode would begin with an inpatient admission assigned to one of the following MS-DRGs upon beneficiary discharge: for AMI episodes, AMI

[136] Episodes for AMI, CABG, and SHFFT beneficiaries initiated by all U.S. IPPS hospitals not in Maryland and constructed using standardized Medicare FFS Parts A and B claims, as proposed in this rule that end in CY 2014.

MS-DRGs (280-282) and those PCI MS-DRGs (246-251) representing IPPS admissions for AMI that are treated with PCIs; CABG MS-DRGs (231-236); and SHFFT MS-DRGs (480-482). Episodes would end 90 days after the date of discharge from the anchor or chained anchor hospitalization. The proposed EPM episodes would include the inpatient stays and all related care covered under Medicare Parts A and B within the 90 days after discharge, including hospital care, post-acute care, and physician services. Furthermore, we have proposed to designate EPM participant hospitals as the episode initiators and to be financially responsible for episode cost under the proposed EPMs. We propose to require all hospitals paid under the IPPS and physically located in selected geographic areas to participate, with limited exceptions. Eligible beneficiaries who receive care at these hospitals will automatically be included in the models. Geographic areas, based on MSAs, are proposed to be selected through a random sampling methodology. We believe the proposed EPMs may have financial and quality of care effects on non-hospital providers that are involved in the care of Medicare beneficiaries during model episodes, improving the coordination of items and services paid for through Medicare FFS, encouraging more provider investment in infrastructure and redesigned care processes for higher quality and more efficient service delivery, and incentivizing higher value across the inpatient and post-acute care spectrum spanning the episode of care.

As described in section III.D.2. of this proposed rule, we propose to continue paying hospitals and other providers and suppliers according to the usual Medicare FFS payment systems. After the completion of a performance year, the Medicare claims payments for services furnished to the beneficiary during the EPM episode, based on claims data, would be combined to calculate an actual EPM episode payment. The actual EPM episode payment would then be reconciled against an established EPM quality-adjusted target price. The amount of this

calculation, if positive, would be paid to the participant in a reconciliation payment. If negative, we would require repayment from the participant beginning in performance year 2 of the EPMs. EPM participants' quality performance also would be assessed at reconciliation; each participant would receive a composite quality score and a corresponding quality category. EPM participants achieving a quality category of "acceptable" or higher would be eligible for a reconciliation payment.

We also propose to phase in the requirement that participants whose actual EPM episode payments exceed the quality-adjusted target price pay the difference back to Medicare beginning for performance year 2. Under this proposal, Medicare would not require repayment from participants for performance year 1 for actual EPM episode payments that exceed their quality-adjusted target price in performance year 1, and an applicable discount factor would be used for calculating repayment amounts for performance years 2 and 3, consistent with our final policies for the CJR model.

Due to the clinical characteristics and common patterns of care in AMI model episodes, we propose payment adjustments in the cases of certain transfers and readmissions of beneficiaries to inpatient hospitals for these episodes. These payment adjustments are discussed in detail in section III.D.4.b.(1). of this proposed rule. We also propose to limit how much a participant can gain or lose based on its actual EPM episode payments relative to quality-adjusted target prices; we propose additional policies to further limit the risk of high payment cases for all EPM participants and for special categories of EPM participants as described in section III.D. of this proposed rule.

Based on the mix of financial and quality incentives, the proposed EPMs could result in a range of possible outcomes for participants. The effects on hospitals of potential savings and liabilities will have varying degrees.

(1) Assumptions

We used standardized Medicare claims data from July 2012 through September 2015 to simulate the impact that the proposed EPMs would have on Medicare spending for AMI, CABG, and SHFFT model episodes. Specifically, we applied the methodology provided in this proposed rule for calculating quality-adjusted target prices. For the SHFFT model, we applied this methodology to hospitals in the MSAs in which CJR is currently operating. For the AMI and CABG models, we applied this methodology to a hypothetic cohort including all eligible hospitals in a randomly selected group of 115 MSAs among 294 MSAs eligible for selection. The results for the AMI and CABG models were then multiplied by 98/115 to adjust for only 98 MSAs being selected. Quality-adjusted target prices were calculated based on hospital performance from 90-day episodes starting between July 2012 and June 2015. Specifically, all IPPS hospitals in the selected MSAs were included in this analysis; model-specific hospital exclusions were applied based on participation in BPCI Models 2 or 4 for the AMI, PCI, CABG, or SHFFT models as appropriate.

We identified the anchor hospitalization based on episode definition criteria in section III.C. of this proposed rule and included the related spending that occurred 90 days after discharge. We removed payments excluded from the episode as unrelated to the EPM episode diagnosis and procedures based on clinical rationale, as defined in section III.C.3.b. of this proposed rule. Payments during the 90-day episodes were calculated using CMS standardized payment amounts.

We trended utilization and prices in the prior years to match national performance for episodes starting from July 2014 through June 2015. BPCI reconciliation payments were then credited to BPCI episodes during this time frame. We then incorporated the proposed outlier policy to cap spending for high cost outlier episodes such that payments are capped at the price MS–DRG anchor value that is 2 standard deviations above the regional mean as described in section III.C of this proposed rule.

After we pooled episodes for each price MS-DRG, we calculated average episode prices for each hospital and region, as well as a hospital-specific weight representing a case mix value for each hospital that is dependent only on episode volume for a given price MS-DRG and the national anchor factor. We then calculated blended prices for each hospital, with prices set at two-thirds of the hospital's experience and one-third of the region's average experience for performance years 1 and 2 of the model, as one-third of the hospital's experience and two-thirds of the region's experience performance year 3 of the model, and as the region's average experience for performance years 4 and 5 of the model. We made an exception for hospitals with low historical episode volume across the 3 historical years, with low volume as defined in section III.C.4.b.(6) of this proposed rule, by setting their episode benchmark price as the region's experience. These average prices were then disaggregated based on the national severity factor of average episode spending as described in section III.C.4.b.(9) of this proposed rule, the computed hospital-specific weight, the hospital's wage index was then applied back to the price, and a discount specific to the hospital's quality category was applied.

After calculating quality-adjusted target prices for price MS–DRGs for each hospital appropriate for the first 2 performance years, we compared these quality-adjusted target prices against actual performance between July 2014 and June 2015. We capped actual spending for

individual episodes based on the methodology in this proposed rule for high cost outlier spending episodes. After incorporating the proposed outlier policy, total Medicare FFS spending was reconciled against the quality-adjusted target price and total number of episodes for the hospital. The aggregate impacts were then determined by multiplying by the total episodes for each price MS–DRG.

We propose that the difference between each episode's actual payment and the relevant quality-adjusted target price (calculated as quality-adjusted target price subtracted by actual episode payment) would be aggregated for all episodes for a participant within the performance year, creating the NPRA. Any positive NPRA amount greater than the stop-gain limit will be capped at the stop-gain limit of 5 percent for performance years 1 and 2 of the model, 10 percent in performance year 3 and 20 percent in performance years 4 and 5. In addition, any negative NPRA amount exceeding the stop-loss limit will be capped at the stop-loss limit as described in section III.C.8.b. of this proposed rule, with a 5 percent repayment limit in performance year 2, 10 percent repayment limit in performance year 3 and a 20 percent repayment limit in performance years 4 and 5. For rural hospitals, MDHS, SCHs and RRCs, we are proposing a 3 percent repayment limit in performance year 2 and a 5 percent repayment limit in performance year 3 and subsequent years. As described in section III.C.7.e. of this proposed rule, if average 30-day post-episode spending for an EPM participant in any given EPM performance year is greater than 3 standard deviations above the regional average 30-day post-episode spending, based on the 30-day post-episode spending for episodes attributed to all regional hospitals in the same region as the EPM participant hospital, the EPM participant hospital would repay Medicare for the difference. This is not modelled as we would expect the repayments from EPM hospitals to CMS under this post-episode spending calculation to be minimal.

As described in section III.E. of this proposed rule, we propose the use of a composite quality score for each EPM, where the composite quality score reflects a combination of outcome and patient experience measures. Points for quality performance and improvement (as applicable) will be awarded for each episode measure and then summed to develop a composite quality score that will determine the EPM participant's quality category for the episode. Quality performance will make up the majority of available points in the composite quality score, with improvement points available as "bonus" points for the measure. Additionally, participants may voluntarily submit outcome measures data in the SHFFT and AMI models, resulting in an extra 2 points in their overall quality scores, up to a maximum score of 20. The composite quality score will be used as part of a pay-for-performance methodology to assign respective EPM participants to four quality categories.

Hospitals assigned as 'below acceptable' would not be eligible for a reconciliation payment and would be subject to a 3 percent discount. Hospitals assigned as 'acceptable' would be eligible for a reconciliation payment and would be subject to a 3 percent discount. Hospitals assigned as 'good' would be eligible for a reconciliation payment and would be subject to a 2 percent discount. Lastly, hospitals assigned as 'excellent' would be eligible for a reconciliation payment and would be subject to a 1.5 percent discount. We note that in performance year 2 and 3, the discount for repayment would be 1 percentage point less than the discount applied for a reconciliation payment.

In general, we used quality data as publicly reported on Hospital Compare in 2015 and 2016 to model the impact of this policy, with 2016 measures used to calculate performance and the difference between 2015 and 2016 measures used to calculate improvement. We proposed to calculate the HLMR by using 10 of the 11 publicly reported measures, taking the average of all

publicly reported measures except how well hospital staff help patients manage pain, consistent with revisions under consideration for this HCAHPS measure.

Specifically, we used the following data to model the impact of this policy:

- To calculate performance for the AMI model, we utilized: hospital 30-day, all-cause, risk-standardized mortality rate following acute myocardial infarction hospitalization (NQF #0230) measure results based on the performance period of April 1, 2012 through March 31, 2015; excess days in acute care after hospitalization for acute myocardial infarction measure results based on the performance period of April 1, 2012 through March 31, 2015; and HCAHPS survey data (NQF #0166) 2015 based on the performance period of January 1, 2015 through December 31, 2015.

- To calculate improvement for the AMI model, we utilized: hospital 30-day, all-cause, risk-standardized mortality rate following acute myocardial infarction hospitalization (NQF #0230) measure results based on the performance period of April 1, 2011 through March 31, 2014; excess days in acute care after hospitalization for acute myocardial infarction measure results based on the performance period of April 1, 2011 through March 31, 2014; and HCAHPS survey data (NQF #0166) 2015 based on the performance period of January 1, 2014 through December 31, 2014.

- To calculate performance for the CABG model, we utilized hospital 30-day, all-cause, risk-standardized mortality rate following coronary artery bypass graft surgery (NQF #2558) measure results based on the performance period of April 1, 2012 through March 31, 2015 and HCAHPS survey data (NQF #0166) 2015 based on the performance period of January 1, 2015 through December 31, 2015.

- To calculate improvement for the CABG model, we utilized hospital 30-day, all-cause, risk-standardized mortality rate following coronary artery bypass graft surgery (NQF #2558) measure results based on the performance period of April 1, 2011 through March 31, 2014 and HCAHPS survey data (NQF #0166) 2015 based on the performance period of January 1, 2014 through December 31, 2014.

- To calculate performance for the SHFFT model, we utilized hospital-level risk-standardized complication rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) measure results based on the performance period of April 1, 2012 through March 31, 2015 and HCAHPS survey data (NQF #0166) 2015 based on the performance period of January 1, 2015 through December 31, 2015.

- To calculate improvement for SHFFT, we utilized hospital-level risk-standardized complication rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) measure results based on the performance periods of April 1, 2011 through March 31, 2015 and HCAHPS survey data (NQF #0166) 2015 based on the performance period of January 1, 2014 through December 31, 2014.

Consistent with prior experience in the Medicare program, which indicates that when payment is tied to voluntary reporting of quality measures most hospitals report such measures, we assume that most hospitals in the AMI and SHFFT models will submit voluntary measures to qualify for the reduced discount. For the AMI and CABG models, we developed composite quality scores for all eligible hospitals among the 294 MSAs eligible for selection. Selected hospitals were assigned to a performance percentile and assigned the corresponding quality performance score points listed in Tables 15 and 17 of this proposed rule, based on their performance in the historical performance data described earlier. Hospitals that did not have a

reported measure result were assigned to the 50th performance percentile. Hospitals assigned a quality measure performance percentile for the most recent year that were in the top 10 percent of the improvement distribution received quality improvement points. Because 2015 data were not available for the AMI excess days measure, we randomly assigned improvement points for this measure (0.5 points) to 10 percent of hospitals. For SHFFT, hospitals in selected MSAs were assigned to a performance percentile and assigned the corresponding quality performance score points listed in Table 19 of this proposed rule, based on their performance in the historical performance data described earlier. Hospitals that did not have a reported measure result were assigned to the 50th performance percentile. Hospitals assigned a quality measure performance percentile for the most recent year that improved by at least 2 deciles from the prior year received quality improvement points.

Based on these composite quality scores, hospitals were assigned to a quality category of "below acceptable", "acceptable", "good" or "excellent" based on their composite quality scores. As discussed in section III.C.5 of this proposed rule, composite quality scores will affect hospitals' eligibility for reconciliation payments and determine hospitals' effective discount percentages at reconciliation.

To simulate the impact for performance year 1, or July 1 2017 through December 31, 2017, we calculated the NPRA assuming no downside risk to participants, and using the quality-adjusted target price calculated for performance year 1, that is two-thirds hospital experience and one-third region experience. If the estimated NPRA is negative (that is, in the aggregate, the actual episode payments for all episodes is greater than the sum of quality-adjusted target prices for all episodes) for performance year 1, Medicare will not require repayment of the NPRA because we are not requiring participant responsibility for repayment for

the first performance year. Additionally, as part of this estimate, we accounted for whether a participant met the minimum composite quality score to be eligible for a reconciliation payment. Lastly, we have applied the 5 percent stop-gain limit on the estimated reconciliation payments made to participants, and a 3 percent cap for rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral centers.

For the simulation in performance year 2, we used the quality-adjusted target price calculated for performance year 2 that is two-thirds hospital experience and one-third regional experience. A 5 percent stop-loss and stop-gain limit was applied to reconciliation payments and repayments, and 3 percent stop-loss and stop-gain limit was applied for rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral centers.

For the simulation in year 3, we rebased episode prices to incorporate the reconciliation payments simulated from the first performance year. To simulate reconciliation in year 3 we used the quality-adjusted target price calculated as one-third of the hospital's experience and two-thirds of the regional experience. We included a 10 percent stop-loss and stop-gain limit on reconciliation payments and repayments from acute care hospitals included in this analysis, but used a 5 percent stop-loss and stop-gain limit on reconciliation payments and repayments from rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral centers. For performance year 4 we simulated the reconciliation process using the episode quality-adjusted target price based on 100 percent of the regional experience, and a stop-loss and stop-gain limit set to 20 percent for acute care hospitals, and a stop-loss and stop-gain limit of 10 percent for rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral centers.

For performance year 5 we rebased prices to include the simulated EPM reconciliation payments and repayments from performance years 1, 2, and 3. We simulated reconciliation in the fifth performance year using quality-adjusted target prices that are based on 100 percent of the regional experience, and applied the stop-loss and stop-gain limits of 20 percent.

(2) Analyses

TABLE 38: ESTIMATES OF IMPACT ON THE MEDICARE PROGRAM BY PROPOSED EPM*

	Year(s)					**Across all 5 years of proposed models**
	2017	2018	2019	2020	2021	
AMI & CABG net financial impact	7	(3)	(6)	(17)	(21)	(40)
SHFFT net financial impact	6	(10)	(24)	(45)	(57)	(130)
Total: Net financial impact of all EPM proposals	12	(13)	(30)	(61)	(79)	(170)

*Note: In millions. Totals do not necessarily equal the sums of rounded components.

Table 38 summarizes the estimated impact for the AMI, CABG, and SHFFT models. Our model estimates that the Medicare program will save $170 million over the 5 performance years (2017 through 2021).

The first performance year of the EPMs is expected to cost the Medicare program $12 million in reconciliation payments made by CMS to participants. We have proposed that no repayments will be assessed because hospitals are not subject to downside risk in performance year 1. Participants that would receive reconciliation payments are the hospitals that provide lower cost care relative to their regional average.

In the second performance year of the EPMs, participants on net are expected to pay $13 million to CMS. Downside risk is waived for all participants in the first quarter of the second performance year. For the final 3 quarters in the second performance year, we have proposed a 5 percent stop-loss and stop-gain limit for acute care hospitals in the second performance year, with exception for rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral center hospitals which would be subject to a 3 percent stop-loss and stop-gain limit. These limits would cap the total amount of repayments paid by hospitals to CMS.

In the third performance year of the models, net reconciliation payments are expected to be $30 million in savings to the Medicare program. For performance years 4 and 5 of the models, the episode quality-adjusted target price will be based on full regional pricing. This creates greater variation between the quality-adjusted target price and hospitals own experience. The stop-gain and stop-loss limits of 20 percent are applied, with a stop-gain and stop-loss limit of 5 percent for rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral centers hospitals. As a result, net payments are expected to be $61 million from participants to the Medicare program in the fourth year and $79 million in the fifth year. These estimated savings in years 4 and 5 represent 2.0 percent of total episode spending in those years. The total savings to the Medicare program after the 5 performance years are expected to be $170 million out of $13.8 billion or 1.2 percent in total episode spending. Costs to the Medicare program may increase if providers are able to use waivers provided to increase episode volume among beneficiaries that would be expected to be less costly than the hospital's quality-adjusted target price without the need for improving the coordination of car

(3) Uncertainties

These estimates are somewhat uncertain. As a result, the proposed models could produce more Medicare savings or could result in additional costs to the Medicare program. This analysis assumes that the demonstration incentives drive no change in utilization for the use of services within the bundled episode, as this would not materially affect the financial impact. The prospective prices for the proposed episodes incorporate price updates from the FFS payment systems, but assume no change in utilization for the performance years. If there is a national increase in utilization within each episode that is not driven by the demonstration incentives, then savings to the Medicare program may increase due to greater repayments paid back to Medicare. If there is a national decrease in utilization within each episode that is not driven by the demonstration incentives, then costs to the Medicare program may increase due to greater reconciliation payments paid by Medicare to participants.

We are also assuming that most hospitals will submit voluntary measures to qualify for the reduced discount. As a sensitivity test, if no hospitals report this data, the AMI model and SHFFT models together are estimated to save the Medicare program an additional $36 million over the 5 performance years.

Additionally, we were unable to fully estimate the impact of the proposal in section III.D. which addresses beneficiaries in EPMs who are also aligned or attributed to a Medicare Shared Savings Program participant or a participant in an ACO model initiated by the CMS Innovation Center. Savings achieved during an EPM episode are proposed to be attributed to the EPM participant, with EPM reconciliation payments for ACO-aligned beneficiaries treated as ACO expenditures, which should serve to minimize the financial impact of ACO overlap on overall savings. As described in section III.D.6, beginning in July 2017 we are proposing to exclude from AMI, CABG, and SHFFT episodes beneficiaries aligned to ACOs in the Next Generation

ACO model and ESRD ESCOs in the Comprehensive ESRD Care Initiative in tracks with downside risk for financial losses. Excluding these beneficiaries from the proposed EPMs will have the effect of reducing the number of eligible episodes and therefore the expected savings generated by implementation of the EPMs. Due to the uncertainty associated with projecting future beneficiary alignment to ACOs, ACO participation, and beneficiaries experiencing EPM episodes across the performance years of the models, we are unable to quantify the impact of this proposed exclusion.

Due to the uncertainty of estimating this model, actual results could be higher or lower than this estimate. Our analysis to the best of our ability presents the cost and transfer payment effects of this proposed rule to the best of our ability. We solicit comments on the assumptions and analysis presented. Additionally, we note that for these estimates, we did not make assumptions for changes in efficiency or utilization over the course of the performance period.

b. CJR

We propose to modify the CJR model to include reconciliation payments and Medicare repayments in our calculations when updating CJR episode quality-adjusted target prices for performance years 3 through 5. We also propose to create consistency between the CJR composite quality scores and SHFFT composite quality scores by –(1) awarding quality improvement points based on an improvement of 2 deciles (rather than 3 deciles as in the final CJR rule); (2) capping the total composite quality score at 20; and(3) utilizing an updated HCAHPS algorithm.

(1) Assumptions and Uncertainties

We used final action Medicare claims data from January 1, 2012 through December 31, 2014 to update the impact originally outlined in the CJR final rule (80 FR 73288) to reflect the

changes proposed here for the CJR model. Specifically, we estimated the effect of including BPCI and CJR reconciliation payments and Medicare repayments in setting quality-adjusted target prices in performance years 3-5 to include the new quality adjusted discounts that begin in the first performance year, and by updating our prior assumption regarding CJR participation with voluntary reporting of quality metrics to be more consistent with prior experience in the Medicare program.

Due to proposed changes in the calculation of the CJR composite scores, we used quality data as publicly reported on Hospital Compare in 2015 and 2016 to model the impact of this policy, with 2016 measures used to calculate performance and the difference between 2015 and 2016 measures used to calculate improvement. We proposed to calculate the HLMR by using 10 of the 11 publicly reported measures, taking the average of all publicly reported measures except how well hospital staff help patients manage pain, consistent with revisions under consideration for this HCAHPS measure. Calculations are as follows:

- To calculate performance for the CJR model, we utilized hospital-level risk-standardized complication rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) measure results based on the performance period of April 1, 2012 through March 31, 2015 and HCAHPS survey data (NQF #0166) 2015 based on the performance period of January 1, 2015 through December 31, 2015.

- To calculate improvement for CJR, we utilized hospital-level risk-standardized complication rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) measure results based on the performance periods of April 1, 2011 through March 31, 2015 and HCAHPS survey data (NQF #0166) 2015 based on the performance period of January 1, 2014 through December 31, 2014.

For the purpose of this analysis, we assumed that hospitals participating in the CJR model will voluntarily submitted patient-reported outcome measures to qualify for the lower discount, consistent with prior experience in the Medicare program.

CJR participants were assigned to a performance percentile and assigned the corresponding quality performance score as described in the CJR final rule (80 FR 73288). Hospitals that did not have a reported measure result were assigned to the 50th performance percentile. Hospitals assigned a quality measure performance percentile for the most recent year that improved by at least 2 deciles from the prior year received quality improvement points, with the total composite quality score capped at 20. These composite quality scores, updated to be consistent with the methodology proposed in the CJR modifications, were then applied to the development of quality-adjusted target prices as described in the CJR final rule (80 FR 73288).

We note that we are proposing a modification to the application of the stop-loss and stop-gain limits to exclude hospital responsibility for post-episode spending from the application of these limits. We assume that the number of hospitals affected by this change would be small and have not modelled the impact of this change.

(2) Analyses

TABLE 39: ESTIMATES OF IMPACT ON THE MEDICARE PROGRAM FOR CJR MODEL*

	Year(s)					Across all 5 years of the proposed model
	2016	**2017**	**2018**	**2019**	**2020**	
Original CJR net financial impact from final rule	11	(36)	(71)	(120)	(127)	(343)
CJR modifications net financial impact	3	6	13	11	2	35

* In millions. Totals do not necessarily equal the sums of rounded components.

Modifications to the CJR model proposed in section V. of this proposed rule would begin at the time of reconciliation for performance year 1 and therefore affect estimates of the impact of the model from April 2016-December 2020. The change in the estimated net financial impact to the Medicare program from the modifications in this proposed rule is $22 million, and the updated assumptions regarding the number of hospitals that report quality data is modelled to be $14 million dollars. The total estimated net financial impact to the Medicare program from both the modifications in the proposed rule and revised assumptions are $35 million. Due to the uncertainty of estimating this model, actual results could be higher or lower than this estimate. Additionally, we note that due to the uncertainty associated with projecting future beneficiary alignment to ACOs, ACO participation, and beneficiaries experiencing CJR episodes across the performance years of the models, we are unable to quantify the impact of proposed exclusions related to ACOs. We are also unable at this time to estimate the impacts of considering certain CJR and EPM providers and Affiliated Practitioners to be participating in Advanced APMs. Eligible clinicians that qualify as QPs for a year through participation in EPMs and CJR will receive a bonus equal to 5 percent of their prior year Medicare payments, thereby increasing Medicare expenditures.

c. CR Incentive Payment Model

As detailed in section VI of this proposed rule, the CR incentive payment model will test whether a financial incentive for hospitals that encourages the management of beneficiaries that have had an AMI or a CABG in ways that may contribute to long-term improvements in quality and reductions in Medicare spending. We proposed the CR incentive payment model to test the effects on quality of care and Medicare expenditures of providing explicit financial incentives to CR participants for beneficiaries hospitalized for treatment of AMI or CABG to encourage care coordination and greater utilization of medically necessary CR/ICR services for 90 days post-hospital discharge where the beneficiary's overall care is paid under either an EPM or the Medicare FFS program.

Under the CR incentive payment model, we proposed to provide a CR incentive payment to selected hospitals with financial responsibility for AMI or CABG model episodes (hereinafter EPM-CR participants) because they are already engaged in managing the AMI or CABG model beneficiary's overall care for a period of time following hospital discharge. We also proposed to provide a CR incentive payment to selected hospitals that are not AMI or CABG model participants (hereinafter FFS-CR participants), enabling us to test and improve our understanding of the effects of the CR incentive payment within the context of an EPM and the Medicare FFS program, as well as to identify potential interactions between the proposed CR incentive payment and the underlying EPM and FFS payment methodologies. We have therefore proposed to test the CR incentive payment model in 45 of the 98 MSAs selected for the AMI and CABG EPMs, as well as 45 FFS MSAs selected through stratified random sampling.

(1) Assumptions and Uncertainties

We used final action Medicare claims data from January 1, 2012 through December 31, 2015 to identify CR and ICR services that count towards CR incentive payments on the basis of

the presence of the HCPCS codes on PFS and OPPS claims and APC codes on OPPS claims that report CR/ICR services. We then compared total Medicare spending over 3 years post hospital discharge for AMI and CABG for patients that received cardiac rehabilitation services within 90 days of discharge, to patients that did not receive cardiac rehabilitation services within 90 days of discharge. We found that among patients continuously enrolled over 3 years in FFS Medicare Part A and B those receiving cardiac rehabilitation services within 90 days of discharge from an AMI and or CABG hospitalization had lower Medicare spending relative to patients whom did not receive cardiac rehabilitation services post discharge from an AMI and or CABG hospitalization, even after adjusting for differences in age, sex, and case-mix between the two populations. The difference in average spending between the group that received cardiac rehabilitation services and the group that did not receive cardiac rehabilitation services within 90 days of discharge represents the reduction in Medicare spending we would anticipate from an additional beneficiary receiving cardiac rehabilitation services due to the cardiac rehabilitation incentive payment model.

CR incentive payments apply to CR/ICR sessions during the 90-day episode (for EPM participants) or 90-day care period (for FFS participants) from date of discharge. CR and ICR services paid by Medicare to any provider or supplier for model beneficiaries during AMI or CABG model episodes/care periods would result in participant eligibility for CR incentive payments.

To model the impact of the cardiac rehabilitation incentive payment model we calculated the costs of the incentive payments for patients receiving cardiac rehabilitation services, as well as any reduction in Medicare spending due to more patients receiving cardiac rehabilitation services. For the 294 MSAs eligible for the AMI and CABG EPM, we used Medicare claims

data for the 2015 calendar year to calculate what the cardiac rehabilitation incentive payments would be for all patients receiving cardiac rehabilitation services within 90 days of an AMI and CABG hospitalization. For a given increase in the proportion of patients observed in the 2015 calendar year that receive cardiac rehabilitation services, we calculated both the cost of the cardiac rehabilitation incentive payments for these additional patients, as well as the estimated reduction in Medicare spending over a 3 year period due to these new patients receiving cardiac rehabilitation services. We calculated pricing based on the structure described in section VI.E. For a given rate of patients receiving cardiac rehabilitation services we summed the costs of CR incentive payments. We then subtracted the estimated reduction in Medicare spending due to any increase in the rate of patients receiving cardiac rehabilitation services relative to the rate receiving such services in the 2015 calendar year to arrive at the net financial impact. To adjust the results to account for only 90 MSAs being selected for the cardiac rehabilitation incentive payment model we multiplied the final results by 90/294. The final results were then multiplied by 90/294 as only 90 MSAs are to be selected for the cardiac rehabilitation incentive payment model.

We recognize that utilization of CR/ICR services is driven by many factors, and we lack sufficient data to reliably estimate the effect of a CR incentive payment on beneficiary utilization of CR/ICR services, particularly during the 90-day episode/care period. Therefore, we calculated a range of potential impacts based on alternatives in the increase in cardiac rehabilitation utilization, ranging from no change to an increase in utilization of 4 percentage points.

(2) Analyses

TABLE 40: RANGE OF POTENTIAL LONG-TERM IMPACT OF CARDIAC REHABILITATION INCENTIVE PAYMENT MODEL ON THE MEDICARE PROGRAM*

Year	Increase in Cardiac Rehabilitation Utilization:		
	No increase	2 percentage points	4 percentage points
2017	1	1	1
2018	6	5	5
2019	6	4	1
2020	6	2	(3)
2021	7	-	(7)
2022	-	(7)	(15)
2023	-	(5)	(10)
2024	-	(2)	(5)
Total: 2017-2024	27	(2)	(32)

* In millions of dollars. Totals do not necessarily equal the sums of rounded components.

Table 40 summarizes the estimated impact for the CR incentive payment model. Our model estimates that the impact on the Medicare program may range from up to $27 million of spending to $32 million of savings between 2017 and 2024, depending on the change in utilization of CR/ICR services based on the proposed incentive structure. The model only estimates the financial effects of additional patients receiving CR/ICR services, and does not take into account potential changes in the volume of CR/ICR services that patients may receive within 90 days of hospital discharge. Increasing CR/ICR services within 90 days of hospital discharge will increase CR/ICR incentive payments, and may influence Medicare spending after the 90 day episode. Due to the uncertainty of estimating this model, actual results could be higher or lower

than this estimate. Our analysis to the best of our ability presents the cost and transfer payment effects of this proposed rule. We solicit comments on the assumptions and analysis presented.

d. Further Consideration

We can use our experience in previous implementation of bundled payment models to help inform our impact analyses. We have previously used our statutory authority to create payment models such as the BPCI initiative and the ACE Demonstration to test bundled payments, as well as the CJR model. Under the authority of section 1866C of the Act, CMS funded a 3-year demonstration, the ACE Demonstration. The demonstration used a prospective global payment for a single episode-of-care as an alternative approach to payment for service delivery under traditional Medicare FFS. The episode-of-care was defined as a combination of Parts A and B services furnished to Medicare FFS beneficiaries during an inpatient hospital stay for any one of a specified set of cardiac and orthopedic MSDRGs. The discounted bundled payments generated an average gross savings to Medicare of $585 per episode for a total of $7.3 million across all episodes (12,501 episodes) or 3.1 percent of the total expected costs for these episodes. After netting out the savings produced by the Medicare Parts A and B discounted payments and some increased PAC costs that were observed at two sites, Medicare saved approximately $4 million, or 1.72 percent of the total expected Medicare spending.

Additionally, we are currently testing the BPCI initiative. Under the initiative, entities enter into payment arrangements with CMS that include financial and performance accountability for episodes of care. The BPCI initiative is evaluating the effects of episode-based payment approaches on patient experience of care, outcomes, and cost of care for Medicare FFS beneficiaries. We believe that our experiences with BPCI support the design of the EPMs.

Although there is some evidence from BPCI and ACE suggesting that providers may improve their performance, the participants that volunteered to participate may be in a better position to reduce episode spending relative to the average provider. The CJR model is testing the first bundled payment model under the Innovation Center authority in which providers are required to participate. The CJR model test began in April 2016. The design of the EPMs proposed here incorporates early learnings from the CJR model, and we propose additional refinements to the CJR rule in this proposed rule to support successful implementation.

Finally, although we project savings to Medicare under the proposed EPMs and CJR, as stated earlier, we note that under section 1115A(b)(3)(B) of the Act, the Secretary is required to terminate or modify a model unless certain findings can be made with respect to savings and quality after the model has begun. If during the course of testing it is determined that termination or modification is necessary, such actions would be undertaken through rulemaking.

3. Effects on Beneficiaries

We believe that episode payment models may have the potential to benefit beneficiaries because the intent of the models is to test whether providers under episode payment models are able to improve the coordination and transition of care, invest in infrastructure and redesigned care processes for high quality and efficient service delivery, and incentivize higher value care across the inpatient and post-acute care spectrum spanning the episode of care. We believe that episode payment models have a patient-centered focus such that they incentivize improved healthcare delivery and communication delivered around the needs of the beneficiary, thus potentially benefitting the beneficiary community. However, the demonstration does not affect beneficiary cost sharing with each provider or premiums paid by beneficiaries. If there is a shift

in provider usage within each bundle, then beneficiary cost sharing could be higher or lower than would otherwise be experienced.

We propose several patient outcomes and patient experience measures to tie payment to quality performance with the intent that this approach would encourage the provider community to focus on and deliver improved quality care for Medicare beneficiaries. Additionally, participants must meet an acceptable level of quality performance in order to qualify to receive a reconciliation payment. The accountability of participants for both quality and cost of care provided for Medicare beneficiaries within an episode provides participants with new incentives to improve the health and well-being of the Medicare beneficiaries they treat.

Additionally, the proposed EPMs and CJR do not affect the beneficiary's freedom of choice to obtain health services from any individual or organization qualified to participate in the Medicare program guaranteed under section 1802 of the Act. Eligible beneficiaries who choose to receive services from a participant would not have the option to opt out of inclusion in the models. Although the proposed EPMs and CJR allow participants to enter into risk-sharing arrangements with certain other providers, and participants may recommended those providers to the beneficiary, participants may not prevent or restrict beneficiaries to any list of preferred or recommended providers.

Many controls exist under Medicare to ensure beneficiary access and quality, and we have proposed to use our existing authority, if necessary, to audit participants if claims analysis indicates an inappropriate change in delivered services. As described in section III.G. of this proposed rule, given that participants would receive a reconciliation payment when they are able to reduce average costs per case and achieve acceptable or greater quality performance, they could have an incentive to avoid complex, high cost cases by referring them to nearby facilities

or specialty referral centers. We intend to monitor the claims data from participants—for example, to compare a hospital's case mix relative to a pre-model historical baseline to determine whether complex patients are being systematically excluded. Furthermore, we also proposed to require providers to supply beneficiaries with written information regarding the design and implications of these EPMs as well as their rights under Medicare, including their right to use their provider of choice.

We have proposed to implement several safeguards to ensure that Medicare beneficiaries do not experience a delay in services. We believe that the longer the episode duration, the lower the risk of delaying care beyond the episode duration, and we believe that a 90-day post-hospital discharge episode duration is sufficiently long to minimize the risk that any episode-related care will be delayed beyond the end of the episode. Moreover, we propose that as part of the payment definition (see section III.D of this proposed rule) that certain outlier costs post-episode payments occurring in the 30-day window subsequent to the end of the 90-day episode will be counted as an adjustment against savings.

Lastly, we note that Medicare payments for services will continue to be made for each Medicare FFS payment system under CJR and these EPMs. Because we propose to waive beneficiary coinsurance for reconciliation payments and repayments, beneficiaries will be subject to copayments, deductibles, and coinsurance consistent with Medicare FFS payments, rather than as determined by quality-adjusted target prices. We assume that beneficiary payments will not be affected, as only the hospital will be subject to the reconciliation process. If EPM participants are successful in improving quality or care while reducing costs, beneficiaries may benefit through reduced out-of-pocket expenditures. Alternatively, if participating providers respond to the demonstration by shifting medical care outside of the 90 day bundle,

than this may negatively impact the quality of care that beneficiaries receive. We welcome public comments on our estimates of the impact of our proposals on Medicare beneficiaries.

4. Effects on Small Rural Hospitals

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a proposed rule or final rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, a small rural hospital is defined as a hospital that is located outside of an MSA and has fewer than 100 beds. We note that, according to this definition, the models proposed here would not include any rural hospitals, given that the models would only include hospitals located in MSAs, as proposed in section III.A. However, we also note that for purposes of our proposal to include a more protective stop-loss policy for certain hospitals, we are proposing to define a rural hospital as an IPPS hospital that is either located in a rural area in accordance with § 412.64(b) or in a rural census tract within an MSA defined at § 412.103(a)(1) or has reclassified to rural in accordance with § 412.103. The proposed models will affect some rural hospitals based on this definition.

Because of our concerns that rural hospitals may have lower risk tolerance and less infrastructure and support to achieve efficiencies for high payment episodes, we have proposed additional financial protections for certain categories of hospitals, including rural hospitals. In performance year 2, an EPM participant could owe Medicare no more than 10 percent of the sum of quality-adjusted target prices for the hospital's episodes in an EPM as we phase in repayment responsibility under the models. In performance year 3 and beyond when full repayment responsibility is in place, no more than 20 percent of the sum of quality-adjusted target prices for the hospital's episodes in an EPM could be owed by a hospital to Medicare. However, for rural

hospitals, Medicare Dependent Hospitals, Rural Referral Centers and Sole Community, we proposed a stop loss limit policy of 3 percent of episode payments for these categories of hospitals. More specifically, in performance year 2, a hospital could owe Medicare no more than 3 percent of the sum of quality-adjusted target prices for the hospital's episodes in an EPM. In performance years 3 through 5, a hospital could owe Medicare no more than 5 percent of the sum of quality-adjusted target prices for the hospital's episodes. Although we propose these additional protections, we believe that few rural hospitals will be included in the models, and therefore that few will need those protections.

AMI, CABG, and SHFFT episodes account for less than 5 percent of all discharges, and because relatively few of these procedures are performed at small rural hospitals, and because the EPMs are designed to minimize adverse effects on rural hospitals, we do not believe that rural hospitals will experience significant adverse economic impacts. Accordingly, we conclude that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

We are soliciting public comments on our estimates and analysis of the impact of our proposals on those small rural hospitals.

5. Effects on Small Entities

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities, either by virtue of their nonprofit status or by qualifying as small businesses under the Small Business Administration's size standards (revenues of less than $7.5 to $38.5 million in

any 1 year; NAIC Sector–62 series). States and individuals are not included in the definition of a small entity. For details, see the Small Business Administration's Web site at http://www.sba.gov/content/smallbusiness-size-standards.

For purposes of the RFA, we generally consider all hospitals and other providers and suppliers to be small entities. We believe that the provisions of this proposed rule relating to acute care hospitals would have some effects on a substantial number of other providers involved in these episodes of care including surgeons and other physicians, skilled nursing facilities, physical therapists, and other providers.

Although we acknowledge that many of the affected entities are small entities, and the analysis discussed throughout this proposed rule discusses aspects of episode payment models that may or will affect them, we have no reason to assume that these effects will reach the threshold level of 3 percent of revenues used by HHS to identify what are likely to be "significant" impacts. We assume that all or almost all of these entities will continue to serve these patients, and to receive payments commensurate with their cost of care. Hospitals currently experience frequent changes to payment (for example, as both hospital affiliations and preferred provider networks change) that may impact revenue, and we have no reason to assume that this will change significantly under the proposed models.

Accordingly, we have determined that this proposed rule will not have a significant impact on a substantial number of small entities. We solicit public comments on our estimates and analysis of the impact of our proposals on those small entities.

6. Effects of information collection

There are three primary sets of information collection activities that EPM participants may be engaged in: activities related to quality reporting, activities related to Advanced APM

participation, and ad hoc reporting of beneficiary notification upon request by CMS. Here, we briefly describe the anticipated scope and effects of information collection in each of these three areas for EPM participants.

Quality reporting associated with the EPMs includes EPM-specific quality measures, HCAHPS, and voluntarily reported quality measures (AMI and SHFFT models only), described in more detail in section III.E. of this proposed rule. IPPS hospitals are subject to incentives under quality reporting incentives such as the HVBP program and Medicare Electronic Health Record (EHR) Incentive Program, among others. Most IPPS hospitals already report information for the EPM-specific quality measures and HCAHPS for other CMS programs, and those hospitals that do not otherwise report this information to CMS would not be required to report under the EPMs. Thus, EPM participants would have no additional information collection activities for the required quality measures under the EPMs.

For the AMI model, participants have the option of reporting data for the Hybrid AMI Mortality measure. This measure includes a combination of claims and EHR data for a total of five EHR-based clinical data elements and six claims-based elements. AMI voluntary data submission must occur within 60 days of most recent data collection period. Successful submission of optional Hybrid AMI Mortality measure data will be based upon inclusion of five key clinical data elements.

We anticipate that participants who choose to engage in voluntary reporting of the Hybrid AMI Mortality measure will engage in the following process:

- Hospitals receive the measure authoring tool (MAT) output, a template layout for the data reporting file, and other artifacts that describe what they are supposed to do and how. The only data elements required are simple labs and vital signs that are collected consistently in structured

fields. All hospitals with EHRs should be able to extract these from structured fields. Many will have some experience based on work with eCQMs.

- Hospitals review the MAT output and submit questions or request clarification via ongoing Q&A.
- Hospitals create a query for their EHR database using the MAT output and populate the reporting file with the core clinical data elements (CCDE). The hospital IT staff will typically run some queries on a small set of admissions and look at the corresponding charts to make sure they are getting the right data and may modify the query if needed.
- Hospitals submit the CCDE to CMS on the prescribed template (QRDA, consolidated clinical document architecture (CCDA), or simple excel file are all options).
- Hospitals do not need to do any measure calculation. Once data elements are submitted, CMS will link with claims data to calculate measure scores.

Given this process, the initial effort of establishing operability will create the majority of burden. Once the initial effort of establishing the query is complete, the burden will be minimal, as the same query can be run against the EHR for ongoing reporting. We assume that the primary cost for a hospital will be the IT support to set up the initial query and ensure the correct data is being pulled from the EHR. The data elements should be less burdensome than a typical eCQM because participants do not need to create new fields, all data is feasibly accessed in current EHRs without creating new clinical workflows, and hospitals do not need to do any measure calculation.

AMI model participants must meet the following requirements for each performance year in order to fulfill the successful Hybrid AMI Mortality data collection criterion. In performance year 1, participants will be required to submit this data for 50 percent of eligible AMI episodes

occurring during the 2-month period between July 1, 2017 and August 31, 2017. In performance year 2, AMI voluntary data submission will be for 10 months of eligible discharges. In performance years 3 through 5, participants will need to submit data for the entire performance year. Furthermore, in performance years 2 through 5, participants will be required to submit the five key clinical data elements for at least 90 percent of eligible AMI discharges.

We are unable to provide a direct cost estimate for hospitals at this time, but hope to learn through commenters and expect to learn more as part of model testing. The voluntary data submission initiative will allow AMI model participants to build processes to extract and report the EHR data elements, as well as support CMS testing of systems required for Hybrid AMI Mortality measure (NQF #2473) production including data receiving and auditing, the merging EHR and claims data, calculation and production of measure results.

For the SHFFT model, the optional quality measure is based on a patient reported outcomes measure, which draws upon patient interviews to gain insights into patient experience and related outcomes.

We anticipate that participants who choose to engage in voluntary reporting of the THA/TKA PRO and limited risk variable data submission will engage in the following process:

- Participating hospitals will need to establish a means to collect patient-reported outcome data from patients pre-operatively and, again, post-operatively. In addition, they would need to collect select additional risk variables from patient charts.

- The specific instruments (and risk variables) have been vetted by a Technical Expert Panel and public comment: Veterans RAND 12 Item Health Survey (VR-12) or Patient-Reported Outcomes Measurement Information System (PROMIS) Global-10 generic PRO survey; Hip disability and Osteoarthritis Outcome Score (HOOS)/Knee injury and Osteoarthritis Outcome

Score (KOOS) Jr. or HOOS/KOOS subscales PRO survey; additional risk variables that can be physician-reported or chart-abstracted.

- If hospitals select the least burdensome instruments, data collection requires patients to answer 16 through 17 outcome questions and 3 risk factor questions. Estimates from instrument developers, input from the patient members of a Technical Expert Panel, and empirical results from a survey of physicians collecting similar data on THA/TKA patients support minimal patient burden (under 5 minutes) to collect the required data.
- Pre-operative survey completion could be arranged to be completed online, by phone, or at pre-operative clinic or hospital admission intake visits. Post-operative survey completion must occur between 270 and 365 days after the eligible elective primary procedure, and may occur in a variety of ways, such as online or by phone.
- Hospitals will collect or extract 6 risk variables that are commonly available in the medical record.

Currently available data suggests costs associated with information collection for this measure can vary tremendously. We anticipate the SHFFT patient-reported outcomes reporting costs to a participant hospital would decrease over time as the collection process in streamlined and integrated into clinical care workflows. A number of hospitals are already collecting this data either as a part of an established registry or for participation in the existing CJR bundled payment. For these participants, the burden of developing data collection systems will be minimal. We also seek comment, in particular from hospitals already collecting this data, on our assumptions and information on any costs associated with this work.

Participating hospitals must meet the following requirements for each performance year in order to fulfill the successful PRO data collection criterion. In performance year 1,

participants must submit data for at least 50 percent of eligible procedures or at least 50 cases. In performance year 2, participants must submit data for at least 60 percent of eligible procures or at least 75 cases. In performance year 3, participants must submit data for at least 70 percent of eligible procures or at least 100 cases. In performance years 4 and 5, participants must submit data for at least 80 percent of eligible procures or at least 200 cases.

We are unable to provide a direct cost estimate for hospitals at this time, but expect to learn more as part of SHFFT and CJR model testing, but seek comment our assumptions.

Overall, we anticipate the net burden of voluntary data submissions in the AMI and SHFFT models will be marginal, as we anticipate hospitals will only choose to proceed with optional data submission if they believe the net financial benefit will be positive.

Information collection related to the Track 1 EPMs and the Track 1 CJR model to meet the Advanced APM requirements included in the Quality Payment Program proposed rule and to operationalize the EPMs and CJR as Advanced APMs includes EPM and CJR participant attestation to CEHRT and clinician financial arrangements lists submission. We believe that the selection by EPM and CJR participants to meet and attest to the CEHRT use requirement would create no significant additional administrative burden on EPM and CJR model participants. With respect to the submission of clinician financial arrangements lists (no more frequently than quarterly), while the required submission of this information under the Track 1 EPMs and the Track 1 CJR model may create some additional administrative requirements for certain EPM and CJR participants, we expect that Track 1 EPM participants could modify their contractual relationships with their EPM collaborators with which the EPM participant directly contracts to require the EPM collaborators to submit this information to the EPM participants. We also expect that EPM participants could modify their contracts with EPM collaborators to include

similar requirements in their contracts with collaboration agents and in the contracts of collaboration agents with downstream collaboration agents.

Finally, we expect that participants are able to produce lists of beneficiaries who have received compliant notification of participation in model. We provided flexible guidelines for this requirement as specific record keeping methods can be chosen by individual participants so long as the necessary information is maintained readily available to report upon request. We seek comment on any burden derived from this requirement. In total, we anticipate marginal additional reporting burden resulting from this proposed rule. We are interested in comments from stakeholders regarding methodology for data submission which minimizes duplication and optimizes information collection for participants.

7. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2016, that is approximately $146 million. This proposed rule does not include any mandate that would result in spending by state, local or tribal governments, in the aggregate, or by the private sector in the amount of $146 million in any 1 year.

D. Alternatives Considered

Throughout this proposed rule, we have identified our proposed policies and alternatives that we have considered, and provided information as to the effects of these alternatives and the rationale for each of the proposed policies. We solicit and welcome comments on our proposals, on the alternatives we have identified, and on other alternatives that we should consider, as well as on the costs, benefits, or other effects of these. We note that our estimates are limited to

hospitals in the CJR model, hospitals proposed for inclusion in the SHFFT model, and to hospitals that could be selected to participate in the proposed AMI and CABG models. This proposed rule will not impinge directly on hospitals that are not participating in CJR or the EPMs. However, it may encourage innovations in health care delivery in other areas or in care paid through other payers. For example, a hospital and affiliated providers may choose to extend their arrangements for an EPM to other payers, not just those beneficiaries paid under Medicare FFS. Alternatively, a hospital and affiliated providers in one city may decide to hold themselves forth as "centers of excellence" for patients from other cities, both those included and not included in the EPMs. We welcome comments that address these or other possibilities.

We present the implications of alternatives considered in the development of the EPMs here. As discussed in section III.C., we propose to define beneficiary inclusion in the AMI model by discharge under an AMI MS-DRG (280–282), representing those individuals admitted with AMI who receive medical therapy but no revascularization, and discharge under a PCI MS-DRG (246–251) with an ICD-10-CM diagnosis code of AMI on the IPPS claim for the anchor hospitalization in the principal or secondary diagnosis code position. Alternately, we could define beneficiary inclusion based only on the principal diagnosis code. Doing so would result in a 2.4 percent fewer episodes included in the AMI model annually.

As discussed in section III.E., we proposed to allow participants to qualify for a higher composite quality score in the AMI and SHFFT models based on submission of voluntary measures. If we had not provided the option for participants to achieve an increased composite quality score for voluntary reporting (or if we assume no hospitals report this data), the AMI model and SHFFT models are estimated to save the Medicare program an additional 36 million over the 5 performance years.

As discussed in section VI. of this proposed rule, we have proposed the selection of CR MSAs via a modified stratified random selection based on several key dimensions related to CR/ICR service provision, including percent of eligible cases in the MSA who receive CR/ICR services, percent who complete CR or ICR services, and the number of CR/ICR providers. We also outlined alternative MSA selection strategies and solicited comments on the MSA selection approach. We anticipate that, because these approaches draw from the same pool of eligible MSAs without regard to MSA size or total cost of care during the episode or care period, the overall financial impact of different selection methodologies will be minimal, and the primary impact of varied MSA selection approaches will be on balance among model arms for evaluation.

E. Accounting Statement and Table

As required by OMB Circular A–4 under Executive Order 12866 (available at http://www.whitehouse.gov/omb/circulars_a004_a-4) in Table 41, we have prepared an accounting statement showing the classification of transfers, benefits, and costs associated with the provisions in this proposed rule. The accounting statement is based on estimates provided in this regulatory impact analysis.

TABLE 41: ACCOUNTING STATEMENT ESTIMATED IMPACTS FOR NEW EPISODE PAYMENT MODELS AND PROPOSED CHANGES TO COMPREHENSIVE CARE FOR JOINT REPLACEMENT

Category	Primary estimate	Source citation (RIA, preamble, etc.)
BENEFITS		
Annualized monetized transfers: Discount rate 7%	$19 million	Change from baseline to proposed changes (Tables 38 and 39)
Annualized monetized transfers: Discount rate 3%	$21 million	
From whom to whom?	From Participant IPPS Hospitals to Federal Government	

TABLE 42: ACCOUNTING STATEMENT ESTIMATED IMPACTS FOR CARDIAC REHABILITATION INCENTIVE PAYMENT MODEL

Category	**Assuming no change in the rate of patients receiving cardiac rehabilitation services**	**Source citation (RIA, preamble, etc.)**
BENEFITS		
Annualized monetized transfers: Discount rate 7%	$5 million	Change from baseline to proposed changes (Table 40)
Annualized monetized transfers: Discount rate 3%	$5 million	
From whom to whom?	From Federal Government to Participant IPPS Hospitals	

Category	**Assuming a 2 percentage point increase in the rate of patients receiving cardiac rehabilitation services**	**Source citation (RIA, preamble, etc.)**
BENEFITS		
Annualized monetized transfers: Discount rate 7%	$0 million	Change from baseline to proposed changes (Table 40)
Annualized monetized transfers: Discount rate 3%	-$0 million	
From whom to whom?	From Federal Government to Health Care Providers	

Category	**Assuming a 4 percentage point**	**Source citation (RIA, preamble, etc.)**

	increase in the rate of patients receiving cardiac rehabilitation services	
BENEFITS		
Annualized monetized transfers: Discount rate 7%	-$3 million	Change from baseline to proposed changes (Table 40)
Annualized monetized transfers: Discount rate 3%	-$4 million	
From whom to whom?	From Federal Government to Health Care Providers	

F. Conclusion

This analysis, together with the remainder of this preamble, provides the Regulatory Impact Analysis of a rule with a significant economic effect. As a result of this proposed rule, we estimate that the financial impact of the AMI, CABG, and SHFFT EPM models proposed here would be net federal savings of $170 million over a 5-year performance period (2017 through 2021), the financial impact of the CJR model as modified here with the revised assumptions on hospital reporting of quality data would be an estimated net federal cost of $35 million over a 5-year period (2016 through 2020) relative to the estimates published in the CJR final rule. The financial impact of the CR incentive payment model would be net change in federal spending between $27 million in additional costs and $32 million in savings to the Medicare program over an 8-year period (2017 through 2024).

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 510

Administrative Practice and Procedure, Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 512

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, under the authority at section 1115A of the Social Security Act, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR Chapter IV as follows:

Subchapter H--Health Care Infrastructure and Model Programs

PART 510—COMPREHENSIVE CARE FOR JOINT REPLACEMENT MODEL

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

Authority: Secs. 1102, 1115A, and 1871 of the Social Security Act (42 U.S.C. 1302, 1315(a), and 1395hh).

2. Section 510.2 is amended by –

a. Revising the definition of "ACO";

b. Adding in alphabetical order definitions for "ACO participant" and "ACO provider/supplier";

c. Revising the definition for "Alignment payment";

d. Adding in alphabetical order definitions for “Applicable discount factor”, “CEHRT”, and “CJR activities”;

e. Revising the definition of “CJR collaborator”;

f. Adding in alphabetical order a definition for “Collaboration agent”;

g. Removing the definition of “Collaborator agreement”;

h. Revising the definitions of “Distribution arrangement” and “Distribution payment”;

i. Adding in alphabetical order definitions for “Downstream collaboration agent”, “Downstream distribution arrangement”, “Downstream distribution payment”, and “Episode benchmark price”;

j. Removing the definition of “Episode target price”;

k. Revising the definitions of “HHA” and “Historical episode payment”;

l. Adding in alphabetical order a definition for “Hospital”;

m. Removing the definitions of “IPPS hospital (or hospital)” and “practice collaboration agent”;

n. Adding in alphabetical order a definition for “Quality-adjusted target price”; and

o. Revising the definition of “Quality improvement points”.

The additions and revisions read as follows:

§ 510.2 Definitions.

* * * * *

ACO means an accountable care organization, as defined at § 425.20 of this chapter, that participates in the Medicare Shared Savings Program.

ACO participant has the meaning set forth in § 425.20 of this chapter.

ACO provider/supplier has the meaning set forth in § 425.20 of this chapter.

* * * * *

Alignment payment means a payment from a CJR collaborator to a participant hospital under a sharing arrangement, for the sole purpose of sharing the participant hospital's responsibility for making repayments to Medicare.

* * * * *

Applicable discount factor means the discount percentage established by the participant hospital’s quality category as determined in § 510.315 and that is applied to the episode benchmark price for purposes of determining a participant hospital’s Medicare repayment in performance years 2 and 3.

* * * * *

CEHRT means certified electronic health record technology that meet the requirements of 45 CFR 170.102.

CJR activities means activities related to promoting accountability for the quality, cost, and overall care for CJR beneficiaries, including managing and coordinating care; encouraging investment in infrastructure enabling technologies and redesigned care processes for high quality and efficient service delivery; the provision of items and services during a CJR episode in a manner that reduces costs and improves quality; or carrying out any other obligation or duty under CJR.

CJR collaborator means an ACO or one of the following Medicare-enrolled individuals or entities that enters into a sharing arrangement:

(1) SNF.

(2) HHA.

(3) LTCH.

(4) IRF.

(5) Physician.

(6) Nonphysician practitioner.

(7) Provider or supplier of outpatient therapy services.

(8) Physician group practice (PGP).

(9) Hospital.

(10) CAH.

* * * * *

Collaboration agent means an individual or entity that is not a CJR collaborator and that is either of the following:

(1) A PGP member that has entered into a distribution arrangement with the same PGP in which he or she is an owner or employee;

(2) An ACO participant or ACO provider/supplier that has entered into a distribution arrangement with the same ACO in which it is participating.

* * * * *

Distribution arrangement means a financial arrangement between a CJR collaborator that is an ACO or PGP and a collaboration agent for the sole purpose of distributing some or all of a gainsharing payment received by the ACO or PGP.

Distribution payment means a payment from a CJR collaborator that is an ACO or PGP to a collaboration agent, under a distribution arrangement, composed only of gainsharing payments.

* * * * *

Downstream collaboration agent means an individual who is not a CJR collaborator or a collaboration agent and who is a PGP member that has entered into a downstream distribution

arrangement with the same PGP in which he or she is an owner or employee, and where that PGP is a collaboration agent.

Downstream distribution arrangement means a financial arrangement between a collaboration agent that is both a PGP and an ACO participant and a downstream collaboration agent for the sole purpose of distributing some or all of a distribution payment received by the PGP.

Downstream distribution payment means a payment from a collaboration agent that is both a PGP and an ACO participant to a downstream collaboration agent, under a downstream distribution arrangement, composed only of distribution payments.

* * * * *

Episode benchmark price means a dollar amount assigned to CJR episodes based on historical episode payment data (3 years of historical Medicare payment data grouped into CJR episodes according to the episode definition as described in § 510.200(b)) prior to the application of the effective discount factor or applicable discount factor, as described in § 510.300(c).

* * * * *

HHA means a Medicare enrolled home health agency.

Historical episode payment means the expenditures for historical episodes that occurred during the historical period used to determine the episode benchmark price.

Hospital means a provider subject to the prospective payment system specified in § 412.1(a)(1) of this chapter.

* * * * *

Quality-adjusted target price means the dollar amount assigned to CJR episodes as the result of adjusting the episode benchmark price by the participant hospital's effective discount

factor or applicable discount factor based on the participant hospital's quality category, as described in § 510.300(c) and § 510.315(f).

Quality improvement points are points that CMS adds to a participant hospital's composite quality score for a measure if the hospital's performance percentile on an individual quality measure for performance years 2 through 5 increases from the previous performance year by at least 2 deciles on the performance percentile scale, as described in § 510.315(d). For performance year 1, CMS will add quality improvement points to a participant hospital's composite quality score for a measure if the hospital's performance percentile on an individual quality measure increases from the corresponding time period in the previous year by at least 2 deciles on the performance percentile scale, as described in § 510.315(d).

* * * * *

3. Section 510.110 is added to subpart B to read as follows:

§ 510.110 Access to records and retention.

Participant hospitals, CJR collaborators, collaboration agents, downstream collaboration agents, and any other individuals or entities performing CJR activities must do all of the following:

(a) Allow the Government, including CMS, OIG, HHS and the Comptroller General or their designees, scheduled and unscheduled access to all books, contracts, records, documents and other evidence (including data related to utilization and payments, quality criteria, billings, lists of CJR collaborators, sharing arrangements, distribution arrangements, downstream distribution arrangements and the documentation required under §§ 510.500(d) and 510.525(c)) sufficient to enable the audit, evaluation, inspection or investigation of any of the following:

(1) The individual's or entity's compliance with CJR model requirements.

(2) The calculation, distribution, receipt, or recoupment of gainsharing payments, alignment payments, distribution payments, and downstream distribution payments.

(3) The obligation to repay any reconciliation payments owed to CMS.

(4) The quality of the services furnished to a CJR beneficiary during a CJR episode.

(5) The sufficiency of CJR beneficiary notifications.

(6) The accuracy of the CJR participant hospital's submissions under CEHRT use requirements.

(b) Maintain all such books, contracts, records, documents, and other evidence for a period of 10 years from the last day of the participant hospital's participation in the CJR model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

(1) CMS determines a particular record or group of records should be retained for a longer period and notifies the participant hospital at least 30 calendar days before the disposition date; or

(2) There has been a dispute or allegation of fraud or similar fault against the participant hospital, CJR collaborator, collaboration agents, downstream collaboration agent, or any other individual or entity performing CJR activities in which case the records must be maintained for 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

4. Section 510.120 is added to subpart B to read as follows:

§ 510.120 CJR participant hospital CEHRT track requirements.

(a) CJR CEHRT use. For performance years 2 through 5, CJR participant hospitals choose either of the following:

(1) CEHRT use. Participant hospitals attest in a form and manner required by CMS to their use of CEHRT as defined in § 414.1305 of this chapter to document and communicate clinical care with patients and other health professionals.

(2) No CEHRT use. Participant hospitals do not attest in a form and manner required by CMS to their use of CEHRT as defined in § 414.1305 to document and communicate clinical care with patients and other health professionals.

(b) Clinician financial arrangements list. Each participant hospital that chooses CEHRT use as provided in paragraph (a)(1) of this section must submit to CMS a clinician financial arrangements list in a form and manner specified by CMS on a no more than quarterly basis. The list must include the following information on individuals for the period of the CJR performance year specified by CMS:

(1) CJR collaborators. For each CJR collaborator who is a physician, nonphysician practitioner, or provider of outpatient therapy services during the period of the CJR performance year specified by CMS:

(i) The name, TIN, and NPI of the CJR collaborator.

(ii) The start date and, if applicable, end date, for the sharing arrangement between the CJR participant hospital and the CJR collaborator.

(2) Collaboration agents. For each collaboration agent who is a physician or nonphysician practitioner of a PGP that is a CJR collaborator during the period of the CJR performance year specified by CMS:

(i) The TIN of the PGP that is the CJR collaborator, and the name and NPI of the physician or nonphysician practitioner.

(ii) The start date and, if applicable, end date, for the distribution arrangement between the CJR collaborator that is a PGP and the physician or nonphysician practitioner who is a PGP member.

(3) Downstream collaboration agents. For each downstream collaboration agent who is a physician or nonphysician practitioner member of a PGP that is also an ACO participant in an ACO that is an CJR collaborator during the period of the CJR performance year specified by CMS:

(i) The TIN of the PGP that is the ACO participant, and the name and NPI of the physician or nonphysician practitioner.

(ii) The start date and, if applicable, end date, for the downstream distribution arrangement between the collaboration agent that is both PGP and an ACO participant and the physician or nonphysician practitioner who is a PGP member.

(4) Attestation to no individuals. If there are no individuals that meet the requirements to be reported, as specified in paragraphs (b)(1) through (3) of this section, the participant hospital must attest in a form and manner required by CMS that there are no individuals to report on the clinician financial arrangements list.

(c) Documentation requirements. (1) Each participant hospital that chooses CEHRT use as provided in paragraph (a)(1) of this section must maintain documentation of their attestation to CEHRT use and clinician financial arrangements lists.

(2) The participant hospital must retain and provide access to the required documentation in accordance with § 510.110.

5. Section 510.205 is amended by adding paragraph (a)(6) to read as follows:

§ 510.205 Beneficiary inclusion criteria.

(a) * * *

(6) For episodes that begin on or after July 1, 2017, are not aligned to an ACO in the Next Generation ACO model or an ACO in a track of the Comprehensive ESRD Care Initiative incorporating downside risk for financial losses.

* * * * *

6. Section 510.300 is amended by:

a. Revising the section heading;

b. Revising paragraphs (a) introductory text, (a)(1) through (3), and (a)(5);

d. Revising the heading for paragraph (b) and revising paragraphs (b)(1) introductory text, (b)(3), (5), and (7);

e. Adding paragraph (b)(8); and

f. Revising paragraph (c).

The revisions and additions read as follows:

§ 510.300 Determination of episode quality-adjusted target prices.

(a) General. CMS establishes episode quality-adjusted target prices for participant hospitals for each performance year of the model as specified in this section. Episode quality-adjusted target prices are established according to the following:

(1) MS-DRG and fracture status. MS-DRG assigned at discharge for anchor hospitalization and present of hip fracture diagnosis for anchor hospitalization—

(i) MS-DRG 469 with hip fracture;

(ii) MS-DRG 469 without hip fracture;

(iii) MS-DRG 470 with hip fracture; or

(iv) MS-DRG 470 without hip fracture.

(2) Applicable time period for performance year episode quality-adjusted target prices. Episode quality-adjusted target prices are updated to account for Medicare payment updates no less than 2 times per year, for updated quality-adjusted target prices effective October 1 and January 1, and at other intervals if necessary.

(3) Episodes that straddle performance years or payment updates. The quality-adjusted target price that applies to the type of episode as of the date of admission for the anchor hospitalization is the quality-adjusted target price that applies to the episode.

* * * * *

(5) Quality performance. Quality-adjusted target prices reflect effective discount factors or applicable discount factors based on a hospital's composite quality score, as specified in §§ 510.300(c) and 510.315(f).

* * * * *

(b) Episode quality-adjusted target price. (1) CMS calculates quality-adjusted target prices based on a blend of each participant hospital's hospital-specific and regional episode expenditures. The region corresponds to the U.S. Census Division associated with the primary address of the CCN of the participant hospital and the regional component is based on all hospitals in said region, except as follows. In cases where an MSA selected for participation in CJR spans more than one U.S. Census Division, the entire MSA will be grouped into the U.S. Census Division where the largest city by population in the MSA is located for quality-adjusted target price and reconciliation calculations. The calendar years used for historical expenditure calculations are as follows:

* * * * *

(3) Exception for low-volume hospitals. Quality-adjusted target prices for participant hospitals with fewer than 20 CJR episodes in total across the 3 historical years of data used to calculate the quality-adjusted target price are based on 100 percent regional historical episode payments.

* * * * *

(5) Exception for high episode spending. Episode payments are capped at 2 standard deviations above the mean regional episode payment for both the hospital-specific and regional components of the quality-adjusted target price.

* * * * *

(7) Communication of episode quality-adjusted target prices. CMS communicates episode quality-adjusted target prices to participant hospitals before the performance period in which they apply.

(8) Inclusion of reconciliation payments and repayments. For performance years 3, 4, and 5 only, reconciliation payments and repayment amounts under §§ 510.305(f)(2) and 510.305(f)(3) and from LEJR episodes included in the BPCI initiative are included in historical episode payments.

(c) Discount factor. A participant hospital's episode quality-adjusted target prices incorporate discount factors to reflect Medicare's portion of reduced expenditures from the CJR model as described in this section.

(1) Discount factors affected by the quality incentive payments and the composite quality score. In all performance years, the discount factor may be affected by the quality incentive payment and composite quality score as provided in § 510.315 to create the effective discount factor or applicable discount factor used for calculating reconciliation payments and

repayment amounts. The quality-adjusted target prices incorporate the effective or applicable discount factor at reconciliation.

(2) Discount factor for reconciliation payments. The discount factor for reconciliation payments in all performance years is 3.0 percent.

(3) Discount factors for repayment amounts. The discount factor for repayment amounts is—

(i) Not applicable in performance year 1, as the requirement for hospital repayment under the CJR model is waived in performance year 1;

(ii) In performance years 2 and 3, 2.0 percent; and

(iii) In performance years 4 and 5, 3.0 percent.

* * * * *

7. Section 510.305 is amended by revising paragraphs (e) introductory text, (e)(1)(ii) and (v), (f)(1)(i) and (ii), and (h)(6), adding paragraph (h)(7), revising paragraph (i), and adding paragraph (j) to read as follows:

§ 510.305 Determination of the NPRA and reconciliation process.

*** * * * ***

(e) Calculation of the NPRA. By comparing the quality-adjusted target prices described in § 510.300 and the participant hospital's actual episode spending for the performance year and applying the adjustments in paragraph (e)(1)(v) of this section, CMS establishes an NPRA for each participant hospital for each performance year.

(1) * * *

(ii) Multiplies each episode quality-adjusted target price by the number of episodes included in the performance year (other than episodes that have been canceled in accordance with § 510.210(b)) to which that episode quality-adjusted target price applies.

* * * * *

(v) Applies the following prior to determination of the reconciliation payment or repayment amount:

(A) Limitation on loss. Except as provided in paragraph (e)(1)(v)(C) of this section, the total amount of the NPRA and subsequent reconciliation calculation for a performance year cannot exceed the following:

(1) For performance year 2 only, 5 percent of the amount calculated in paragraph (e)(1)(iii) of this section for the performance year.

(2) For performance year 3, 10 percent of the amount calculated in paragraph (e)(1)(iii) of this section for the performance year.

(3) For performance years 4 and 5, 20 percent of the amount calculated in paragraph (e)(1)(iii) of this section for the performance year.

(4) As provided in paragraph (i) of this section, the subsequent reconciliation calculation reassesses the limitation on loss for a given performance year by applying the limitations on loss to the aggregate of the 2 reconciliation calculations.

(5) The post-episode spending and ACO overlap calculation amounts in paragraphs (j)(1) and (j)(2) of this section are not subject to the limitation on loss.

(B) Limitation on gain. The total amount of the NPRA and subsequent reconciliation calculation for a performance year cannot exceed the following:

(1) For performance years 1 and 2, 5 percent of the amount calculated in paragraph (e)(1)(iii) of this section for the performance year.

(2) For performance year 3, 10 percent of the amount calculated in paragraph (e)(1)(iii) of this section for the performance year.

(3) For performance years 4 and 5, 20 percent of the amount calculated in paragraph (e)(1)(iii) of this section for the performance year.

(4) As provided in paragraph (i) of this section, the subsequent reconciliation calculation reassesses the limitation on gain for a given performance year by applying the limitations on gain limits to the aggregate of the 2 reconciliation calculations.

(5) The post-episode spending and ACO overlap calculation amounts in paragraphs (j)(1) and (j)(2) of this section are not subject to the limitation on gain.

(C) Financial loss limits for rural hospitals, SCHs, MDHs, and RRCs. If a participant hospital is a rural hospital, SCH, MDH, or RRC, then for performance year 2, the total repayment amount for which the participant hospital is responsible due to the NPRA and subsequent reconciliation calculation cannot exceed 3 percent of the amount calculated in paragraph (e)(1)(iii) of this section. For performance years 3 through 5, the amount cannot exceed 5 percent of the amount calculated in paragraph (e)(1)(iii) of this section.

* * * * *

(f) * * *

(1) * * *

(i) Subject to paragraph (f)(1)(iii) of this section, for performance year 1, the reconciliation payment (if any) is equal to the NPRA.

(ii) Subject to paragraph (f)(1)(iii) of this section, for performance years 2 through 5, results from the subsequent reconciliation calculation for a prior year's reconciliation as described in paragraph (i) of this section and the post-episode spending and ACO overlap calculations as described in paragraph (j) of this section are added to the current year's NPRA in order to determine the reconciliation payment or repayment amount.

* * * * *

(h) * * *

(6) The post-episode spending amount and ACO overlap calculation for the previous performance year, as applicable.

(7) The reconciliation payment or repayment amount.

(i) Subsequent reconciliation calculation. (1) Fourteen months after the end of each performance year, CMS performs an additional calculation, using claims data available at that time, to account for final claims run-out and any additional episode cancelations due to overlap between the CJR model and other CMS models and programs, or for other reasons as specified in § 510.210(b).

(2) The subsequent calculation for performance years 1 through 4 occurs concurrently with the first reconciliation process for the following performance year. If the result of the subsequent calculation is different than zero, CMS applies the stop-loss and stop-gain limits in paragraph (e) of this section to the aggregate calculation of the amounts described in paragraphs (e)(1)(iv) and (i)(1) of this section for that performance year (the initial reconciliation and the subsequent reconciliation calculation) to ensure such amount does not exceed the applicable stop-loss or stop-gain limits. Because there will be no additional performance year after

performance year 5, the subsequent reconciliation calculation for performance year 5 will occur independently in 2022.

(j) Additional adjustments to the reconciliation payment or repayment amount. (1) In order to account for shared savings payments, CMS will reduce the reconciliation payment or increase the repayment amount for the subsequent performance year (for years 1 through 4) by the amount of the participant hospital's discount percentage that is paid to the ACO in the prior performance year as shared savings. (This amount will be assessed independently for performance year 5 in 2022.) This adjustment is made only when the participant hospital is a participant or provider/supplier in the ACO and the beneficiary in the CJR episode is assigned to one of the following ACO models or programs:

(i) The Pioneer ACO model.

(ii) The Medicare Shared Savings Program.

(iii) The Comprehensive ESRD Care Initiative (excluding a track with downside risk for episodes that initiate after July 1, 2017).

(iv) The Next Generation ACO model (for CJR episodes that initiate prior to July 1, 2017).

(2) Increases in post-episode spending. If the average post-episode Medicare Parts A and B payments for a participant hospital in the prior performance year is greater than 3 standard deviations above the regional average post-episode payments for the same performance year, then the spending amount exceeding three standard deviations above the regional average post-episode payments for the same performance year is subtracted from the net reconciliation or added to the repayment amount for the subsequent performance year for years 1 through 4, and assessed independently for year 5.

8. Section 510.310 is amended by--

a. Revising paragraphs (a)(1) and (2).

b. Removing paragraph (a)(3)

c. Resdesignating paragraph (a)(4) as paragraph (a)(3).

d. Adding a new paragraph (a)(4).

e. Revising paragraph (c).

f. Redesignating paragraph (d) as paragraph (e).

g. Adding a new paragraph (d).

h. Revising newly designated paragraph (e)(6).

The revisions and addition read as follows:

§ 510.310 Appeals process.

* * * * *

(a) * * *

(1) Unless the participant hospital provides such notice, CMS deems final the CJR reconciliation report 45 calendar days after it is issued and proceeds with the payment or repayment processes as applicable.

(2) If CMS receives a notice of a calculation error within 45 calendar days of the issuance of the reconciliation report, CMS responds in writing within 30 calendar days to either confirm that there was an error in the calculation or verify that the calculation is correct, although CMS reserves the right to an extension upon written notice to the participant hospital.

* * * * *

(4) Only participant hospitals may use the notice of calculation error process described in this part.

* * * * *

(c) Exception to the process. If the participant hospital contests a matter that does not involve an issue contained in, or a calculation that contributes to, a CJR reconciliation report, a notice of calculation error is not required. In these instances, if CMS does not receive a request for reconsideration from the participant hospital within 10 calendar days of the notice of the initial determination, the initial determination is deemed final and CMS proceeds with action indicated in the initial determination.

(d) Notice of a participant hospital's termination from the CJR model. If a participant hospital receives notification that it has been terminated from the CJR model, it must provide a written notice to CMS requesting review of the termination within 10 calendar days of the notice. CMS has 30 days to respond to the participant hospital's request for review. If the participant hospital fails to notify CMS, the termination is deemed final.

(e) * * *

(6) Decisions about expansion of the duration and scope of a model under section 1115A(c) of the Act, including the determination that a model is not expected to meet criteria described in section 1115A(c)(1) or (2) of the Act..

9. Section 510.315 is amended by –

a. Revising paragraph (c) introductory text.

b. Redesignating paragraph (c)(1)(ix) as paragraph (c)(1)(viii).

c. Redesignating paragraph (c)(2)(ix) as paragraph (c)(2)(viii).

d. Revising paragraph (d) and (f).

The revisions read as follows:

§ 510.315 Composite quality scores for determining reconciliation payment eligibility and quality incentive payments.

* * * * *

(c) Quality performance points. CMS computes quality performance points for each quality measure based on the participant hospital's performance relative to the distribution of performance of all "subsection (d)" hospitals that are eligible for payment under IPPS and meet the minimum patient case or survey count for that measure.

* * * * *

(d) Quality improvement points. For performance year 1, if a participant hospital's quality performance percentile on an individual measure described in § 510.400(a) increases from the corresponding time period in the previous year by at least 2 deciles on the performance percentile scale, then the hospitals is eligible to receive quality improvement points equal to 10 percent of the total available point for that individual measure up to a maximum composite quality score of 20 points. For performance years 2 through 5, if a participant hospital's quality performance percentile on an individual measure described in § 510.400(a) increases from the previous performance year by at least 2 deciles on the performance percentile scale, then the hospitals is eligible to receive quality improvement points equal to 10 percent of the total available point for that individual measure up to a maximum composite quality score of 20 points.

* * * * *

(f) Quality incentive payments. CMS provides incentive payments to participant hospitals that demonstrate good or excellent quality performance on the composite quality scores described in paragraph (b) of this section. These incentive payments are implemented in the

form of the following reductions to the effective discount factors or applicable discount factors described in § 510.300(c):

(1) A 1.0 percentage point reduction to the effective discount factor or applicable discount factor for participant hospitals with good quality performance, defined as composite quality scores that are greater than or equal to 6.0 and less than or equal to 13.2.

(2) A 1.5 percentage point reduction to the effective discount factor or applicable discount factor for participant hospitals with excellent quality performance, defined as composite quality scores that are greater than 13.2.

10. Section 510.400 is amended by revising paragraph (c)(3) to read as follows:

§ 510.400 Quality measures and reporting.

* * * * *

(c) * * *

(3) Does not publicly report the voluntary patient-reported outcomes and limited risk variable data during this model, but indicates whether a hospital has successfully submitted such data in accordance with § 510.400(b).

11. Section 510.405 is amended by revising paragraph (b) to read as follows:

§ 510.405 Beneficiary choice and beneficiary notification.

* * * * *

(b) Required beneficiary notification—(1) Hospital detailed notification. Each participant hospital must provide written notice to any Medicare beneficiary that meets the criteria in § 510.205 of his or her inclusion in the CJR model. The notice must be upon admission to the participant hospital or immediately following the decision to schedule an LEJR surgery, whichever occurs later. In circumstances where, due to the patient's condition, it may

not be feasible to provide notification at such times, the notification must be provided to the beneficiary or his or her representative as soon as is reasonably practicable but no later than discharge from the participant hospital accountable for the episode. The beneficiary notification must contain all of the following:

(i) A detailed explanation of the model and how it might be expected to affect the beneficiary's care.

(ii) Notification that the beneficiary retains freedom of choice to choose providers and services.

(iii) Explanation of how patients can access care records and claims data through an available patient portal, and how they can share access to their Blue Button® electronic health information with caregivers.

(iv) A statement that all existing Medicare beneficiary protections continue to be available to the beneficiary. These include the ability to report concerns of substandard care to Quality Improvement Organizations and 1-800-MEDICARE.

(v) A list of the providers and suppliers with whom the participant hospital has a written agreement memorializing a sharing arrangement. This requirement may be fulfilled by the hospital including in the detailed notification provided to Medicare beneficiaries a web address where beneficiaries may access this list.

(2) Physician, nonphysician practitioner, and PGP provision of notice. A participant hospital must require any physician, nonphysician practitioner, or PGP that is a CJR collaborator to provide written notice of the structure of the model and the existence of the physician's sharing arrangement with the participant hospital to any Medicare beneficiary that meets the criteria specified in § 510.205. The notice must be provided at the time that the decision to

undergo LEJR surgery is made if known to the physician, nonphysician practitioner, and PGP collaborators or upon provision of the services during the episode.

(3) Other CJR collaborators. A participant hospital must require each CJR collaborator (other than physicians, nonphysician practitioners, or PGP collaborators) to provide written notice of the structure of the model and the existence of its sharing arrangement with the participant hospital to any Medicare beneficiary that meets the criteria specified in § 510.205. An ACO that is a CJR collaborator must require their ACO participants for which the ACO has an ACO distribution arrangement to provide written notice of the structure of the model and the existence of the ACO's sharing arrangement with the participant hospital to any Medicare beneficiary that meets the criteria specified in § 510.205. The notice must be provided no later than the time at which the beneficiary first receives services from the CJR collaborator during the CJR episode.

(4) Discharge planning notice. A participant hospital must provide the beneficiary with a written notice of any potential financial liability that may arise from non-covered services recommended or presented as an option as part of discharge planning. This notice must be provided to the beneficiary no later than the time that the beneficiary discusses a particular PAC option or at the time the beneficiary is discharged, whichever occurs earlier.

(i) If the participant hospital knows or should have known that the beneficiary is considering or has decided to receive a non-covered post-acute service or other non-covered associated service or supply, the participant hospital must notify the beneficiary that the service would not be covered by Medicare.

(ii) If the participant hospital is discharging a beneficiary to a SNF prior to the occurrence of a 3 day hospital stay, and the beneficiary is being admitted to or is considering a

SNF that would not qualify under the SNF 3-day waiver in § 510.610, the participant hospital must notify the beneficiary in accordance with paragraph (b)(4)(i) of this section that the beneficiary will be responsible for costs associated with that stay except those that would be covered by Medicare Part B during a non-covered inpatient SNF stay.

(5) Participant hospitals and CJR collaborators must be able to generate upon request a list of all beneficiaries who have received a notice required by this section, including the type of notice and the date the notice was delivered. Lists of beneficiaries that receive notifications must be retained and provided access to CMS, or its designees, in accordance with § 510.110.

12. Section 510.410 is amended by revising paragraphs (b)(1) introductory text, (b)(1)(i) introductory text, (b)(1)(i)(F), (b)(1)(ii), (b)(1)(vi) through (x), (b)(2)(i) through (v), (vi), and (b)(3) to read as follows:

§ 510.410 Compliance enforcement.

* * * * *

(b) Failure to comply. (1) CMS may take one or more of the remedial actions set forth in paragraph (b)(2) of this section if a participant hospital or its related CJR collaborators, collaboration agents , or downstream collaboration agents –

(i) Fails to comply with any requirements of this part or is identified as noncompliant through monitoring by HHS (including CMS and OIG) of the CJR model, including but not limited to the following:

* * * * *

(F) Failing to follow the requirements related to sharing arrangements.

(ii) Has signed a sharing arrangement, distribution arrangement, or downstream distribution arrangement that is noncompliant with the requirements of this part.

* * * * *

(vi) Fails to provide an accurate clinician financial arrangements list as specified in § 510.120(b).

(vii) Is subject to sanctions or final actions of an accrediting organization or Federal, state, or local government agency that could lead to the inability to comply with the requirements and provisions of this part.

(viii) Takes any action that CMS determines for program integrity reasons is not in the best interests of the CJR model, or fails to take any action that CMS determines for program integrity reasons should have been taken to further the best interests of CJR.

(ix) Is subject to action by HHS (including OIG and CMS) or the Department of Justice to redress an allegation of fraud or significant misconduct, including intervening in a False Claims Act qui tam matter, issuing a pre-demand or demand letter under a civil sanction authority, or similar actions.

(x) Is subject to action involving violations of the physician self-referral law, civil monetary penalties law, Federal anti-kickback statute, antitrust laws, or any other applicable Medicare laws, rules, or regulations that are relevant to CJR.

(2) * * *

(i) Issuing a warning letter to the participant hospital.

(ii) Requiring the participant hospital to develop a corrective action plan, commonly referred to as a CAP.

(iii) Reducing or eliminating a participant hospital’s reconciliation payment.

(iv) Requiring a participant hospital to terminate a sharing arrangement with a CJR collaborator and prohibiting further engagement in sharing arrangements with the participant hospital by that CJR collaborator.

(v) Prohibiting the participant hospital from participating in the CEHRT track.

(vi) Terminating the participant hospital's participation in the CJR model. Where a participant is terminated from the CJR model, the participant hospital will remain liable for all negative NPRA generated from episodes of care that occurred prior to termination.

(3) CMS may add 25 percent to a repayment amount on a participant hospital's reconciliation report if all of the following conditions are true:

(i) CMS has required a corrective action plan from a participant hospital;

(ii) The participant hospital owes a repayment amount to CMS; and

(iii) The participant hospital fails to timely comply with the corrective action plan or is noncompliant with the CJR model's requirements.

13. Section 510.500 is revised to read as follows:

§ 510.500 Sharing arrangements under the CJR model.

(a) General. (1) A participant hospital may enter into a sharing arrangement with a CJR collaborator to make a gainsharing payment, or to receive an alignment payment, or both. A participant hospital must not make a gainsharing payment or receive an alignment payment except in accordance with a sharing arrangement.

(2) A sharing arrangement must comply with the provisions of this section and all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.

(3) Participant hospitals must develop, maintain, and use a set of written policies for selecting individuals and entities to be CJR collaborators. These policies must contain criteria related to, and inclusive of, the quality of care delivered by the potential CJR collaborator. The selection criteria cannot be based directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent.

(4) If a participant hospital enters into a sharing arrangement, its compliance program must include oversight of sharing arrangements and compliance with the applicable requirements of the CJR model.

(b) Requirements. (1) A sharing arrangement must be in writing and signed by the parties, and entered into before care is furnished to CJR beneficiaries under the sharing arrangement.

(2) Participation in a sharing arrangement must be voluntary and without penalty for nonparticipation.

(3) The sharing arrangement must require the CJR collaborator and its employees, contractors (including collaboration agents), and subcontractors (including downstream collaboration agents) to comply with the following:

(i) The applicable provisions of this part (including requirements regarding beneficiary notifications, access to records, record retention, and participation in any evaluation, monitoring, compliance, and enforcement activities performed by CMS or its designees);

(ii) All applicable Medicare provider enrollment requirements at § 424.500 of this chapter, including having a valid and active TIN or NPI, during the term of the sharing arrangement; and

(iii) All other applicable laws and regulations.

(4) The sharing arrangement must require the CJR collaborator to have a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the CJR model.

(5) The sharing arrangement must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care.

(6) The board or other governing body of the participant hospital must have responsibility for overseeing the participant hospital's participation in the CJR model, its arrangements with CJR collaborators, its payment of gainsharing payments, its receipt of alignment payments, and its use of beneficiary incentives in the CJR model.

(7) The written agreement memorializing a sharing arrangement must specify the following:

(i) The purpose and scope of the sharing arrangement;

(ii) The obligations of the parties, including specified CJR activities and other services to be performed by the parties under the sharing arrangement;

(iii) The date of the sharing arrangement;

(iv) Management and staffing information, including type of personnel or contractors that will be primarily responsible for carrying out CJR activities; and

(v) The financial or economic terms for payment, including:

(A) Eligibility criteria for a gainsharing payment.

(B) Eligibility criteria for an alignment payment.

(C) Frequency of gainsharing or alignment payment.

(D) Methodology and accounting formula for determining the amount of a gainsharing payment or alignment payment.

(8) The sharing arrangement must not—

(i) Induce the participant hospital, CJR collaborator, or any employees, contractors, or subcontractors of the participant hospital or CJR collaborator to reduce or limit medically necessary services to any Medicare beneficiary; or

(ii) Restrict the ability of a CJR collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies, and treatments.

(c) Gainsharing payment, alignment payment, and internal cost savings conditions and restrictions. (1) Gainsharing payments, if any, must —

(i) Be derived solely from reconciliation payments, or internal cost savings, or both;

(ii) Be distributed on an annual basis (not more than once per calendar year);

(iii) Not be a loan, advance payment, or payment for referrals or other business; and

(iv) Be clearly identified as a gainsharing payment at the time it is paid.

(2)(i) To be eligible to receive a gainsharing payment, a CJR collaborator must meet quality of care criteria for the performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment. The quality of care criteria must be established by the participant hospital and directly related to the CJR episode.

(ii) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a CJR collaborator other than a PGP or an ACO must have directly

furnished a billable item or service to a CJR beneficiary during a CJR episode that occurred in the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount.

(iii) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a CJR collaborator that is a PGP must meet the following criteria:

(A) The PGP must have billed for an item or service that was rendered by one or more members of the PGP to a CJR beneficiary during a CJR episode that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount; and

(B) The PGP must have contributed to CJR activities and been clinically involved in the care of CJR beneficiaries during the same performance year for which the CJR participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount. For example, a PGP might have been clinically involved in the care of CJR beneficiaries by:

(1) Providing care coordination services to beneficiaries during and/or after inpatient admission;

(2) Engaging with a participant hospital in care redesign strategies, and actually performing a role in implementing such strategies, that are designed to improve the quality of care for CJR episodes and reduce CJR episode spending; or

(3) In coordination with other providers and suppliers (such as members of the PGP, the participant hospital, and post-acute care providers), implementing strategies designed to address and manage the comorbidities of CJR beneficiaries.

(iv) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a CJR collaborator that is an ACO must meet the following criteria:

(A) The ACO must have had an ACO provider/supplier that directly furnished, or an ACO participant that billed for, an item or service that was rendered to a CJR beneficiary during a CJR episode that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount; and

(B) The ACO must have contributed to CJR activities and been clinically involved in the care of CJR beneficiaries during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed the repayment amount. For example, an ACO might be have been clinically involved in the care of CJR beneficiaries by:

(1) Providing care coordination services to CJR beneficiaries during and/or after inpatient admission;

(2) Engaging with a participant hospital in care redesign strategies, and actually performing a role in implementing such strategies, that are designed to improve the quality of care and reduce spending for CJR episodes; or

(3) In coordination with providers and suppliers (such as ACO participants, ACO providers/suppliers, the participant hospital, and post-acute care providers), implementing strategies designed to address and manage the comorbidities of CJR beneficiaries.

(3)(i) The methodology for accruing, calculating and verifying internal cost savings must be transparent, measurable, and verifiable in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book).

(ii) The methodology used to calculate internal cost savings must reflect the actual, internal cost savings achieved by the participant hospital through the documented implementation of CJR activities identified by the participant hospital and must exclude:

(A) Any savings realized by any individual or entity that is not the participant hospital; and

(B) “Paper” savings from accounting conventions or past investment in fixed costs.

(4) The total amount of a gainsharing payment for a performance year paid to a CJR collaborator must not exceed the following:

(i) In the case of a CJR collaborator who is a physician or nonphysician practitioner, 50 percent of the Medicare-approved amounts under the PFS for items and services furnished by that physician or nonphysician practitioner to the participant hospital's CJR beneficiaries during CJR episodes that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being made.

(ii) In the case of a CJR collaborator that is a PGP, 50 percent of the Medicare-approved amounts under the PFS for items and services billed by the PGP and furnished to the participant hospital's CJR beneficiaries by members of the PGP during CJR episodes that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being made.

(5) The amount of any gainsharing payments must be determined in accordance with a methodology that is substantially based on quality of care and the provision of CJR activities. The methodology may take into account the amount of such CJR activities provided by a CJR collaborator relative to other CJR collaborators.

(6) For a performance year, the aggregate amount of all gainsharing payments that are derived from a reconciliation payment must not exceed the amount of the reconciliation payment the participant hospital receives from CMS.

(7) No entity or individual, whether a party to a sharing arrangement or not, may condition the opportunity to make or receive gainsharing payments or to make or receive alignment payments on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent.

(8) A participant hospital must not make a gainsharing payment to a CJR collaborator that is subject to any action for noncompliance with this part or the fraud and abuse laws, or for the provision of substandard care in CJR episodes or other integrity problems.

(9) The sharing arrangement must require the participant hospital to recoup any gainsharing payment that contained funds derived from a CMS overpayment on a reconciliation report or was based on the submission of false or fraudulent data.

(10) Alignment payments from a CJR collaborator to a participant hospital may be made at any interval that is agreed upon by both parties, and must not be—

(i) Issued, distributed, or paid prior to the calculation by CMS of a repayment amount reflected in a reconciliation report;

(ii) Loans, advance payments, or payments for referrals or other business; or

(iii) Assessed by a participant hospital if it does not owe a repayment amount.

(11) The participant hospital must not receive any amounts under a sharing arrangement from a CJR collaborator that are not alignment payments.

(12) For a performance year, the aggregate amount of all alignment payments received by the participant hospital must not exceed 50 percent of the participant hospital's repayment amount.

(13) The aggregate amount of all alignment payments from a CJR collaborator to the participant hospital may not be greater than:

(i) With respect to a CJR collaborator other than an ACO, 25 percent of the participant hospital's repayment amount.

(ii) With respect to a CJR collaborator that is an ACO, 50 percent of the participant hospital's repayment amount.

(14) The methodology for determining alignment payments must not directly account for the volume or value of past or anticipated referrals or business otherwise generated by, between or among the participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent.

(15) All gainsharing payments and any alignment payments must be administered by the participant hospital in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book).

(16) All gainsharing payments and alignment payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(d) Documentation requirements. (1) Participant hospitals must:

(i) Document the sharing arrangement contemporaneously with the establishment of the arrangement;

(ii) Maintain accurate current and historical lists of all CJR collaborators, including collaborator names and addresses; update such lists on at least a quarterly basis; and publicly report the current and historical lists of CJR collaborators on a webpage on the participant hospital's website; and

(iii) Maintain and require each CJR collaborator to maintain contemporaneous documentation with respect to the payment or receipt of any gainsharing payment or alignment payment that includes at a minimum the:

(A) Nature of the payment (gainsharing payment or alignment payment);

(B) Identity of the parties making and receiving the payment;

(C) Date of the payment;

(D) Amount of the payment; and

(E) Date and amount of any recoupment of all or a portion of a CJR collaborator's gainsharing payment.

(2) The participant hospital must keep records of:

(i) Its process for determining and verifying its potential and current CJR collaborators' eligibility to participate in Medicare;

(ii) Its plan to track internal cost savings;

(iii) Information on the accounting systems used to track internal cost savings;

(iv) A description of current health information technology, including systems to track reconciliation payments and internal cost savings; and

(v) Its plan to track gainsharing payments and alignment payments.

(3) The participant hospital must retain and provide access to, and must require each CJR collaborator to retain and provide access to, the required documentation in accordance with § 510.110.

14. Section 510.505 is revised to read as follows:

§ 510.505 Distribution arrangements.

(a) General. (1) A PGP or ACO that has entered into a sharing arrangement with a participant hospital may distribute all or a portion of any gainsharing payment it receives from the participant hospital only in accordance with a distribution arrangement.

(2) All distribution arrangements must comply with the provisions of this section and all other applicable laws and regulations, including the fraud and abuse laws.

(b) Requirements. (1) All distribution arrangements must be in writing and signed by the parties, contain the date of the agreement, and be entered into before care is furnished to EPM beneficiaries under the distribution arrangement.

(2) Participation in a distribution arrangement must be voluntary and without penalty for nonparticipation.

(3) The distribution arrangement must require the collaboration agent to comply with all applicable laws and regulations.

(4) The opportunity to make or receive a distribution payment must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent.

(5) The amount of any distribution payments from an ACO must be determined in accordance with a methodology that is substantially based on quality of care and the provision of CJR activities and that may take into account the amount of such CJR activities provided by a collaboration agent relative to other collaboration agents.

(6) The amount of any distribution payments from a PGP to a member must be determined either in a manner that complies with §411.352(g) of this chapter or in accordance with a methodology that is substantially based on quality of care and the provision of CJR activities and that may take into account the amount of such CJR activities provided by a collaboration agent relative to other collaboration agents.

(7) Except for a distribution payment from a PGP to a PGP member that complies with §411.352(g), a collaboration agent is eligible to receive a distribution payment only if the collaboration agent furnished or billed for an item or service rendered to a CJR beneficiary during a CJR episode that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed.

(8) Except for a distribution payment from a PGP to a PGP member that complies with §411.352(g), the total amount of distribution payments for a performance year paid to a collaboration agent must not exceed the following:

(i) In the case of a collaboration agent who is physician or nonphysician practitioner, 50 percent of the total Medicare-approved amounts under the PFS for items and services furnished by the collaboration agent to the participant hospital's CJR beneficiaries during CJR episodes that occurred during the same performance year for which the participant hospital accrued the

internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed.

(ii) In the case of a collaboration agent that is a PGP, 50 percent of the total Medicare-approved amounts under the PFS for items and services billed by the PGP for items and services furnished to the participant hospital's CJR beneficiaries during a CJR episode that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed.

(9) With respect to the distribution of any gainsharing payment received by a PGP or ACO, the total amount of all distribution payments must not exceed the amount of the gainsharing payment received by the CJR collaborator from the participant hospital.

(10) All distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(11) The collaboration agent must retain the ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

(12) The distribution arrangement must not—

(i) Induce the collaboration agent to reduce or limit medically necessary items and services to any Medicare beneficiary; or

(ii) Reward the provision of items and services that are medically unnecessary.

(13) The CJR collaborator must maintain contemporaneous documentation regarding distribution arrangements in accordance with § 510.110, including the following:

(i) The relevant written agreements.

(ii) The date and amount of any distribution payment(s).

(iii) The identity of each collaboration agent that received a distribution payment.

(iv) A description of the methodology and accounting formula for determining the amount of any distribution payment.

(14) The CJR collaborator may not enter into a distribution arrangement with any individual or entity that has a sharing arrangement with the same participant hospital.

(15) The CJR collaborator must retain and provide access to, and must require collaboration agents to retain and provide access to, the required documentation in accordance with § 510.110.

15. Section 510.506 is added to read as follows:

§ 510.506 Downstream distribution arrangements.

(a) General. (1) An ACO participant that is a PGP and that has entered into a distribution arrangement with a CJR collaborator that is an ACO may distribute all or a portion of any distribution payment it receives from the CJR collaborator only in accordance with downstream distribution arrangement.

(2) All downstream distribution arrangements must comply with the provisions of this section and all applicable laws and regulations, including the fraud and abuse laws.

(b) Requirements. (1) All downstream distribution arrangements must be in writing and signed by the parties, contain the date of the agreement, and be entered into before care is furnished to CJR beneficiaries under the downstream distribution arrangement.

(2) Participation in a downstream distribution arrangement must be voluntary and without penalty for nonparticipation.

(3) The downstream distribution arrangement must require the downstream collaboration agent to comply with all applicable laws and regulations.

(4) The opportunity to make or receive a downstream distribution payment must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the participant hospital, any CJR collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a participant hospital, CJR collaborator, collaboration agent, or downstream collaboration agent.

(5) The amount of any downstream distribution payment must be determined either in a manner that complies with §411.352(g) of this chapter or in accordance with a methodology that is substantially based on the quality of care and the provision of CJR activities and that may take into account the amount of such CJR activities provided by a downstream collaboration agent relative to other downstream collaboration agents.

(6) Except for a downstream distribution payment that complies with §411.352(g), a downstream collaboration agent is eligible to receive a downstream distribution payment only if the PGP billed for an item or service furnished by the downstream collaboration agent to a CJR beneficiary during a CJR episode that occurred during the same performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprise the gainsharing payment from which the ACO made the distribution payment to the PGP that is an ACO participant.

(7) Except for a downstream distribution payment that complies with §411.352(g), the total amount of downstream distribution payments for a performance year paid to a downstream collaboration agent must not exceed 50 percent of the total Medicare-approved amounts under the PFS for services billed by the PGP and furnished by the downstream collaboration agent to the participant hospital's CJR beneficiaries during CJR episodes that occurred during the same

performance year for which the participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment from which the ACO made the distribution payment to the PGP that is an ACO participant.

(8) The total amount of all downstream distribution payments made to downstream collaboration agents must not exceed the amount of the distribution payment received by the PGP from the ACO.

(9) All downstream distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(10) The downstream collaboration agent must retain his or her ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

(11) The downstream distribution arrangement must not—

(i) Induce the downstream collaboration agent to reduce or limit medically necessary services to any Medicare beneficiary; or

(ii) Reward the provision of items and services that are medically unnecessary.

(12) The PGP must maintain contemporaneous documentation regarding downstream distribution arrangements in accordance with § 510.110, including the following:

(i) The relevant written agreements.

(ii) The date and amount of any downstream distribution payment.

(iii) The identity of each downstream collaboration agent that received a downstream distribution payment.

(iv) A description of the methodology and accounting formula for determining the amount of any downstream distribution payment.

(13) The PGP may not enter into a downstream distribution arrangement with any PGP member who has either of the following:

(i) A sharing arrangement with a participant hospital.

(ii) A distribution arrangement with the ACO the PGP is a participant in.

(14) The PGP must retain and provide access to, and must require downstream collaboration agents to retain and provide access to, the required documentation in accordance with § 510.110.

16. Section 510.515 is amended by revising paragraphs (a)(2) and (3) and (b) through (d) and removing paragraph (e).

The revisions read as follows:

§ 510.515 Beneficiary incentives under the CJR model.

* * * * *

(a) * * *

(2) The item or service provided must be reasonably connected to medical care provided to a beneficiary during a CJR episode of care.

(3) The item or service must be a preventive care item or service or an item or service that advances a clinical goal, as listed in paragraph (c) of this section, for a beneficiary in a CJR episode by engaging the beneficiary in better managing his or her own health.

(b) Technology provided to a CJR beneficiary. Beneficiary engagement incentives involving technology are subject to the following additional conditions:

(1) Items or services involving technology provided to a beneficiary may not exceed $1,000 in retail value for any one beneficiary in any one CJR episode.

(2) Items or services involving technology provided to a beneficiary must be the minimum necessary to advance a clinical goal, as listed in paragraph (c) of this section, for a beneficiary in a CJR episode.

(3) Items of technology exceeding $100 in retail value must—

(i) Remain the property of the CJR participant; and

(ii) Be retrieved from the beneficiary at the end of the CJR episode. The participant hospital must document all retrieval attempts, including the ultimate date of retrieval. Documented, diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement.

(c) Clinical goals of the CJR model. The following are the clinical goals of the CJR model, which may be advanced through beneficiary incentives:

(1) Beneficiary adherence to drug regimens.

(2) Beneficiary adherence to a care plan.

(3) Reduction of readmissions and complications resulting from LEJR procedures.

(4) Management of chronic diseases and conditions that may be affected by the LEJR procedure.

(d) Documentation of beneficiary incentives. (1) Participant hospitals must maintain documentation of items and services furnished as beneficiary incentives that exceed $25 in retail value.

(2) The documentation must be established contemporaneously with the provision of the items and services and must include at least the following:

(i) The date the incentive is provided.

(ii) The identity of the beneficiary to whom the item or service was provided.

(3) The documentation regarding items of technology exceeding $100 in retail value must also include contemporaneous documentation of any attempt to retrieve technology at the end of a CJR episode as described in paragraph (b)(3) of this section.

(4) The CJR participant hospital must retain and provide access to the required documentation in accordance with § 510.110.

17. Section 510.610 is revised to read as follows:

§ 510.610 Waiver of SNF 3-day rule.

(a) Waiver of the SNF 3-day rule. For episodes being tested in the CJR model that begin on or after January 1, 2017, CMS waives the SNF 3-day rule for coverage of a SNF stay for a beneficiary who meets the eligibility criteria in 510.205 on the date of discharge from the anchor hospitalization, but only if the SNF is identified on the applicable calendar quarter list of qualified SNFs at the time of the CJR beneficiary's admission to the SNF.

(b) Financial liability for non-covered SNF services. (1) If CMS determines that the waiver requirements specified in paragraph (a) of this section were not met, the following apply:

(1) CMS makes no payment to a SNF for SNF services if the SNF admits a CJR beneficiary who has not had a qualifying inpatient stay.

(2) In the event that CMS makes no payment for SNF services furnished by a SNF as a result of paragraph (b)(1) of this section, the beneficiary protections specified in paragraph (b)(3) of this section apply, unless the participant hospital has provided the beneficiary with a discharge planning notice in accordance with 501.405(b)(4).

(3) If the participant hospital does not provide the beneficiary with a discharge planning notice in accordance with §510.405(b)(4)--

(A) The SNF must not charge the beneficiary for the expenses incurred for such services;

(B) The SNF must return to the beneficiary any monies collected for such services; and

(C) The participant hospital is financially liable for the expenses incurred for such services.

(4) If the participant hospital provided a discharge planning notice to the beneficiary in accordance with §510.405(b)(4), then normal SNF coverage requirements apply and the beneficiary may be financially liable for noncovered SNF services.

(c) Other requirements. All other Medicare rules for coverage and payment of Part A-covered services continue to apply except as otherwise waived in this part.

18. Section 510.620 is amended by revising paragraph (a) to read as follows:

§ 510.620 Waiver of deductible and coinsurance that otherwise apply to reconciliation payments and repayments.

(a) Waiver of deductible and coinsurance. CMS waives the requirements of sections 1813 and 1833(a) of the Act for Medicare Part A and Part B payment systems only to the extent necessary to make reconciliation payments or receive repayments based on the NPRA that reflect the episode payment methodology under the final payment model for CJR participant hospitals.

* * * * *

19. Part 512 is added to subchapter H to read as follows:

PART 512—EPISODE PAYMENT MODEL

Sec.

Subpart A—General Provisions

512.1 Basis and scope.
512.2 Definitions.

Subpart B—Episode Payment Model Participants

512.100 EPM episodes being tested.

512.105 Geographic areas.
512.110 Access to records and retention.
512.120 EPM participant CEHRT track requirements.

Subpart C—Scope of Episodes

512.200 Time periods for EPM episodes.
512.210 Included and excluded services.
512.230 Beneficiary inclusion criteria.
512.240 Determination of the EPM episode.

Subpart D—Pricing and Payment

512.300 Determination of episode quality-adjusted target prices and actual episode payments.
512.305 Determination of the NPRA and reconciliation process.
512.307 Subsequent calculations.
512.310 Appeals process.
512.315 Composite quality scores for determining reconciliation payment eligibility and effective and applicable discount factors.
512.320 Treatment of incentive programs or add-on payments under existing Medicare payment systems.
512.350 Data sharing.

Subpart E—Quality Measures, Beneficiary Protections, and Compliance Enforcement

512.400 Quality measures and reporting - general.
512.411 Quality measures and reporting for AMI model.
512.412 Quality measures and reporting for CABG model.
512.413 Quality measures and reporting for SHFFT model.
512.450 Beneficiary choice and beneficiary notification.
512.460 Compliance enforcement.

Subpart F—Financial Arrangements and Beneficiary Incentives

512.500 Sharing arrangements under the EPM.
512.505 Distribution arrangements under the EPM.
512.510 Downstream distribution arrangements under the EPM.
512.520 Enforcement authority under the EPM.
512.525 Beneficiary engagement incentives under the EPM.

Subpart G—Waivers

512.600 Waiver of direct supervision requirement for certain post-discharge home visits.
512.605 Waiver of certain telehealth requirements.
512.610 Waiver of SNF 3-day rule.

512.615 Waiver of certain post-operative billing restrictions.
512.620 Waiver of deductible and coinsurance that otherwise apply to reconciliation payments or repayments.
512.630 Waiver of physician definition for furnishing cardiac rehabilitation and intensive cardiac rehabilitation services to an EPM beneficiary.

Subpart H—CR Incentive Payment Model for EPM and Medicare Fee-for-Service Participants

512.700 Basis and scope.
512.703 CR incentive payment model participants.
512.705 CR/ICR services that count towards CR incentive payments.
512.710 Determination of CR incentive payments.

PROVISIONS FOR FFS-CR PARTICIPANTS

512.715 Access to records and retention for FFS-CR participants.
512.720 Appeals process for FFS-CR participants.
512.725 Data sharing for FFS-CR participants.
512.730 Compliance enforcement for FFS-CR participants.
512.735 Enforcement authority for FFS-CR participants.
512.740 Beneficiary engagement incentives for FFS-CR participant use.
512.745 Waiver of physician definition for furnishing CR and ICR services to a FFS-CR beneficiary.

Subparts I-J [Reserved]

Subpart K—Model Termination

512.900 Termination of an episode payment model.
512.905 Termination of the CR Incentive Payment Model.

Authority: Secs. 1102, 1115A, and 1871 of the Social Security Act (42 U.S.C. 1302, 1315(a), and 1395hh).

Subpart A--General Provisions

§ 512.1 Basis and scope.

(a) Basis. This part implements the test of episode payment models under section 1115A of the Act. Except as specifically noted in this part, the regulations under this part must not be construed to affect the payment, coverage, program integrity, or other requirements (such as

those in parts 412 and 482 of this chapter) that apply to providers and suppliers under this chapter.

(b) Scope. This part sets forth the following:

(1) The participants in each episode payment model.

(2) The episodes being tested in each episode payment model.

(3) The methodology for pricing and payment under each episode payment model.

(4) Quality performance standards and quality reporting requirements.(5) Safeguards to ensure preservation of beneficiary choice and beneficiary notification.

§ 512.2 Definitions.

For the purposes of this part, the following definitions are applicable unless otherwise stated:

ACO means an accountable care organization, as defined at § 425.20 of this chapter, that participates in the Shared Savings Program.

ACO participant has the meaning set forth in § 425.20 of this chapter.

ACO provider/supplier has the meaning set forth in § 425.20 of this chapter.

Actual episode payment means the sum of Medicare claims payments for items and services that are included in the episode in accordance with § 512.210(a), excluding the items and services described in § 512.210(b).

Alignment payment means a payment from an EPM collaborator to an EPM participant under a sharing arrangement, for the sole purpose of sharing the EPM participant's responsibility for making repayments to Medicare.

AMI means acute myocardial infarction, an event caused by diminished blood supply to the heart leading to irreversible heart muscle cell damage or death.

AMI care period means a period of AMI care that would meet the requirements to be an AMI model episode in accordance with all provisions in subpart B if the FFS-CR participant were an AMI model participant.

AMI model means the EPM for AMI.

AMI model participant means an EPM participant that is an IPPS hospital (other than those hospitals specifically excepted under § 512.100(b)) with a CCN primary address in one of the geographic areas selected for participation in the AMI model in accordance with § 512.105(b), as of the date of selection or any time thereafter during any performance year.

Anchor hospitalization means a hospitalization that initiates an EPM episode and has no subsequent inpatient-to-inpatient transfer chained anchor hospitalization.

Anchor hospitalization portion means the part of an EPM episode that occurs during the anchor or chained anchor hospitalization.

Anchor MS-DRG means the MS-DRG assigned to the first hospitalization discharge, which initiates an EPM episode.

Applicable discount factor means the discount percentage established by the EPM participant's quality category as determined in § 512.315, that is applied to the episode benchmark price for purposes of determining an EPM participant's Medicare repayment in performance years 2 (DR) and 3.

BPCI stands for the Bundled Payment for Care Improvement initiative.

CABG means coronary artery bypass graft, a surgical procedure that diverts the flow of blood around a section of a blocked or partially blocked artery in the heart, creating a new pathway that improves blood flow to heart muscle.

CABG care period means a period of CABG care that would meet the requirements to be a CABG model episode in accordance with all provisions in subpart B if the FFS-CR participant were a CABG model participant.

CABG model means the EPM for CABG.

CABG model participant means an EPM participant that is an IPPS hospital (other than those hospitals specifically excepted under § 512.100(b)) with a CCN primary address in one of the geographic areas selected for participation in the CABG model in accordance with § 512.105(b), as of the date of selection or any time thereafter during any performance year.

CAH means a critical access hospital designated under subpart F of part 485 of this chapter.

CCN stands for CMS certification number.

CEC stands for Comprehensive ESRD Care Initiative.

CEHRT means certified electronic health record technology that meet the requirements of 45 CFR 170.102.

Chained anchor hospitalization means an anchor hospitalization that initiates an AMI model episode and has at least one subsequent inpatient-to-inpatient transfer.

Collaboration agent means an individual or entity that is not an EPM collaborator and that is either of the following:

(1) A PGP member that has entered into a distribution arrangement with the same PGP in which he or she is an owner or employee.

(2) An ACO participant or ACO provider/supplier that has entered into a distribution arrangement with the same ACO in which it is participating.

Core-based statistical area (CBSA) means a statistical geographic entity consisting of the county or counties associated with at least one core (urbanized area or urban cluster) of at least 10,000 population, plus adjacent counties having a high degree of social and economic integration with the core as measured through commuting ties with the counties containing the core.

CR means cardiac rehabilitation as defined in § 410.49(a) of this chapter, a physician-supervised program that furnishes physician prescribed exercise, cardiac risk factor modification, psychosocial assessment, and outcomes assessment.

CR amount means the dollar amount determined by the number of CR/ICR services paid by Medicare to any provider or supplier for a beneficiary in an AMI or CABG model episode or AMI care period or CABG care period.

CR incentive payment means a payment made by CMS to an EPM-CR participant or FFS-CR participant for CR/ICR service use that is the sum of the CR amounts as determined in accordance with § 512.710.

CR incentive payment model means the model testing CR incentive payments for CR/ICR service use made in accordance with subpart H.

CR participant means all EPM-CR participants and FFS-CR participants.

CR performance year means one of the years in which the CR incentive payment model is being tested. Performance years for the CR incentive payment model correlate to calendar years with the exception of performance year 1, which is July 1, 2017 through December 31, 2017.

CR service count means the number of CR/ICR services paid by Medicare to any provider or supplier for a beneficiary in an AMI or CABG model episode or AMI care period or CABG care period.

Distribution arrangement means a financial arrangement between an EPM collaborator that is an ACO or PGP and a collaboration agent for the sole purpose of distributing some or all of a gainsharing payment received by the ACO or PGP.

Distribution payment means a payment from an EPM collaborator that is an ACO or PGP to a collaboration agent, under a distribution arrangement, composed only of gainsharing payments.

DME stands for durable medical equipment.

Downstream collaboration agent means an individual who is not an EPM collaborator or a collaboration agent and who is a PGP member that has entered into a downstream distribution arrangement with the same PGP in which he or she is an owner or employee, and where that PGP is a collaboration agent.

Downstream distribution arrangement means a financial arrangement between a collaboration agent that is both a PGP and an ACO participant and a downstream collaboration agent for the sole purpose of distributing some or all of a distribution payment received by the PGP.

Downstream distribution payment means a payment from a collaboration agent that is both a PGP and an ACO participant to a downstream collaboration agent, under a downstream distribution arrangement, composed only of distribution payments.

Effective discount factor means the discount factor established by the EPM participant's quality category as determined in § 512.315, that is applied to the episode benchmark price to calculate the quality-adjusted target price.

Episode attribution means the process of assigning financial responsibility for an EPM episode to an EPM participant.

Episode benchmark price means a dollar amount assigned to EPM episodes based on historical episode data (3 years of historical Medicare payment data grouped into EPM episodes according to the EPM episode definitions as discussed in § 512.300(b)) prior to the application of the effective discount factor, as described in § 512.300(d).

Episode payment model (EPM) means the AMI model, CABG model, SHFFT model, or another model with payment made on an episode basis in accordance with this part. For each section of regulations, a single model applies when reading the entire section.

EPM activities means activities related to promoting accountability for the quality, cost, and overall care for EPM beneficiaries, including managing and coordinating care; encouraging investment in infrastructure, enabling technologies, and redesigned care processes for high quality and efficient service delivery; the provision of items and services during an EPM episode in a manner that reduces costs and improves quality; or carrying out any other obligation or duty under the EPM.

EPM beneficiary means a beneficiary who meets the beneficiary inclusion criteria in § 512.230 and who is in an EPM episode.

EPM collaborator means an ACO or one of the following Medicare-enrolled individuals or entities that enters into a sharing arrangement:

(1) SNF.

(2) HHA.

(3) LTCH.

(4) IRF.

(5) Physician.

(6) Nonphysician practitioner.

(7) Provider or supplier of outpatient therapy services.

(8) PGP.

(9) Hospital.

(10) CAH.

EPM composite quality score means a score computed for each EPM participant's level of quality performance and improvement and successful reporting of voluntary data, if applicable, on specified EPM quality measures as described in § 512.315.

EPM-CR participant means an AMI or CABG model participant that is eligible to receive CR incentive payments from CMS in accordance with § 512.710.

EPM episode of care (or Episode) means all Medicare Part A and Part B items and services described in § 512.210(a) (and excluding the items and services described in § 512.210(b)) that are furnished to an EPM beneficiary described in § 512.240 that begins with the beneficiary's admission to an anchor hospitalization, with the day of discharge itself from the anchor hospitalization or from the final hospital in a chained anchor hospitalization being counted as the first day of the 90-day post-discharge period.

EPM participant means a Medicare provider or supplier that is eligible to receive payment from CMS on an episode basis for services rendered to EPM beneficiaries.

ESRD stands for end-stage renal disease.

FFS-CR beneficiary means a beneficiary attributed to an FFS-CR participant and receiving care during an AMI care period or CABG care period.

FFS-CR participant means a hospital that is not an EPM participant and that is eligible to receive CR incentive payments from CMS in accordance with § 512.710.

Gainsharing payment means a payment from an EPM participant to an EPM collaborator, under a sharing arrangement, composed of only reconciliation payments or internal cost savings or both.

HCAHPS stands for Hospital Consumer Assessment of Healthcare Providers and Systems.

HCPCS stands for CMS Common Procedure Coding System.

Health Insurance Claim Number (HICN) means the unique number assigned by the Social Security Administration to an individual for the purpose of identifying that individual as a Medicare beneficiary.

HHA means a Medicare-enrolled home health agency.

Historical episode payment means the expenditures for episodes that occurred during the historical period used to determine the EPM episode benchmark price.

Hospital means a provider subject to the prospective payment system specified in § 412.1(a)(1) of this chapter.

ICD-CM stands for International Classification of Diseases, Clinical Modification

ICR means intensive cardiac rehabilitation as defined in § 410.49(a) of this chapter, a physician-supervised program that furnishes cardiac rehabilitation and has shown, in peer-reviewed published research, that it improves patients' cardiovascular disease through specific outcome measurements described in § 410.49(c) of this chapter.

Inpatient prospective payment systems (IPPS) means the payment systems for subsection (d) hospitals as defined in section 1886(d)(1)(B) of the Act.

Internal cost savings means the measurable, actual, and verifiable cost savings realized by the EPM participant resulting from care redesign undertaken by such participant in connection with providing items and services to beneficiaries within specific EPM episodes. Internal cost savings does not include savings realized by any individual or entity that is not the EPM participant.

Intracardiac procedures means procedures performed within the heart chambers, rather than within coronary artery blood vessels, through percutaneous access to blood vessels. These procedures are indicated for the treatment of congenital cardiac malformations, cardiac valve disease, and cardiac arrhythmias.

IPF stands for inpatient psychiatric facility.

IRF stands for inpatient rehabilitation facility.

LTCH stands for long-term care hospital.

MDH means a Medicare-dependent, small rural hospital that meets the classification criteria specified under § 412.108 of this chapter.

Member of the PGP or PGP member means a physician, nonphysician practitioner, or therapist who is an owner or employee of a PGP and who has reassigned to the PGP his or her right to receive Medicare payment.

MSA stands for metropolitan statistical area and means a CBSA associated with at least one urbanized area that has a population of at least 50,000.

MS-DRG stands for Medicare severity diagnosis-related group, which is the classification of inpatient hospital discharges updated in accordance with § 412.10 of this chapter.

Nonphysician practitioner means (except for purposes of subpart G of this part) one of the following:

(1) A physician assistant who satisfies the qualifications set forth at § 410.74(a)(2)(i) and (ii) of this chapter.

(2) A nurse practitioner who satisfies the qualifications set forth at § 410.75(b) of this chapter.

(3) A clinical nurse specialist who satisfies the qualifications set forth at § 410.76(b) of this chapter.

(4) A certified registered nurse anesthetist (as defined at § 410.69(b) of this chapter).

(5) A clinical social worker (as defined at § 410.73(a) of this chapter).

(6) A registered dietician or nutrition professional (as defined at § 410.134 of this chapter).

NPI stands for National Provider Identifier.

NPRA means the net payment reconciliation amount determined in accordance with § 512.305(c).

OIG stands for the Department of Health and Human Services Office of Inspector General.

PAC stands for post-acute care.

PBPM stands for per-beneficiary-per-month.

PCI means percutaneous coronary intervention, a procedure used to open blocked arteries in the heart through percutaneous placement of a small wire mesh tube that keeps the artery open and minimizes the risk of it later narrowing.

Performance year means one of the years in which the EPM is being tested. Performance years for the EPMs correlate to calendar years with the exception of performance year 1, which is July 1, 2017 through December 31, 2017.

Performance year 2 (DR) means the second, third, and fourth quarters of performance year 2, which is from April 1, 2018 to December 31, 2018, and during which an EPM participant assumes downside risk and would have Medicare repayment responsibility under the models.

Performance year 2 (NDR) means the first quarter of performance year 2, which is from January 1, 2018 to March 31, 2018, and during which an EPM participant assumes no downside risk and therefore would have no Medicare repayment responsibility under the models.

PFS means the Medicare Physician Fee Schedule authorized under section 1848 of the Social Security Act.

PGP stands for physician group practice.

Physician has the meaning set forth in section 1861(r) of the Act.

Post-anchor hospitalization portion means the part of an episode that occurs after the anchor or chained anchor hospitalization.

Post-episode spending amount means the sum of Medicare Parts A and B payments for items and services that are furnished to a beneficiary within 30 days after the end of the beneficiary's EPM episode.

Price MS-DRG means the MS-DRG that applies when establishing the EPM benchmark episode price that applies to an EPM episode. For episodes without a chained anchor

hospitalization, the price MS-DRG is the anchor MS-DRG. For episodes with a chained anchor admission, the price MS-DRG is assigned based on § 512.300(c)(7).

Provider of outpatient therapy services means a provider or supplier furnishing one or more of the following:

(1) Outpatient physical therapy services as defined in § 410.60 of this chapter.

(2) Outpatient occupational therapy services as defined in § 410.59 of this chapter.

(3) Outpatient speech-language pathology services as defined in § 410.62 of this chapter.

Quality-adjusted target price means the dollar amount assigned to EPM episodes as the result of reducing the episode benchmark price by the EPM participant's effective discount factor based on the EPM participant's quality category, as described in § 512.315(b)(5), (c)(5) or (d)(5).

Quality improvement points are points that CMS adds to an EPM participant's EPM composite quality score for a measure if the EPM participant's performance improves from the previous performance year according to the relevant EPM measure improvement methodology.

Quality performance points are points that CMS adds to an EPM participant's EPM composite quality score for a measure based on the performance percentile scale and for successful submission of voluntary data if applicable to the EPM.

Reconciliation payment means a payment made by CMS to an EPM participant as determined in accordance with § 512.305(d).

Repayment amount means the amount owed by an EPM participant to CMS, as reflected on a reconciliation report.

RRC means a rural referral center that satisfies the criteria set forth in § 412.96 of this chapter.

Rural hospital means an IPPS hospital that meets one of the following definitions:

(1) Is located in a rural area as defined under § 412.64 of this chapter.

(2) Is located in a rural census tract defined under § 412.103(a)(1) of this chapter.

(3) Has reclassified as a rural hospital under § 412.103 of this chapter.

SCH means a sole community hospital that meets the classification criteria specified in § 412.92 of this chapter.

Sharing arrangement means a financial arrangement between an EPM participant and an EPM collaborator for the sole purpose of making gainsharing payments or alignment payments under the EPM.

SHFFT stands for surgical hip/femur fracture treatment and means surgical treatment for hip and femur fractures, other than hip replacements, consisting primarily of hip fixation procedures, with or without reduction of the fracture, as well as open and closed surgical approaches.

SHFFT model means the EPM for SHFFT.

SHFFT model participant means an EPM participant that is an IPPS hospital (other than those hospitals specifically excepted under § 512.100(b)) with a CCN primary address in one of the geographic areas selected for participation in a SHFFT model in accordance with § 512.105(a), as of the date of selection or any time thereafter during any performance year.

SNF stands for skilled nursing facility.

THA/TKA stands for total hip arthroplasty/total knee arthroplasty.

Therapist means one of the following as defined at § 484.4 of this chapter:

(1) Physical therapist.

(2) Occupational therapist.

(3) Speech-language pathologist.

TIN stands for taxpayer identification number.

Two-sided risk arrangement means an arrangement in which the ACO may share savings with the Medicare program, if it meets the requirements for doing so, and is also liable for sharing losses incurred under the program or model, if it meets the criteria under which sharing losses occurs.

Subpart B—Episode Payment Model Participants

§ 512.100 EPM episodes being tested.

(a) Initiation of an episode. An episode is initiated when an EPM participant admits a Medicare beneficiary described in § 512.230 for an anchor hospitalization.

(b) Hospital exclusions. (1) A hospital is excluded from participating in EPMs for EPM anchor MS-DRGs that are included in BPCI episodes in which the hospital currently participates.

(2) These exclusions cease to apply as of the date that the hospital no longer meets the conditions specified in this paragraph (b) or September 30, 2018, whichever date is sooner.

(c) Types of EPM episodes. An EPM episode is initiated by a beneficiary's admission to an EPM participant for an anchor hospitalization that is paid under an EPM anchor MS-DRG and, in the case of the AMI model, with an AMI ICD-10-CM diagnosis code if the admission is under a PCI MS-DRG. The EPM anchor MS-DRGs and ICD-10-CM diagnosis codes for the EPM episodes are as follows:

(1) Acute myocardial infarction (AMI). (i) Discharge under an AMI MS-DRG (MS-DRGs 280 to 282); or

(ii) Discharge under a PCI MS-DRG (MS-DRGs 246 to 251) with an ICD-10-CM diagnosis code of AMI on the claim for the anchor hospitalization in the principal or secondary diagnosis code position.

(2) Coronary artery bypass graft (CABG). Discharge under a CABG MS-DRG (MS-DRGs 231 to 236).

(3) Surgical hip/femur fracture treatment (SHFFT). Discharge under a SHFFT MS-DRG (MS-DRG 480 to 482).

(d) Identifying AMI historical episodes and EPM episodes with AMI ICD-CM diagnosis codes. CMS develops a list of AMI ICD-9-CM and ICD-10-CM diagnosis codes that identify the initiation of historical episodes or initiate AMI model episodes when reported in the principal or secondary diagnosis code position on the inpatient hospital claim for a historical hospitalization or the anchor hospitalization discharged under PCI MS-DRGs (MS-DRGs 246 to 251). The list of ICD-9-CM and ICD-10-CM diagnosis codes representing AMI is posted on the CMS Web site.

(1) On an annual basis, or more frequently as needed, CMS updates the list of ICD-10-CM diagnosis codes representing AMI to reflect coding changes or other issues brought to CMS's attention.

(2) CMS applies the following standard when revising the list of ICD-10-CM diagnosis codes representing AMI: The ICD-10-CM diagnosis code is sufficiently specific that it represents an AMI.

(3) CMS posts the following to the CMS Web site:

(i) Potential AMI ICD-10-CM diagnosis codes for public comment; and

(ii) A final AMI ICD-10-CM diagnosis code list after consideration of public comment.

(4) CMS excludes AMI historical episodes with PCI MS-DRGs and inpatient claims that contain intracardiac ICD-9-CM procedure codes. CMS excludes historical AMI model episodes discharged under PCI MS-DRGs with an AMI ICD-9-CM diagnosis code in the principal or secondary diagnosis code position on the inpatient hospital claim from the AMI historical episodes that set episode benchmark prices if there is an intracardiac ICD-9-CM procedure code in any procedure code field on the inpatient hospital claim. The intracardiac ICD-9-CM procedure codes are as follows:

(i) 35.52 (Repair of atrial septal defect with prosthesis, closed technique).

(ii) 35.96 (Percutaneous balloon valvuloplasty).

(iii) 35.97 (Percutaneous mitral valve repair with implant).

(iv) 37.26 (Catheter based invasive electrophysiologic testing).

(v) 37.27 (Cardiac mapping).

(vi) 37.34 (Excision or destruction of other lesion or tissue of heart, endovascular approach).

(vii) 37.36 (Excision, destruction, or exclusion of left atrial appendage).

(viii) 37.90 (Insertion of left atrial appendage device).

§ 512.105 Geographic areas.

(a) The SHFFT model shall be implemented in the same geographic areas as the CJR model as described under 42 CFR part 510.105.

(b) The geographic areas for inclusion in the CABG and AMI models will be obtained using a random sampling of certain MSAs in the United States. All counties within each of the selected MSAs are selected for inclusion in the AMI and CABG models. CMS excludes MSAs

that met the following criteria between January 1, 2014 and December 31, 2014 from the possibility of being selected geographic areas. MSAs are excluded if they:

(1) Had fewer than 75 AMI episodes;

(2) Had fewer than 75 AMI episodes that were not attributable to BPCI Model 2 or 4 AMI, CABG or PCI episodes; or

(3) Had more than 50 percent of otherwise qualifying (BPCI or non BPCI) episodes attributable to a BPCI Model 2 or 4 AMI, CABG or PCI episodes.

(c) In all geographic areas where the AMI, CABG, or SHFFT models are being implemented, the accountable financial entity shall be an acute care IPPS hospital.

§ 512.110 Access to records and retention.

EPM participants, EPM collaborators, collaboration agents, downstream collaboration agents, and any other individuals or entities performing EPM activities must:

(a) Allow the Government, including CMS, OIG, HHS and the Comptroller General or their designees, scheduled and unscheduled access to all books, contracts, records, documents, and other evidence (including data related to utilization and payments, quality of care criteria, billings, lists of EPM collaborators, sharing arrangements, distribution arrangements, downstream distribution arrangements, and the documentation required under §§ 512.500(d) and 512.525(d)) sufficient to enable the audit, evaluation, inspection, or investigation of the following:

(1) The individual's or entity's compliance with EPM requirements and, if applicable, the individual's or entity's compliance with CR incentive payment model requirements.

(2) The calculation, distribution, receipt, or recoupment of gainsharing payments, alignment payments, distribution payments, and downstream distribution payments.

(3) The obligation to repay any reconciliation payments or CR incentive payments, if applicable, owed to CMS.

(4) The quality of the services furnished to an EPM beneficiary during an EPM episode.

(5) The sufficiency of EPM beneficiary notifications.

(6) The accuracy of the EPM participant's submissions under CEHRT use requirements.

(b) Maintain all such books, contracts, records, documents, and other evidence for a period of 10 years from the last day of the EPM participant's participation in the EPM or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

(1) CMS determines a particular record or group of records should be retained for a longer period and notifies the EPM participant at least 30 calendar days before the disposition date; or

(2) There has been a dispute or allegation of fraud or similar fault against the EPM participant, EPM collaborator, collaboration agent, downstream collaboration agent, or any other individual or entity performing EPM activities in which case the records must be maintained for 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

§ 512.120 EPM participant CEHRT track requirements.

(a) EPM CEHRT use. For performance year 2 (DR) and performance years 3-5, EPM participants choose either of the following:

(1) CEHRT use. EPM participants attest in a form and manner required by CMS to their use of CEHRT as defined in section 414.1305 to document and communicate clinical care with patients and other health professionals.

(2) No CEHRT use. EPM participants do not attest in a form and manner required by CMS to their use of CEHRT as defined in §414.1305 to document and communicate clinical care with patients and other health professionals.

(b) Clinician financial arrangements list. Each EPM participant that chooses CEHRT use as provided in paragraph (a)(1) of this section must submit to CMS a clinician financial arrangements list in a form and manner specified by CMS on a no more than quarterly basis. The list must include the following information on individuals for the period of the EPM performance year specified by CMS:

(1) EPM collaborators. For each EPM collaborator who is a physician, nonphysician practitioner, or provider of outpatient therapy services during the period of the EPM performance year specified by CMS:

(i) The name, TIN, and NPI of the EPM collaborator.

(ii) The start date and, if applicable, end date, for the sharing arrangement between the EPM participant and the EPM collaborator.

(2) Collaboration agents. For each collaboration agent who is a physician or nonphysician practitioner of a PGP that is an EPM collaborator during the period of the EPM performance year specified by CMS:

(i) The TIN of the PGP that is the EPM collaborator, and the name and NPI of the physician or nonphysician practitioner.

(ii) The start date and, if applicable, end date, for the distribution arrangement between the EPM collaborator that is a PGP and the physician or nonphysician practitioner who is a PGP member.

(3) Downstream collaboration agents. For each downstream collaboration agent who is a physician or nonphysician practitioner member of a PGP that is also an ACO participant in an ACO that is an EPM collaborator during the period of the EPM performance year specified by CMS:

(i) The TIN of the PGP that is the ACO participant, and the name and NPI of the physician or nonphysician practitioner.

(ii) The start date and, if applicable, end date, for the downstream distribution arrangement between the collaboration agent that is both PGP and an ACO participant and the physician or nonphysician practitioner who is a PGP member.

(4) Attestation to no individuals. If there are no individuals that meet the requirements to be reported, as specified in paragraphs (b)(1) through (3) of this section, the EPM participant must attest in a form and manner required by CMS that there are no individuals to report on the clinician financial arrangements list.

(c) Documentation requirements. (1) Each EPM participant that chooses CEHRT use as provided in paragraph (a)(1) of this section must maintain documentation of their attestation to CEHRT use and clinician financial arrangements lists.

(2) The EPM participant must retain and provide access to the required documentation in accordance with § 512.110.

Subpart C—Scope of Episodes

§ 512.200 Time periods for EPM episodes.

All AMI, CABG, and SHFFT episodes begin on or after July 1, 2017 and end on or before December 31, 2021.

§ 512.210 Included and excluded services.

(a) Included services for an EPM. All Medicare Parts A and B items and services are included in the EPM episode, except as specified in paragraph (b) of this section. These services include, but are not limited to, the following:

(1) Physicians' services.

(2) Inpatient hospital services.

(3) IPF services.

(4) LTCH services.

(5) IRF services.

(6) SNF services.

(7) HHA services.

(8) Hospital outpatient services.

(9) Independent outpatient therapy services.

(10) Clinical laboratory services.

(11) DME.

(12) Part B drugs and biologicals.

(13) Hospice.

(14) PBPM payments under models tested under section 1115A of the Act.

(b) Excluded services. The following items, services, and payments are excluded from the EPM episode:

(1) Hemophilia clotting factors provided in accordance with § 412.115 of this chapter.

(2) New technology add-on payments for medical devices as defined in part 412, subpart F, of this chapter.

(3) Transitional pass-through payments for medical devices as defined in § 419.66 of this chapter.

(4) Items and services unrelated to the anchor MS-DRG that initiates the EPM episode, or price anchor MS-DRG as applicable, as determined by CMS. Excluded services include, but are not limited to the following:

(i) Inpatient hospital admissions for MS-DRGs that group to the following categories of diagnoses:

(A) Oncology.

(B) Trauma medical.

(C) Chronic disease surgical unrelated to a condition likely to have been affected by care during the EPM episode, such as prostatectomy.

(D) Acute disease surgical unrelated to a condition resulting from or likely to have been affected by care during the EPM episode, such as appendectomy.

(ii) Medicare Part B services, as identified by the principal ICD-CM diagnosis code on the claim that groups to the following categories of diagnoses:

(A) Acute disease diagnoses unrelated to a condition resulting from or likely to have been affected care during the EPM episode, such as severe head injury.

(B) Certain chronic disease diagnoses, as specified by CMS on a diagnosis-by-diagnosis basis depending on whether the condition was likely to have been affected by care during the EPM episode or whether substantial services were likely to be provided for the chronic condition during the EPM episode.

(iii) Certain PBPM payments under models tested under section 1115A of the Act. PBPM model payments that CMS determines to be primarily used for care coordination or care

management services for clinical conditions in excluded categories of diagnoses for an EPM, as described in paragraph (b)(4) of this section.

(iv) All PBPM model payments funded from CMS' Innovation Center appropriation.

(c) Updating the lists of excluded services for EPMs. (1) The EPM lists that are based on anchor MS-DRG, or price MS-DRG, as applicable, of excluded MS-DRGs, ICD-9-CM and ICD-10-CM diagnosis codes, and CMS model PBPM payments are posted on the CMS Web site.

(2) On an annual basis, or more frequently as needed, CMS updates the EPM lists of excluded services to reflect annual coding changes or other issues brought to CMS' attention.

(3) CMS applies the following standards when revising the EPM lists of excluded services for reasons other than to reflect annual coding changes:

(i) Items or services that are directly related to the EPM episode or the quality or safety of the EPM episode care would be included in the EPM episode.

(ii) Items or services for chronic conditions that may be affected by the EPM episode care would be related and included in the EPM episode.

(iii) Items and services for chronic conditions that are generally not affected by the EPM episode care would be excluded from the EPM episode.

(iv) Items and services for acute clinical conditions not arising from existing, EPM episode-related chronic clinical conditions or complications of EPM episode care would be excluded from the EPM episode.

(v) PBPM payments under CMS models determined to be primarily used for care coordination or care management services for clinical conditions in EPM excluded categories of diagnoses, as described in paragraph (b)(4)(iii) of this section would be excluded from the EPM episode.

(4) CMS posts the following on the CMS Web site:

(i) Potential revisions to the EPM exclusion lists to allow for public comment; and

(ii) Updated EPM exclusion lists after consideration of public comment.

§ 512.230 Beneficiary inclusion criteria.

EPM episode care is furnished to beneficiaries who meet all of the following criteria upon admission to the anchor hospitalization:

(a) Enrolled in Medicare Part A and Part B.

(b) Eligibility for Medicare is not based on end-stage renal disease, as described in § 406.13 of this chapter.

(c) Not enrolled in any managed care plan (for example, Medicare Advantage, health care prepayment plans, or cost-based health maintenance organizations).

(d) Not covered under a United Mine Workers of America health care plan.

(e) Have Medicare as their primary payer pursuant to the requirements in 42 CFR 411.20, et seq.

(f) Not aligned to an ACO in the Next Generation ACO model or an ACO in a track of the Comprehensive ESRD Care Initiative incorporating downside risk for financial losses.

(g) Not under the care of an attending or operating physician, as designated on the inpatient hospital claim, who is a member of a physician group practice that initiates BPCI Model 2 episodes at the EPM participant for the MS-DRG that would be the anchor MS-DRG under the EPM.

(h) Not already in any BPCI model episode.

(i) Not already in an AMI; SHFFT; CABG; or CJR model episode with an episode definition that does not exclude the MS-DRG that would be the anchor MS-DRG under the EPM.

§ 512.240 Determination of the EPM episode.

(a) AMI Model—(1) General. The AMI model episode begins with the admission of a Medicare beneficiary as described in § 512.230 to an AMI model participant for an anchor hospitalization.

(i) If there is no chained anchor hospitalization, then the AMI model episode ends on the 90th day after the date of discharge, with the day of discharge itself being counted as the first day in the 90-day post-discharge period.

(ii) If there is a chained anchor hospitalization, then the AMI model episode ends on the 90th day after the date of discharge from the final hospitalization in the chained anchor hospitalization, with the day of discharge itself being counted as the first day in the 90-day post-discharge period.

(2) AMI model episode attribution in chained anchor hospitalizations. AMI model episodes that include a chained anchor hospitalization are attributed to the AMI model participant that initiated the AMI model episode. The methodology for assigning the price MS-DRG in these circumstances is specified in § 512.300(c)(7).

(3) Cancellation of an AMI model episode. The AMI model episode is canceled and is not included in the determination of NPRA as specified in § 512.305 if the beneficiary does any of the following during the episode:

(i) Ceases to meet any criterion listed in § 512.230(a) through (f).

(ii) Dies during the anchor hospitalization.

(iii) Is discharged from the final hospital in a chained anchor hospitalization under an MS-DRG that is not an AMI MS-DRG (MS-DRGs 280 to 282), PCI MS-DRG (MS-DRGs 246 to 251), or CABG MS-DRG (MS-DRGs 231 to 236), regardless of whether the final transfer hospital is an AMI or CABG model participant.

(iv) Initiates any BPCI model episode.

(b) CABG Model—(1) General. The CABG model episode begins with the admission of a Medicare beneficiary as described in § 512.230 to a CABG model participant for an anchor hospitalization and ends on the 90th day after the date of discharge, with the day of discharge itself being counted as the first day in the 90-day post-discharge period.

(2) Cancellation of a CABG model episode. The CABG model episode is canceled and is not included in the determination of NPRA as specified in § 512.305 if the beneficiary does any of the following during the episode:

(i) Ceases to meet any criterion listed in § 512.230(a) through (f).

(ii) Dies during the anchor hospitalization.

(iii) Initiates any BPCI model episode.

(c) SHFFT Model—(1) General. The SHFFT model episode begins with the admission of a Medicare beneficiary as described in § 512.230 to a SHFFT model participant for an anchor hospitalization and ends on the 90th day after the date of discharge, with the day of discharge itself being counted as the first day in the 90-day post-discharge period.

(2) Cancellation of a SHFFT model episode. The SHFFT model episode is canceled and is not included in the determination of NPRA as specified in § 512.305 if the beneficiary does any of the following during the episode:

(i) Ceases to meet any criterion listed in § 512.230 (a) through (f).

(ii) Dies during the anchor hospitalization.

(iii) Initiates any BPCI model episode.

Subpart D—Pricing and Payment

§ 512.300 Determination of episode quality-adjusted target prices and actual episode payments.

(a) General. CMS establishes episode quality-adjusted target prices and calculates actual episode payments for EPM participants for each performance year of the EPMs as specified in this section.

(b) Calculating episode quality-adjusted target prices. Episode quality-adjusted target prices and actual episode payments are calculated for episodes according to the following:

(1) For episodes involving AMI, MS-DRGs

(i) 280 (Acute myocardial infarction, discharged alive with MCC)

(ii) 281 (Acute myocardial infarction, discharged alive with CC)

(iii) 282 (Acute myocardial infarction, discharged alive without CC/MCC)

(iv) 246 (Perc cardiovasc proc with drug-eluting stent with MCC or 4+ vessels/stents)

(v) 247 (Perc cardiovasc proc with drug-eluting stent without MCC)

(vi) 248 (Perc cardiovasc proc with non-drug-eluting stent with MCC or 4+ vessels/stents)

(vii) 249 (Perc cardiovasc proc with non-drug-eluting stent without MCC)

(viii) 250 (Perc cardiovasc proc without coronary artery stent with MCC)

(ix) 251 (Perc cardiovasc proc without coronary artery stent without MCC).

(2) For episodes involving CABG, MS-DRGs

(i) 231 (Coronary bypass with PTCA with MCC)

(ii) 232 (Coronary bypass with PTCA without MCC)

(iii) 233 (Coronary bypass with cardiac cath with MCC)

(iv) 234 (Coronary bypass with cardiac cath without MCC)

(v) 235 (Coronary bypass without cardiac cath with MCC)

(vi) 236 (Coronary bypass without cardiac cath without MCC)

(3) For episodes involving SHFFT, MS-DRGs

(i) 480 (Hip and femur procedures except major joint with MCC)

(ii) 481 (Hip and femur procedures except major joint with CC)

(iii) 482 (Hip and femur procedures except major joint without CC or MCC)

(c) Calculating quality-adjusted target prices. CMS calculates quality adjusted target prices as specified in § 512.300(c)(1) through (13).

(1) Calculation of the historical expenditures. CMS calculates historical expenditure calculations based on the following calendar years:

(i) Episodes beginning in 2013 through 2015 for performance years 1 and 2.

(ii) Episodes beginning in 2015 through 2017 for performance years 3 and 4.

(iii) Episodes beginning in 2017 through 2019 for performance year 5.

(2) Calculation of the quality-adjusted target prices. CMS calculates quality-adjusted target prices based on a blend of each EPM-participant hospital-specific and regional historical episode expenditures.

(i) The region corresponds to the U.S. Census Division associated with the primary address of the CCN of the EPM participant and the regional component is based on episodes occurring at all acute care hospitals in said region, except as follows.

(ii) In cases where an MSA selected for participation in an EPM spans more than one U.S. Census Division, the entire MSA is grouped into the U.S. Census Division where the largest city by population in the MSA is located for quality-adjusted target price and episode payment calculations.

(3) Calculation of the quality-adjusted target price blend. The quality-adjusted target price blend consists of the following:

(i) Two-thirds of the EPM participant's own historical episode payments and one-third of the regional historical episode payments for performance years 1 and 2.

(ii) One-third of the EPM participant's own historical episode payments and two-thirds of the regional historical episode payments for performance year 3.

(iii) Regional historical episode payments for performance years 4 and 5.

(4) Exception for low-volume hospitals. (i) For the SHFFT model, quality-adjusted target prices for participants with fewer than 50 SHFFT model episodes in total across the 3 historical years of data used to calculate the quality-adjusted target price are based on 100 percent regional historical episode payments.

(ii) For the AMI model, quality-adjusted target prices for price MS-DRGs 280-282 for participants with fewer than 75 AMI model episodes with price MS-DRGs 280-282 in total across the 3 historical years of data used to calculate the quality-adjusted target price are based on 100 percent regional historical episode payments.

(iii) For the AMI model, quality-adjusted target prices for price MS-DRGs 246-251 for participants with fewer than 125 AMI model episodes with price MS-DRGs 246-251 in total across the 3 historical years of data used to calculate the quality-adjusted target price are based on 100 percent regional historical episode payments.

(iv) For the CABG model, quality-adjusted target prices for participants with fewer than 50 CABG model episodes in total across the 3 historical years of data used to calculate the quality-adjusted target price are based on 100 percent regional historical episode payments.

(5) Exception for recently merged or split hospitals. EPM-participant hospital-specific historical episode payments for EPM participants that have undergone a merger, consolidation, spin off or other reorganization that results in a new hospital entity without 3 full years of historical claims data are determined using the historical episode payments attributed to their predecessor(s).

(6) Episodes that straddle performance years or payment updates. Where an episode straddles performance years or payment updates, the quality-adjusted target price is based on the quality-adjusted target price for the type of episode as of the date of admission for the anchor hospitalization.

(7) Adjustments for certain hospitalizations under the AMI and CABG models—(i) Adjustments for chained anchor hospitalizations that initiate AMI model episodes with any of AMI MS-DRGs 280-282 or PCI MS-DRGs 246-251. The episode benchmark price for a chained anchor hospitalization is assigned based on the price MS-DRG designated in accordance with a hierarchy as follows:

(A) If the chained anchor hospitalization does not include CABG MS-DRGs 231-236 within the chain, the price MS-DRG is the AMI or PCI MS-DRG with the highest IPPS weight, subject to possible adjustment for readmission to a CABG MS-DRG as specified in paragraph (c)(7)(iii) of this section.

(B) If the chained anchor hospitalization includes any of CABG MS-DRGs 231-236, the price MS-DRG is the CABG MS-DRG with the highest IPPS weight with the episode benchmark price determined in accordance with paragraph (c)(7)(ii) of this section.

(C) If the final discharge for a chained anchor hospitalization includes an MS-DRG other than AMI MS-DRG 280-282, PCI MS-DRG 246-251, or CABG MS-DRG 231-236, the episode is canceled for purposes of the AMI model and services furnished prior to and following the episode cancellation would continue to be paid by Medicare as usual.

(ii) Adjustments for CABG model episodes with price MS-DRGs 231-236. The episode benchmark price for an episode with CABG price MS-DRG 231-236 is set based on the sum of expenditures during the anchor hospitalization portion and post-anchor hospitalization portion of the episode as follows:

(A) The anchor hospitalization portion of the episode benchmark price is set based on the CABG price MS-DRG at discharge.

(B) The post-anchor hospitalization portion of the episode benchmark price is set separately for episodes:

(1) With AMI ICD-CM diagnosis code on the anchor inpatient claim and CABG price MS-DRG with major complication or comorbidity (231, 233, or 235).

(2) With AMI ICD-CM diagnosis code on the anchor inpatient claim and CABG price MS-DRG without major complication or comorbidity (232, 234, or 236).

(3) Without AMI ICD-CM diagnosis code on the anchor inpatient claim and CABG price MS-DRG with major complication or comorbidity (231, 233, or 235).

(4) Without AMI ICD-CM diagnosis code on the anchor inpatient claim and CABG price MS-DRG without major complication or comorbidity (232, 234, or 236).

(iii) Adjustments for Certain AMI Model Episodes with CABG Readmissions. The episode benchmark price for an AMI model episode with AMI price MS-DRG 280-282 or PCI price MS-DRG 246-251 with a readmission to any of CABG price MS-DRGs 231-236 is the sum of the anchor hospitalization portion of the CABG episode benchmark price corresponding to the MS-DRG of the CABG readmission and the episode benchmark price for the corresponding price MS-DRG that would be applied to the episode if it did not include a CABG readmission.

(8) Inclusion of reconciliation payments and Medicare repayments. CMS will include certain reconciliation payments and Medicare repayments when updating quality adjusted target prices.

(i) Inclusion of reconciliation payments and Medicare repayments in BPCI initiative. Reconciliation payments and Medicare repayments under § 512.305(d)(2) and (3) and those from episodes in the BPCI initiative are included when updating quality-adjusted target prices for performance years 3-5, subject to the adjustment for CABG model episodes in paragraph (c)(8)(ii) of this section.

(ii) Inclusion of reconciliation payments and Medicare repayments in CABG model episodes. When updating prices for CABG episodes, Reconciliation payments and Medicare repayments under § 512.305(d)(2) and § 512.305(d)(3) and from episodes included in the BPCI initiative will be apportioned proportionally to the anchor hospitalization and post-anchor hospitalization portions of historical CABG episodes. The proportions will be based on based on regional average historical episode payments that occurred during the anchor hospitalization portion of CABG model episodes and regional average historical episode payments that occurred

during the post-anchor anchor hospitalization portion of CABG model episodes that were initiated during the three historical years.

(9) Communication of quality-adjusted target prices. CMS communicates quality--adjusted target prices to EPM participants prior to the beginning of the performance period in which they apply.

(10) Applicable time period for updating quality-adjusted target prices. In general quality-adjusted target prices are updated to account for Medicare payment updates no less than 2 times per year, for updated quality-adjusted target prices effective October 1 and January 1, and at other intervals if necessary as determined by CMS.

(i) For CABG model episodes, quality-adjusted target prices are updated by separately updating the anchor hospitalization portion of the episode benchmark price and the post-anchor hospitalization portion of the episode benchmark price and then applying the effective discount factor.

(ii) [Reserved].

(11) Trending of historical expenditure data. CMS trends historical expenditure data by applying separate national trend factors to episode payments in the scenarios described below. A trend factor is calculated for each of the first two years in the historical period based on the ratio of national average episode payments in the third year of the historical period to national average episode payments in each of the first 2 years in the historical period, for the following scenarios:

(i) Separately for each SHFFT price MS-DRG 480-482.

(ii) Separately for each AMI price MS-DRG 280-282 and PCI price MS-DRG 246-251 for AMI model episodes without CABG readmissions.

(iii) For CABG model episodes, separately for the anchor hospitalization portion and post-anchor hospitalization portion as follows:

(A) For the anchor hospitalization portion of CABG model episodes, separately for each CABG price MS-DRG 231-236.

(B) For the post-anchor hospitalization portion of CABG model episodes, separately for episodes:

(1) With AMI ICD-CM diagnosis code on the anchor inpatient claim and CABG price MS-DRG with major complication or comorbidity (231, 233, or 235).

(2) With AMI ICD-CM diagnosis code on the anchor inpatient claim and CABG price MS-DRG without major complication or comorbidity (232, 234, or 236).

(3) Without AMI ICD-CM diagnosis code on the anchor inpatient claim and CABG price MS-DRG with major complication or comorbidity (231, 233, or 235).

(4) Without AMI ICD-CM diagnosis code on the anchor inpatient claim and CABG price MS-DRG without major complication or comorbidity (232, 234, or 236).

(12) Normalizing for wage variation. CMS applies the CMS Price (Payment) Standardization Detailed Methodology to remove wage level differences in calculating EPM-episode benchmark prices and actual EPM-episode payments. CMS reintroduces wage index variations by multiplying the blended and updated historical payments by a wage normalization factor of 0.7 * IPPS wage index + 0.3.

(13) Combining episodes to set stable benchmark and quality-adjusted target prices. For purposes of having sufficient episode volume to set stable EPM episode benchmark and quality-adjusted target prices, where applicable, CMS aggregates EPM episodes and portions of EPM episodes across dimensions that include anchor MS-DRGs, the presence of an AMI ICD-CM

diagnosis code on the anchor inpatient claim, and the presence of a major complication or comorbidity for anchor CABG MS-DRGs.

(i) For each EPM, CMS combines episodes for anchor MS-DRGs adjusted for severity and hospital-specific and region-specific weights both for EPM participants and IPPS hospitals within each region for the purposes of blending EPM-participant hospital-specific components of the episode benchmark price and region-specific components of the episode benchmark price as follows:

(A) For SHFFT model episodes, CMS combines episodes with price MS-DRGs 480-482.

(B) For AMI model episodes with AMI price MS-DRGs in 280-282 or PCI price MS-DRGs 246-251 and without readmissions for CABG MS-DRGs, episodes with AMI price MS-DRGs 280-282 are grouped separately from episodes with PCI price MS-DRGs 246-251.

(C) For CABG model episodes with CABG price MS-DRGs in 231-236, CMS separately groups the anchor hospitalization portion and the post-anchor hospitalization portion.

(1) For the anchor hospitalization portion of CABG model episodes, the anchor hospitalization portion is grouped by the CABG price MS-DRG.

(2) For the post-anchor hospitalization portion of CABG model episodes, the post-anchor hospitalization portion is grouped by episodes:

(i) With AMI ICD-CM diagnosis code on the anchor inpatient claim and price MS-DRG with major complication or comorbidity (231, 233, or 235).

(ii) With AMI ICD-CM diagnosis code on the anchor inpatient claim and price MS-DRG without major complication or comorbidity (232, 234, or 236).

(iii) Without AMI ICD-CM diagnosis code on the anchor inpatient claim and price MS-DRG with major complication or comorbidity (231, 233, or 235).

(iv) Without AMI ICD-CM diagnosis code on the anchor inpatient claim and price MS-DRG without major complication or comorbidity (232, 234, or 236).

(ii) After blending EPM-participant hospital-specific and regional-specific components of the combined episodes, CMS separates episodes to calculate episode benchmark prices according to the episode price MS-DRG, subject to adjustments described in § 512.300(c)(7).

(d) Effective discount factor. An EPM participant's quality-adjusted target prices incorporate an effective discount factor to reflect Medicare's portion of reduced expenditures from the EPM as described in this section.

(1) Effective discount factor for reconciliation payments. The effective discount factor for reconciliation payment in all performance years is determined by the EPM participant's quality category as provided in § 512.315(b)(5), (c)(5), and (d)(5).

(2) Applicable discount factor for repayment amounts. The applicable discount factor for repayment amounts is —

(i) Not applicable in performance year 1 and performance year 2 (NDR), as the requirement for EPM participant repayment is waived.

(ii) In performance year 2 (DR) and performance year 3 when partial EPM participant repayment applies, as determined by the EPM participant's quality category as provided in § 512.315(b)(5), (c)(5), and (d)(5).

(iii) Not applicable in performance years 4 and 5 when full EPM participant repayment applies, as determined by the effective discount factor that applies to repayment amounts as specified in paragraph (d)(1) of this section .

(e) Exceptions that apply to both quality-adjusted target prices and actual episode payments—(1) Exception for high episode payment. For each EPM, actual episode payments

and historical episode payments are capped at 2 standard deviations above the mean regional episode payment for the EPM-participant hospital-specific and regional components of the quality-adjusted target price under the applicable model, as well as for calculating actual episode payments under the applicable EPM during a performance year, subject to the exceptions noted in paragraphs (e)(1)(i) through (iv) of this section.

(i) For AMI model episodes with price MS-DRGs 280-282 or PCI price MS-DRGs 246-251 without readmission for CABG MS-DRGs 231-236, payments are capped separately based on the price MS-DRG.

(ii) For CABG model episodes with price CABG MS-DRGs 231-236, episode payments during the anchor hospitalization portion are capped separately from episode payments during the post-anchor hospitalization portion as follows.

(A) Payments during the anchor hospitalization portion are capped based on the CABG price MS-DRG 231-236.

(B) Payments during the post-anchor hospitalization portion are capped separately for episodes:

(1) With an AMI ICD-CM diagnosis code on the anchor inpatient claim and CABG price MS-DRG with major complication or comorbidity (231, 233, or 235).

(2) With an AMI ICD-CM diagnosis code on the anchor inpatient claim and CABG price MS-DRG without major complication or comorbidity (232, 234, or 236).

(3) Without an AMI ICD-CM diagnosis code on the anchor inpatient claim and CABG price MS-DRG with major complication or comorbidity (231, 233, or 235).

(4) Without an AMI ICD-CM diagnosis code on the anchor inpatient claim and CABG price MS-DRG without major complication or comorbidity (232, 234, or 236).

(iii) For AMI model episodes with a CABG price MS-DRG 231-236, payments are capped separately for those payments that occurred during the chained anchor hospitalization and for those payments that occurred after the chained anchor hospitalization.

(A) For the chained anchor hospitalization portion of the episode, the cap is applied based on the anchor hospitalization portion of a CABG episode for the corresponding price MS-DRG.

(B) For the post-anchor hospitalization portion of the episode, the cap is applied based on the post-anchor hospitalization portion of a CABG episode for the corresponding price MS-DRG with AMI ICD-CM diagnosis code.

(iv) For AMI episodes with either AMI price MS-DRG 280-282 or PCI price MS-DRG 246-251 and with readmission for a CABG MS-DRG 231-236, the cap is applied separately to the payments during the CABG readmission and all other payments during the episode.

(A) For payments during the CABG readmission portion of the episode, the cap is applied for the anchor hospitalization portion of a CABG episode for the corresponding CABG readmission MS-DRG.

(B) For all other payments during the episode, the cap is applied to the AMI model episodes with AMI price MS-DRG 280-282 or PCI price MS-DRGs 246-251 and without readmission for CABG MS-DRGs corresponding to the AMI price MS-DRG.

(2) Exclusion of incentive programs and add-on payments under existing Medicare payment systems. Certain incentive programs and add-on payments are excluded by CMS' application of the CMS Price (Payment) Standardization Detailed Methodology used for the Medicare spending per beneficiary measure in the Hospital Value-Based Purchasing Program

and Physician Value-Based Payment Modifier Program as specified in § 414.1235(a)(6) and (c)(1) of this chapter.

(f) Allocation of payments for services that straddle the episode—(1) General. Services included in the episode that begin before the start of or continue beyond the end of an EPM episode are prorated so that only the portion attributable to care furnished during the episode are included in the calculation of actual episode payments.

(2) Proration of services. Payments for services that straddle the episode are prorated using the following methodology:

(i) Non-IPPS inpatient services and other inpatient services. Non-IPPS inpatient services, and services furnished by other inpatient providers that extend beyond the end of the episode are prorated according to the percentage of the actual length of stay (in days) that falls within the episode.

(ii) Home health agency services. Home health services paid under the prospective payment system in part 484, subpart E of this chapter are prorated according to the percentage of days, starting with the first billable service date ("start of care date") and through and including the last billable service date, that occur during the episode. This methodology is applied in the same way if the home health services begin (the start of care date) prior to the start of the episode.

(3) IPPS services. IPPS claim amounts that extend beyond the end of the episode are prorated according to the geometric mean length of stay, using the following methodology:

(i) The first day of the IPPS stay is counted as 2 days.

(ii) If the actual length of stay that occurred during the episode is equal to or greater than the MS-DRG geometric mean, the normal MS-DRG payment is fully allocated to the episode.

(iii) If the actual length of stay that occurred during the episode is less than the geometric mean, the normal MS-DRG payment amount is allocated to the episode based on the number of inpatient days that fall within the episode.

(iv) If the full amount is not allocated to the episode, any remainder amount is allocated to the post-episode spending calculation (determined in § 512.307(c)).

§ 512.305 Determination of the NPRA and reconciliation process.

(a) General. Providers and suppliers furnishing items and services included in the EPM episode bill for such items and services in accordance with existing rules and as if this part were not in effect.

(b) Annual reconciliation. CMS annually performs the processes described in paragraphs (c) and (d) of this section to determine actual episode payments for each EPM episode for the performance year (except for episodes that have been canceled in accordance with § 512.240(a)(3), (b)(2), and (c)(2)) and determines the amount of a reconciliation payment to or Medicare repayment amount from EPM participants, if any, for that performance year.

(c) Annual reconciliation to establish NPRA. (1) Beginning 2 months after the end of each performance year and using the most recent claims data available, CMS performs a reconciliation calculation to establish an NPRA for each EPM participant based on the following process.

(2) CMS—

(i) Assesses whether EPM participants are in an acceptable or better quality category under § 512.315; and

(ii) Calculates the NPRA for each EPM participant for each performance year, including separately for episodes ending during the performance year 2 (DR) portion and episodes ending

during the performance year 2 (NDR) portion of performance year 2, by comparing the quality-adjusted target prices and the EPM participant's actual episode payments for the performance year or portion of that performance year as described in § 512.300 as follows:

(A) Determines actual EPM episode payments for each EPM episode included in the performance year or portion of that performance year.

(B) Multiplies the quality-adjusted target price by the number of non-canceled EPM episodes included in the performance year or portion of that performance year to which that episode quality-adjusted price applies and aggregates these amounts.

(C) Subtracts the amount determined under paragraph (c)(2)(ii)(A) of this section from the amount determined under paragraph (c)(2)(ii)(B) of this section.

(iii) Applies the following:

(A) Limitation on loss. Except as provided in paragraph (c)(2)(iii)(C) of this section, the total amount of the NPRA and subsequent reconciliation calculation for a performance year or portion of that performance year cannot exceed the following:

(1) For performance year 2 (NDR) only, 0 percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section for the performance year.

(2) For performance year 2 (DR) only, 5 percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section for the performance year.

(3) For performance year 3, 10 percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section for the performance year.

(4) For performance years 4 and 5, 20 percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section for the performance year.

(B) Limitation on gain. The total amount of the NPRA and subsequent reconciliation calculation for a performance year cannot exceed the following:

(1) For performance years 1 and 2, 5 percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section for the performance year.

(2) For performance year 3, 10 percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section for the performance year.

(3) For performance years 4 and 5, 20 percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section for the performance year.

(C) Financial loss limits for rural hospitals, SCHs, MDHs, and RRCs. If an EPM participant is a rural hospital, SCH, MDH or RRC, then for performance year 2 (DR), the total sum of the NPRA and subsequent reconciliation calculation cannot exceed 3 percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section. For performance years 3 through 5, the total cannot exceed 5 percent of the amount calculated in paragraph (c)(2)(ii)(B) of this section.

(D) Application of limitations on losses and gains. CMS establishes limits on losses and gains specifically with respect to and separately for each EPM. For performance year 2, CMS establishes limits on losses for each EPM separately for the performance year 2 (DR) and performance year 2 (NDR) portions of that performance year.

(d) Determination of reconciliation or repayment amount— (1) General. (i) Subject to paragraphs (c)(2)(iii)(B) and (d)(1)(iv) of this section, for performance year 1, the reconciliation payment (if any) is equal to the NPRA.

(ii) Subject to paragraphs (c)(2)(iii)(A) through (c)(2)(iii)(C) and (d)(1)(iv) of this section, for performance year 2, results from the subsequent reconciliation calculation for a prior

year's reconciliation, as described in § 512.307, and the post-episode spending and ACO overlap calculations, as described in § 512.307(b) and (c), are added to the sum of NPRA for performance year 2 (NDR) and NPRA for performance year 2 (DR) in order to determine the reconciliation or repayment amount.

(iii) Subject to paragraphs (c)(2)(iii)(A) through (C) and (d)(1)(iv) of this section, for performance years 3 through 5, results from the subsequent reconciliation calculation for a prior year's reconciliation, as described in § 512.307, and the post-episode spending and ACO overlap calculations, as described in § 512.307(b) and (c), are added to the current year's NPRA in order to determine the reconciliation or repayment amount.

(iv) The reconciliation or repayment amount may be adjusted as described in § 512.460(b)(5).

(2) Reconciliation payment. If the amount described in paragraph (d)(1) of this section is positive and the EPM participant quality category as described in § 512.315 is acceptable, good, or excellent, Medicare pays the EPM participant a reconciliation payment in an amount equal to the amount described in paragraph (d)(1) of this section. If the EPM participant's quality category as described in § 512.315 is unacceptable, the EPM participant is not eligible to be paid a reconciliation payment.

(3) Repayment amount. If the amount described in paragraph (d)(1) of this section is negative, the EPM participant pays to Medicare an amount equal to the amount described in paragraph (d)(1) of this section, in accordance with § 405.371 of this chapter. CMS waives this requirement for performance year 1.

(e) EPM participants found to be engaged in inappropriate and systemic under delivery of care. If the EPM participant is found to be engaged in an inappropriate and systemic under

delivery of care as specified in § 512.460(b)(1)(i)(C), the quality of the care provided must be considered to be seriously compromised and the EPM participant must be ineligible to receive or retain a reconciliation payment for any period in which such under delivery of care was found to occur.

(f) Reconciliation report. (1) CMS issues each EPM participant a reconciliation report for the performance year. Each reconciliation report contains the following:

(i) Information on the EPM participant's composite quality score described in § 512.315.

(ii) The total actual episode payments for the EPM participant.

(iii) The NPRA.

(iv) Whether the EPM participant is eligible for a reconciliation payment or must make a repayment to Medicare.

(v) The NPRA and subsequent reconciliation calculation amount for the previous performance year, as applicable.

(vi) The post-episode spending amount and ACO overlap calculation for the previous performance year, as applicable.

(vii) The reconciliation payment or repayment amount.

(2) For performance year 2, the reconciliation report would also include information separately for the performance year 2 (DR) and performance year 2 (NDR) portions of that year.

§ 512.307 Subsequent calculations.

(a) Subsequent reconciliation calculation. (1) Fourteen months after the end of each performance year, CMS performs an additional calculation, which accounts for changes since the calculation of the initial NPRA, using claims data available at that time, to account for final

claims run-out and any additional episode cancellations due to overlap or other reasons as specified in sections § 512.240(a)(3), (b)(2), and (c)(2).

(2) The additional calculation occurs concurrently with the reconciliation process for the most recent performance year and determines the subsequent calculation amount as follows:

(i) For performance years other than performance year 2, if the result of the subsequent reconciliation calculation is different than zero, CMS applies the stop-loss and stop-gain limits in § 512.305 (c)(2)(iii)(A) through (C) to the calculations in aggregate for that performance year (the initial reconciliation from section § 512.305(c)(2)(ii)(C), before application of the stop-loss and stop-gain limits, and the subsequent reconciliation calculation) to ensure the calculations in aggregate do not exceed the stop-loss or stop-gain limits. CMS then takes the difference between that amount and the initial NPRA after application of the stop-loss and stop-gain limits in section § 512.305 (c)(2)(iii)(A) through (C) to determine the subsequent calculation amount.

(ii) For performance year 2, CMS performs the subsequent reconciliation calculations separately for performance year 2 (NDR) and performance year 2 (DR) and then combines these amounts to determine the subsequent reconciliation calculation for performance year 2 as follows:

(A) If the results of the subsequent reconciliation calculation for performance year 2 (NDR) is different than zero, CMS applies the stop-loss and stop-gain limits in § 512.305 (c)(2)(iii)(A) through (C) to the calculations in aggregate for performance year 2 (NDR) (the initial reconciliation from § 512.305(c)(2)(ii)(C), not including application of the stop-loss and stop-gain limits, and the subsequent reconciliation calculation) to ensure the calculations in aggregate do not exceed the stop-loss or stop-gain limits. CMS then takes the difference between that amount and the initial NPRA after application of the stop-loss and stop-gain limits in section

§ 512.305 (c)(2)(iii)(A) through (C) to calculate the subsequent calculation amount for performance year 2 (NDR).

(B) If the results of the subsequent reconciliation calculation for performance year 2 (DR) is different than zero, CMS applies the stop-loss and stop-gain limits in § 512.305 (c)(2)(iii)(A) through (C) to the calculations in aggregate for performance year 2 (DR) (the initial reconciliation from section § 512.305(c)(2)(ii)(C), prior to application of the stop-loss and stop-gain limits, and the subsequent reconciliation calculation) to ensure the calculations in aggregate do not exceed the stop-loss or stop-gain limits. CMS then takes the difference between that amount and the initial NPRA after application of the stop-loss and stop-gain limits in section § 512.305(c)(2)(iii)(A) through (C) to calculate the subsequent calculation amount for performance year 2 (DR).

(C) The subsequent calculation amount for performance year 2 is the sum of paragraphs (a)(2)(ii)(A) and (a)(2)(ii)(B) in this section.

(iii) CMS then applies the subsequent calculation amount to the NPRA for the most recent performance year in order to determine the reconciliation amount or repayment amount for the most recent performance year.

(iv) Because EPM participants do not have financial repayment responsibility for performance year 1, for the performance year 2 reconciliation report only, the subsequent calculation amount (for performance year 1) is applied to the performance year 1 NPRA to ensure that the combined amount is not less than 0.

(b) <u>Additional calculations to determine the reconciliation payment or repayment amount</u>. CMS will reduce the reconciliation payment or increase the repayment amount for the subsequent performance year to account for shared savings paid to the ACO in the prior

performance year by the amount of the EPM discount factor paid out to the ACO as shared savings in the prior performance year. This adjustment is only made when the EPM participant is a participant or provider/supplier in the ACO and the EPM beneficiary is assigned or aligned to one of the following ACO models or programs:

(1) The Medicare Shared Savings Program.

(2) The Comprehensive ESRD Care Initiative (excluding a track with downside risk).

(c) Increases in post-episode spending. If the average post-episode Medicare Parts A and B payments for an EPM participant in the prior performance year is greater than 3 standard deviations above the regional average post-episode payments for the same performance year, then the spending amount exceeding three standard deviations above the regional average post-episode payments for the same performance year is added to the calculation of the reconciliation or repayment amount for the subsequent performance year.

§ 512.310 Appeals process.

(a) Notice of calculation error (first level of appeal). Subject to the limitations on review in subpart D of this part, if an EPM participant wishes to dispute calculations involving a matter related to payment, a CR incentive payment, reconciliation amounts, repayment amounts, or determinations associated with quality measures affecting payment, the EPM participant is required to provide written notice of the error, in a form and manner specified by CMS.

(1) Unless the EPM participant provides such notice, CMS deems final the reconciliation report and CR incentive payment report 45 calendar days after the reconciliation report or CR incentive payment report is issued and proceeds with the payment or repayment processes as applicable.

(2) If CMS receives a notice of a calculation error within 45 calendar days of the issuance of the reconciliation report or CR incentive payment report, CMS responds in writing within 30 calendar days to either confirm that there was an error in the calculation or verify that the calculation is correct, although CMS reserves the right to an extension upon written notice to the EPM participant.

(3) Only EPM participants may use the notice of calculation error process described in this part.

(b) Dispute resolution process (second level of appeal). (1) If the EPM participant is dissatisfied with CMS's response to the notice of a calculation error, the EPM participant may request a reconsideration review in a form and manner as specified by CMS.

(2) The reconsideration request must provide a detailed explanation of the basis for the dispute and include supporting documentation for the EPM participant's assertion that CMS or its representatives did not accurately calculate the NPRA, the reconciliation payment, the CR incentive payment, or the repayment amount in accordance with subpart D of this part.

(3) If CMS does not receive a request for reconsideration from the EPM participant within 10 calendar days of the issue date of CMS's response to the EPM participant's notice of calculation error, then CMS's response to the calculation error is deemed final and CMS proceeds with the applicable processes, as described in subpart D of this part.

(4) The CMS reconsideration official notifies the EPM participant in writing within 15 calendar days of receiving the EPM participant's review request of the following:

(i) The date, time, and location of the review.

(ii) The issues in dispute.

(iii) The review procedures.

(iv) The procedures (including format and deadlines) for submission of evidence.

(5) The CMS reconsideration official takes all reasonable efforts to schedule the review to occur no later than 30 days after the date of receipt of the notification.

(6) The provisions at § 425.804(b), (c), and (e) of this chapter are applicable to reviews conducted in accordance with the reconsideration review process for the EPM.

(7) The CMS reconsideration official issues a written determination within 30 days of the review. The determination is final and binding.

(8) Only EPM participants may use the dispute resolution process described in this part.

(c) Exception to the notice of calculation error process. If the EPM participant contests a matter that does not involve an issue contained in, or a calculation which contributes to, a reconciliation report or CR incentive payment report a notice of calculation error is not required. In these instances, if CMS does not receive a request for reconsideration from the EPM participant within 10 calendar days of the notice of the initial determination, the initial determination is deemed final and CMS proceeds with the action indicated in the initial determination.

(d) Notice of an EPM participant's termination from the EPM. If an EPM participant receives notification that it has been terminated from the EPM and wishes to appeal such termination, it must provide a written request for reconsideration to CMS requesting review of the termination within 10 calendar days of the notice. CMS has 30 days to respond to the EPM participant's request for review. If the EPM participant fails to notify CMS, the termination is deemed final.

(e) Limitations on review. In accordance with section 1115A (d) (2) of the Act, there is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

(1) The selection of models for testing or expansion under section 1115A of the Act.

(2) The selection of organizations, sites, or participants to test those models selected.

(3) The elements, parameters, scope, and duration of such models for testing or dissemination.

(4) Determinations regarding budget neutrality under section 1115A (b)(3) of Act.

(5) The termination or modification of the design and implementation of a model under section 1115A (b)(3)(B) of Act.

(6) Decisions to expand the duration and scope of a model under section 1115A(c) of the Act, including the determination that a model is not expected to meet criteria described in paragraph (e)(1) or (2) of this section.

§ 512.315 Composite quality scores for determining reconciliation payment eligibility and effective and applicable discount factors.

(a) General. An EPM participant's eligibility for a reconciliation payment under § 512.305, and the determination of effective discount factors and applicable discount factors for reconciliation and repayment, respectively, under paragraphs (b)(5), (c)(5), and (d)(5) of this section, for a performance year depend on the EPM participant's EPM composite quality score (including any quality performance points and quality improvement points earned) for that performance year.

(b) AMI model—(1) AMI model composite quality score. CMS calculates an AMI model composite quality score for each AMI model participant for each performance year, which equals the sum of the following:

(i) The AMI model participant's quality performance points for the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (NQF #0230) measure described in § 512.411(a)(1). This measure is weighted at 50 percent of the AMI model composite quality score.

(ii) The AMI model participant's quality performance points for the Excess Days in Acute Care after Hospitalization for AMI measure described in § 512.411(a)(2). This measure is weighted at 20 percent of the AMI model composite quality score.

(iii) The AMI model participant's quality performance points for the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (NQF #0166) measure described in § 512.411(a)(3). This measure is weighted at 20 percent of the AMI model composite quality score.

(iv) Any additional quality improvement points the AMI model participant may earn as a result of demonstrating improvement on the quality measures in § 512.411(a), as described in paragraph (b)(3) of this section.

(v) If applicable, 2 additional points for successful Hybrid Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #2473) measure voluntary data submission as described in § 512.411(b)(2). Successful submission is weighted at 10 percent of the AMI model composite quality score.

(2) AMI model quality performance points. CMS computes quality performance points for each quality measure based on the AMI model participant's performance percentile relative

to the national distribution of all subsection (d) hospitals that are eligible for payment under the IPPS and meet the minimum measure patient case or survey count.

(i) For the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (NQF #0230) measure described in § 512.411(a)(1), CMS assigns the AMI model participant measure value to a performance percentile and then quality performance points are assigned based on the following performance percentile scale:

(A) 10.00 points for ≥ 90th.

(B) 9.25 points for ≥ 80th and < 90th.

(C) 8.50 points for ≥ 70th and < 80th.

(D) 7.75 points for ≥ 60th and < 70th.

(E) 7.00 points for ≥ 50th and < 60th.

(F) 6.25 points for ≥ 40th and < 50th.

(G) 5.50 points for ≥ 30th and < 40th.

(H) 0.00 points for < 30th.

(ii) For the Excess Days in Acute Care after Hospitalization for AMI measure described in § 512.411(a)(2), CMS assigns the AMI model participant measure value to a performance percentile and then quality performance points are assigned based on the following performance percentile scale:

(A) 4.00 points for ≥ 90th.

(B) 3.70 points for ≥ 80th and < 90th.

(C) 3.40 points for ≥ 70th and < 80th.

(D) 3.10 points for ≥ 60th and < 70th.

(E) 2.80 points for ≥ 50th and < 60th.

(F) 2.50 points for ≥ 40th and < 50th.

(G) 2.20 points for ≥ 30th and < 40th.

(H) 0.00 points for < 30th.

(iii) For the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (NQF #0166) measure described in § 512.411(a)(3), CMS assigns the AMI model participant measure value to a performance percentile and then quality performance points are assigned based on the following performance percentile scale:

(A) 4.00 points for ≥ 90th.

(B) 3.70 points for ≥ 80th and < 90th.

(C) 3.40 points for ≥ 70th and < 80th.

(D) 3.10 points for ≥ 60th and < 70th.

(E) 2.80 points for ≥ 50th and < 60th.

(F) 2.50 points for ≥ 40th and < 50th.

(G) 2.20 points for ≥ 30th and < 40th.

(H) 0.00 points for < 30th.

(3) AMI model quality improvement points. If an AMI model participant's own improvement in the participant's measure point estimate from the previous year on an individual measure described in § 512.411(a), regardless of the participant's measure point estimate starting and ending values, falls into the top 10 percent of all subsection (d) hospitals that are eligible for payment under the IPPS based on the national distribution of measure improvement over the most recent two years, then the AMI model participant is eligible to receive quality improvement points up to 10 percent of the total available points for that measure. The AMI model composite quality score is capped at 20 points.

(4) Exception for AMI model participants without a measure value. In the case of an AMI model participant without a measure value that would allow CMS to assign quality performance points for that quality measure, CMS assigns the 50th percentile quality performance points to the AMI model participant for the individual measure.

(i) An AMI model participant does not have a measure value for the—

(A) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (NQF #0230) measure described in § 512.411(a)(1) if the participant does not meet the minimum 25 case count.

(B) Excess Days in Acute Care after Hospitalization for AMI measure described in § 512.411(a)(2) if the participant does not meet the minimum 25 case count.

(C) Hospital Consumer Assessment of Healthcare Providers and Systems Survey (NQF #0166) measure described in § 512.411(a)(3) if the participant does not meet the minimum of 100 completed surveys and does not have 4 consecutive quarters of HCAHPS data.

(D) Measures described in paragraphs (4)(i)(A) through (C) of this section, if CMS identifies an error in the data used to calculate the measure and suppresses the measure value.

(5) Establishing AMI model reconciliation payment eligibility and effective and applicable discount factors. CMS determines reconciliation payment eligibility and the effective discount factor for reconciliation payments in all performance years and repayment amounts in performance years 4 and 5, as well as the applicable discount factor for repayment amounts in performance years 2 (DR) and 3, for AMI model participants based on the AMI model composite quality score described in paragraph (b)(1) of this section.

(i) Reconciliation payment eligibility requires an acceptable or better quality category, defined as an AMI model composite quality score of greater than or equal to 3.6.

(ii) Effective discount factor for reconciliation payments.

(A) A 3.0 percentage point effective discount factor for AMI model participants in the unacceptable or acceptable category, defined as an AMI model composite quality score that is less than 6.9.

(B) A 2.0 percentage point effective discount factor for AMI model participants in the good quality category, defined as an AMI model composite quality score that is greater than or equal to 6.9 and less than or equal to 14.8.

(C) A 1.5 percentage point effective discount factor for AMI model participants in the excellent quality category, defined as an AMI model composite quality score that is greater than 14.8.

(iii) Applicable discount factor for repayment amount in performance years 2 (DR) and 3.

(A) A 2.0 percentage point applicable discount factor for AMI model participants in the unacceptable or acceptable quality category, defined as an AMI model composite quality score of less than 6.9.

(B) A 1.0 percentage point applicable discount factor for AMI model participants in the good quality category, defined as an AMI model composite quality score that is greater than or equal to 6.9 and less than or equal to 14.8.

(C) A 0.5 percentage point applicable discount factor for AMI model participants in the excellent quality category, defined as an AMI model composite quality scores that is greater than 14.8.

(c) CABG model—(1) CABG model composite quality score. CMS calculates a CABG model composite quality score for each CABG model participant for each performance year, which equals the sum of the following:

(i) The CABG model participant's quality performance points for the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF# 2558) measure described in § 512.412(a)(1). This measure is weighted at 75 percent of the CABG model composite quality score.

(ii) The CABG model participant's quality performance points for the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (NQF #0166) measure described in § 512.412(a)(2). This measure is weighted at 25 percent of the CABG model composite quality score.

(iii) Any additional quality improvement points the CABG model participant may earn as a result of demonstrating improvement on the quality measures in paragraphs (b)(1)(i) and (ii) of this section, as described in paragraph (c)(3) of this section.

(2) CABG model quality performance points. CMS computes quality performance points for each quality measure based on the CABG model participant's performance percentile relative to the national distribution of all subsection (d) hospitals that are eligible for payment under the IPPS and meet the minimum measure patient case or survey count.

(i) For the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF# 2558) measure described in § 512.412(a)(1), CMS assigns the CABG model participant measure value to a performance percentile and then quality performance points are assigned based on the following performance percentile scale:

(A) 15.00 points for ≥ 90th.

(B) 13.88 points for ≥ 80th and < 90th.

(C) 12.75 points for ≥ 70th and < 80th.

(D) 11.63 points for ≥ 60th and < 70th.

(E) 10.50 points for ≥ 50th and < 60th.

(F) 9.38 points for ≥ 40th and < 50th.

(G) 8.25 points for ≥ 30th and < 40th.

(H) 0.00 points for < 30th.

(ii) For the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (NQF #0166) measure described in § 512.412(a)(2), CMS assigns the CABG model participant measure value to a performance percentile and then quality performance points are assigned based on the following performance percentile scale:

(A) 5.00 points for ≥ 90th.

(B) 4.63 points for ≥ 80th and < 90th.

(C) 4.25 points for ≥ 70th and < 80th.

(D) 3.88 points for ≥ 60th and < 70th.

(E) 3.50 points for ≥ 50th and < 60th.

(F) 3.13 points for ≥ 40th and < 50th.

(G) 2.75 points for ≥ 30th and < 40th.

(H) 0.00 points for < 30th.

(3) CABG model quality improvement points. If a CABG model participant's own improvement in the participant's measure point estimate from the previous year on an individual measure described in § 512.412(a), regardless of the participant's measure point estimate starting

and ending values, falls into the top 10 percent of all subsection (d) hospitals that are eligible for payment under the IPPS based on the national distribution of measure improvement over the most recent two years, then the CABG model participant is eligible to receive quality improvement points up to 10 percent of the total available points for that measure. The total CABG model composite quality score is capped at 20 points.

(4) Exception for CABG model participants without a measure value. In the case of a CABG model participant without a measure value that would allow CMS to assign quality performance points for that quality measure, CMS assigns the 50th percentile quality performance points to the hospital for the individual measure.

(i) A CABG model participant does not have a measure value for the—

(A) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF# 2558) measure described in § 512.412(a)(1) if the CABG model participant does not meet the minimum 25 case count.

(B) Hospital Consumer Assessment of Healthcare Providers and Systems Survey (NQF #0166) measure described in § 512.412(a)(2) if the CABG model participant does not meet the minimum of 100 completed surveys and does not have 4 consecutive quarters of HCAHPS data.

(C) Measures described in paragraphs (c)(4)(i)(A) and (c)(4)(i)(B) of this section, if CMS identifies an error in the data used to calculate the measure and suppresses the measure value.

(5) Establishing CABG model reconciliation payment eligibility and effective and applicable discount factors. CMS determines reconciliation payment eligibility and the effective discount factor for reconciliation payments in all performance years and repayment amounts in performance years 4 and 5, as well as applicable discount factor for repayment amounts in

performance years 2 (DR) and 3, for CABG model participants based on the CABG model composite quality score described in paragraph (c)(1) of this section.

(i) Reconciliation payment eligibility requires an acceptable or better quality category, defined as a CABG model composite quality score of greater than or equal to 2.8.

(ii) Effective discount factor for reconciliation payments.

(A) A 3.0 percentage point effective discount factor for CABG model participants in the unacceptable or acceptable quality category, defined as a CABG model composite quality score that is less than 4.8.

(B) A 2.0 percentage point effective discount factor for CABG model participants in the good quality category, defined as a CABG model composite quality score that is greater than or equal to 4.8 and less than or equal to 17.5.

(C) A 1.5 percentage point effective discount factor for CABG model participants in the excellent quality category, defined as a CABG model composite quality score that are greater than 17.5.

(iii) Applicable discount factor for repayment amount in performance years 2 (DR) and 3.

(A) A 2.0 percentage point applicable discount factor for CABG model participants in the unacceptable or acceptable quality category, defined as a CABG model composite quality score of less than 4.8.

(B) A 1.0 percentage point applicable discount factor for CABG model participants in the good quality category, defined as a CABG model composite quality score that is greater than or equal to 4.8 and less than or equal to 17.5.

(C) A 0.5 percentage point applicable discount factor for CABG model participants in the excellent quality category, defined as a CABG model composite quality scores that is greater than 17.5.

(d) SHFFT model—(1) SHFFT model composite quality score. CMS calculates a SHFFT model composite quality score for each SHFFT model participant for each performance year, which equals the sum of the following:

(i) The SHFFT model participant's quality performance points for the Hospital-Level Risk-Standardized Complication Rate following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (NQF #1550) measure described in § 512.413(a)(1). This measure is weighted at 50 percent of the SHFFT model composite quality score.

(ii) The SHFFT model participant's quality performance points for the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (NQF #0166) measure described in § 512.413(a)(2). This measure is weighted at 40 percent of the SHFFT model composite quality score.

(iii) Any additional quality improvement points the SHFFT model participant may earn as a result of demonstrating improvement on either or both of the quality measures in paragraphs (d)(1)(i) and (ii) of this section, as described in paragraph (d)(3) of this section.

(iv) If applicable, 2 additional points for successful THA/TKA voluntary data submission of patient-reported outcomes and limited risk variable data, as described in § 512.413(b)(2). Successful submission is weighted at 10 percent of the SHFFT model composite quality score.

(2) SHFFT model quality performance points. CMS computes quality performance points for each quality measure based on the SHFFT model participant's performance percentile

on that measure relative to the national distribution of all subsection (d) hospitals that are eligible for payment under the IPPS and meet the minimum measure patient case or survey count.

(i) For the Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (NQF #1550) measure described in § 512.413(a)(1), CMS assigns the SHFFT model participant measure value to a performance percentile and then quality performance points are assigned based on the following performance percentile scale:

(A) 10.00 points for ≥ 90th.

(B) 9.25 points for ≥ 80th and < 90th.

(C) 8.50 points for ≥ 70th and < 80th.

(D) 7.75 points for ≥ 60th and < 70th.

(E) 7.00 points for ≥ 50th and < 60th.

(F) 6.25 points for ≥ 40th and < 50th.

(G) 5.50 points for ≥ 30th and < 40th.

(H) 0.00 points for < 30th.

(ii) For the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (NQF #0166) measure described in § 512.413(a)(2), CMS assigns the SHFFT model participant measure value to a performance percentile and then quality performance points are assigned based on the following performance percentile scale:

(A) 8.00 points for ≥ 90th.

(B) 7.40 points for ≥ 80th and < 90th.

(C) 6.80 points for ≥ 70th and < 80th.

(D) 6.20 points for ≥ 60th and < 70th.

(E) 5.60 points for ≥ 50th and < 60th.

(F) 5.00 points for ≥ 40th and < 50th.

(G) 4.40 points for ≥ 30th and < 40th.

(H) 0.00 points for < 30th.

(3) SHFFT quality improvement points. If a SHFFT model participant's quality performance percentile on an individual measure described in § 512.413(a) increases from the previous performance year by at least 2 deciles on the performance percentile scale, then the SHFFT model participant is eligible to receive quality improvement points up to 10 percent of the total available points for that individual measure. The total SHFFT model composite quality score is capped at 20 points.

(4) Exception for SHFFT model participants without a measure value. In the case of a SHFFT model participant without a measure value that would allow CMS to assign quality performance points for that quality measure, CMS assigns the 50th percentile quality performance points to the participant for the individual measure.

(i) A SHFFT model participant does not have a measure value for the—

(A) Hospital-Level Risk-Standardized Complication Fate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (NQF #1550) measure described in § 510.413(a)(1) if the participant does not meet the minimum 25 case count; or

(B) Hospital Consumer Assessment of Healthcare Providers and Systems Survey measure (NQF #0166) described in § 510.413(a)(2) if the participant does not meet the minimum of 100 completed surveys and does not have 4 consecutive quarters of HCAHPS data.

(C) Measures described in paragraphs (d)(4)(i)(A) and (d)(4)(i)(B) of this section, if CMS identifies an error in the data used to calculate the measure and suppresses the measure value.

(5) Establishing SHFFT model reconciliation payment eligibility and effective and applicable discount factors. CMS determines reconciliation payment eligibility and the effective discount factor for reconciliation payments in all performance years and repayment amounts in performance years 4 and 5, as well as the applicable discount factor for repayment amounts in performance years 2 (DR) and 3, for SHFFT model participants based on the SHFFT model composite quality score described in paragraph (d)(1) of this section.

(i) Reconciliation payment eligibility requires an acceptable or better quality category, defined as a SHFFT model composite quality score of greater than or equal to 5.0.

(ii) Effective discount factor for reconciliation payments.

(A) A 3.0 percentage point effective discount factor for SHFFT model participants in the unacceptable or acceptable quality category, defined as a SHFFT model composite quality score that is less than 6.9.

(B) A 2.0 percentage point effective discount factor for SHFFT model participants in the good quality category, defined as a SHFFT model composite quality score that is greater than or equal to 6.9 and less than or equal to 15.0.

(C) A 1.5 percentage point effective discount factor for SHFFT model participants in the excellent quality category, defined as a SHFFT model composite quality score that are greater than 15.0.

(iii) Applicable discount factor for repayment amount in performance years 2 (DR) and 3.

(A) A 2.0 percentage point applicable discount factor for SHFFT model participants in the unacceptable or acceptable quality category, defined as a SHFFT model composite quality score of less than 6.9.

(B) A 1.0 percentage point applicable discount factor for SHFFT model participants in the good quality category, defined as a SHFFT model composite quality score that is greater than or equal to 6.9 and less than or equal to 15.0.

(C) A 0.5 percentage point applicable discount factor for SHFFT model participants in the excellent quality category, defined as a SHFFT model composite quality scores that is greater than 15.0.

§ 512.320 Treatment of incentive programs or add-on payments under existing Medicare payment systems.

No EPM replaces any existing Medicare incentive programs or add-on payments. The quality-adjusted target prices and NPRAs for an EPM participant under such models are independent of, and do not affect, any incentive programs or add-on payments under existing Medicare payment systems.

§ 512.350 Data sharing.

(a) General. CMS makes available to EPM participants, through the most appropriate means, data that CMS determines may be useful to EPM participants to do the following:

(1) Determine appropriate ways to increase the coordination of care.

(2) Improve quality.

(3) Enhance efficiencies in the delivery of care.

(4) Otherwise achieve the goals of the models described in this section.

(b) Beneficiary-identifiable data. (1) CMS makes beneficiary-identifiable data available to an EPM participant in accordance with applicable privacy laws and only in response to the EPM participant's request for such data for a beneficiary who has been furnished a billable service by the EPM participant corresponding to the episode definitions for the EPM.

(2) The minimum data necessary to achieve the goals of the EPM, as determined by CMS, may be provided under this section for an EPM participant's baseline period and as frequently as on a quarterly basis throughout the EPM participant's participation in an EPM.

Subpart E—Quality Measures, Beneficiary Protections, and Compliance Enforcement

§ 512.400 Quality measures and reporting - general.

(a) Reporting of quality measures. Quality measures are used for public reporting, for determining whether an EPM participant is eligible for reconciliation payments under § 512.305(d)(1)(iii)), and for assigning the effective and applicable discount factors for the performance year to an EPM participant as described in § 512.315(b)(5), (c)(5), and (d)(5).

(b) Quality measures. Quality measures differ by EPM.

(c) Public reporting. CMS—

(1) Makes the required quality measurement results for each EPM participant in each performance year publicly available on the CMS Web site in a form and manner as determined by CMS;

(2) Shares each EPM participant’s quality metrics with the participant prior to display on the CMS Web site; and

(3) Does not publicly report the voluntary measure data submitted under an EPM in § 512.411(b) or § 512.413(b) but does indicate whether an EPM participant has voluntarily submitted such data.

§ 512.411 Quality measures and reporting for AMI model.

(a) Required measures. (1) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (NQF #0230) (MORT-30-AMI).

(2) Excess Days in Acute Care after Hospitalization for AMI (AMI Excess Days).

(3) HCAHPS Survey (NQF #0166).

(b) Voluntary measure. (1) Voluntary Hybrid Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #2473) (Hybrid AMI Mortality).

(2) To be eligible to receive the additional points added to the AMI composite quality score for successful voluntary data submission of clinical electronic health record data, as described in § 512.411(b)(1), AMI model participants must submit the clinical electronic health record data requested by CMS related to each eligible AMI anchor hospitalization during the performance period. The data must be submitted within 60 days of the end of the most recent performance period and be accompanied by the limited risk variable data (five elements finalized) as outlined in § 512.315(b)(1)(iv).

(i) For each eligible AMI anchor hospitalization, all five risk variable data elements are required to be submitted. The five risk variables are as follows:

(A) Age.

(B) First-captured heart rate measured within 2 hours of a patient presenting to the hospital.

(C) First-captured systolic blood pressure measured within 2 hours of a patient presenting to the hospital.

(D) First-captured troponin values measured within 24 hours of a patient presenting to the hospitals.

(E) First-captured creatinine values measured within 24 hours of a patient presenting to the hospitals.

(ii) For each eligible AMI anchor hospitalization, six linking variables are required to merge the electronic health record data with the CMS claims data:

(A) AMI model participant CCN.

(B) Medicare Health Insurance Claim Number.

(C) Sex.

(D) Date of birth.

(E) Admission date.

(F) Discharge date.

(iii) For years 1 through 5 of the AMI model an increasing amount of data are requested by CMS for each performance period as follows:

(A) Year 1. Submit electronic health record data on > 50% of eligible AMI anchor hospitalizations between July 1, 2017 and August 31, 2017.

(B) Year 2. Submit electronic health record data on over 90% of eligible AMI anchor hospitalizations between September 1, 2017 and June 30, 2018.

(C) Year 3. Submit electronic health record data on over 90% of eligible AMI anchor hospitalizations between July 1, 2018 and June 30, 2019.

(D) Year 4. Submit electronic health record data on over 90% of eligible AMI anchor hospitalizations between July 1, 2019 and June 30, 2020.

(E) Year 5. Submit electronic health record data on over 90% of eligible AMI anchor hospitalizations between July 1, 2020 and June 30, 2021.

§ 512.412 Quality measures and reporting for CABG model.

(a) Required measures. (1) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF# 2558) (MORT-30-CABG).

(2) HCAHPS Survey (NQF #0166).

(b) [Reserved]

§ 512.413 Quality measures and reporting for SHFFT model.

(a) Required measures. (1) Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (NQF #1550) (Hip/Knee Complications)

(2) HCAHPS Survey (NQF #0166)

(b) Voluntary measure. (1) Patient-reported outcomes and limited risk variable data following elective primary THA/TKA.

(2) To be eligible to receive the additional points added to the SHFFT model composite quality score for successful voluntary data submission of patient-reported outcomes and limited risk variable data, as described in § 512.315(d)(1)(iv), SHFFT model participants must submit the THA/TKA patient-reported outcome and limited risk variable data requested by CMS related to the pre- and post-operative periods for elective primary total hip and/or total knee arthroplasty procedures. The data must be submitted within 60 days of the end of the most recent performance period and be accompanied by the patient-reported outcomes and limited risk variable data (eleven elements finalized) as outlined in § 512.315(d)(1)(iv).

(i) For each eligible procedure all eleven risk variable data elements are required to be submitted. The eleven risk variables are as follows:

(A) Date of birth.

(B) Race.

(C) Ethnicity.

(D) Date of admission to anchor hospitalization.

(E) Date of eligible THA/TKA procedure.

(F) Medicare Health Insurance Claim Number.

(G) Body mass index.

(H) Use of chronic (≥ 90 days) narcotics.

(I) Total painful joint count.

(J) Quantified spinal pain.

(K) Single Item Health Literacy Screening (SILS2) questionnaire.

(ii) Participants must also submit the amount of requested THA/TKA patient-reported outcomes data required for each year of the SHFFT model in order to be considered successful in submitting voluntary data.

(A) The amount of requested THA/TKA patient-reported outcomes data to submit, in order to be considered successful increases each subsequent year of the SHFFT model over the 5 years of the model.

(B) A phase-in approach that determines the amount of requested THA/TKA patient-reported outcomes data to submit over the 5 years of the SHFFT model is applied so that in year 1 successful submission of data would mean CMS received all requested THA/TKA patient-reported outcomes and limited risk variable data on both of the following:

(1) Greater than or equal to 60 percent of eligible procedures or greater than or equal to 75 percent eligible patients during the data collection period.

(2) Submission of requested THA/TKA PRO and limited risk variable data is completed within 60 days of the most recent performance period.

(iii) For years 1 through 5 of the model an increasing amount of data is requested by CMS for each performance period as follows:

(A) Year 1 (2017). Submit pre-operative data on primary elective THA/TKA procedures for ≥ 60% or ≥ 75% procedures performed between September 1, 2016 through June 30, 2017, unless CMS requests a more limited data set, in which case, submit all requested data elements.

(B) Year 2 (2018). Submit—

(1) Post-operative data on primary elective THA/TKA procedures for ≥ 60 percent or ≥ 75 procedures performed between September 1, 2016 and June 30, 2017; and

(2) Pre-operative data on primary elective THA/TKA procedures for ≥ 70% or ≥ 100 procedures performed between July 1, 2017 and June 30, 2018, unless CMS requests a more limited data set, in which case, submit all requested data elements.

(C) Year 3 (2019). Submit—

(1) Post-operative data on primary elective THA/TKA procedures for ≥ 70% or ≥ 100 procedures performed between July 1, 2017 and June 30, 2018; and

(2) Pre-operative data on primary elective THA/TKA procedures for ≥ 80% or ≥ 200 procedures performed between July 1, 2018 and June 30, 2019, unless CMS requests a more limited data set, in which case, submit all requested data elements.

(D) Year 4 (2020). Submit—

(1) Post-operative data on primary elective THA/TKA procedures for ≥ 80% or ≥ 200 procedures performed between July 1, 2018 and June 30, 2019; and

(2) Pre-operative data on primary elective THA/TKA procedures for ≥ 80% or ≥ 200 procedures performed between July 1, 2019 and June 30, 2020, unless CMS requests a more limited data set, in which case, submit all requested data elements.

(E) Year 5 (2021). Submit—

(1) Post-operative data on primary elective THA/TKA procedures for ≥ 80% or ≥ 200 procedures performed between July 1, 2019 and June 30, 2020; and

(2) Pre-operative data on primary elective THA/TKA procedures for ≥ 80% or ≥ 200 procedures performed between July 1, 2020 and June 30, 2021, unless CMS requests a more limited data set, in which case, submit all requested data elements.

§ 512.450 Beneficiary choice and beneficiary notification.

(a) Beneficiary choice. The EPMs do not restrict Medicare beneficiaries' ability to choose any Medicare enrolled provider or supplier, or any physician or practitioner who has opted out of Medicare.

(1) As part of discharge planning and referral, participant hospitals must inform beneficiaries of all Medicare participating post-acute care providers in an area and must identify those post-acute care providers with whom they have sharing arrangements. Participant hospitals may recommend preferred providers and suppliers, consistent with applicable statutes and regulations. Participant hospitals may not limit beneficiary choice to any list of providers or suppliers in any manner other than that permitted under applicable statutes and regulations. Participant hospitals must take into account patient and family preferences when they are expressed.

(2) Participant hospitals may not charge any episode payment model collaborator a fee to be included on any list of preferred providers or suppliers, nor may the participant hospital accept such payments.

(b) Required beneficiary notification—(1) Hospital detailed notification. Each participant hospital must provide written notice to any Medicare beneficiary that meets the criteria in § 512.240 of his or her inclusion in the episode payment model. The notice must be upon admission to the participant hospital or immediately following the decision to schedule a procedure or provide services which would result in a patient being discharged under a covered episode. In circumstances where, due to the patient's condition, it may not be feasible to provide notification at such times, the notification must be provided to the beneficiary or his or her representative as soon as is reasonably practicable but no later than discharge from the hospital accountable for the episode. The hospital must be able to generate a list of all beneficiaries receiving such notification including the date on which the notification was provided to the beneficiary to CMS or its designee upon request for monitoring purposes. The beneficiary notification must contain all of the following:

(i) A detailed explanation of the model and how it might be expected to affect the beneficiary's care.

(ii) Notification that the beneficiary retains freedom of choice to choose providers and services.

(iii) Explanation of how patients can access care records and claims data through an available patient portal, and how they can share access to their Blue Button® electronic health information with caregivers.

(iv) A statement that all existing Medicare beneficiary protections continue to be available to the beneficiary. These include the ability to report concerns of substandard care to Quality Improvement Organizations and 1-800-MEDICARE.

(v) A list of the providers and suppliers with whom the participant hospital has a sharing arrangement.

(2) Physician, non-physician practitioner, and PGP provision of notice. A participant hospital must require any physician, non-physician practitioner, or PGP that is an episode payment model collaborator to provide written notice of the structure of the model and the existence of the physician's or PGP's sharing arrangement with the participant hospital to any Medicare beneficiary that meets the criteria specified in § 512.240. The notice must be provided at the time that the decision to undergo a procedure or service covered under an episode payment model is made. In circumstances where, due to the patient's condition, it may not be feasible to provide notification at such times, the notification must be provided to the beneficiary or his or her representative as soon as is reasonably practicable but no later than discharge from the hospital accountable for the episode. The physician or PGP must be able to generate a list of all beneficiaries receiving such notification including the date on which the notification was provided to the beneficiary to CMS upon request for monitoring purposes.

(3) PAC provider/supplier notification. A participant hospital must require any provider or supplier, other than the treating physician or member of a PGP discussed in paragraph (b)(2) of this section, with whom it has executed a sharing arrangement to provide written notice of the existence of its sharing arrangement with the participant hospital to any Medicare beneficiary that meets the criteria specified in § 512.240. The notice must be provided no later than the time at which the beneficiary first receives services from the provider or supplier during the episode

payment model episode of care. In circumstances where, due to the patient's condition, it may not be feasible to provide notification at such times, the notification must be provided to the beneficiary or his or her representative as soon as is reasonably practicable but no later than discharge from the hospital accountable for the episode. The PAC provider/supplier must be able to generate a list of all beneficiaries receiving such notification including the date on which the notification was provided to the beneficiary to CMS upon request for monitoring purposes.

(4) Collaborating hospital notification. An EPM participant must require any hospital that is an EPM collaborator to provide written notice of the structure of the model and the existence of the hospital's sharing arrangement with the EPM participant to any Medicare beneficiary that meets the criteria specified in § 512.240. The notice must be upon admission to the collaborating hospital, or immediately following the decision to undertake a procedure or provide services covered under an EPM, whichever occurs later. In circumstances where, due to the patient's condition, it may not be feasible to provide notification at such times, the notification must be provided to the beneficiary or his or her representative as soon as is reasonably practicable but no later than discharge from the hospital accountable for the episode. Hospitals must be able to generate a list of all beneficiaries receiving such notification including the date on which the notification was provided to the beneficiary to CMS, or its designees, upon request for monitoring purposes.

(5) ACO notification. An EPM participant must require any ACO that is an EPM collaborator to require their ACO participants for which the ACO has an ACO distribution arrangement as well as the ACO's providers and suppliers to provide written notice of the structure of the model and the existence of the ACO's sharing arrangement with the EPM participant to any Medicare beneficiary that meets the criteria specified in § 512.240. The notice

must be provided no later than the time at which the beneficiary first receives services from the ACO participant and/or an ACO PGP collaboration agent during the EPM episode. In circumstances where, due to the patient's condition, it may not be feasible to provide notification at such times, the notification must be provided to the beneficiary or his or her representative as soon as is reasonably practicable but no later than discharge from the hospital accountable for the episode. ACOs must be able to generate a list of all beneficiaries receiving such notification including the date on which the notification was provided to the beneficiary to CMS, or its designees, upon request for monitoring purposes.

(6) Discharge planning notice. A participant hospital must provide the beneficiary with a written notice of any potential financial liability, associated with non-covered services recommended or presented as an option as part of discharge planning, no later than the time that the beneficiary discusses a particular PAC option or at the time the beneficiary is discharged, whichever occurs earlier.

(i) If the hospital knows or should have known that the beneficiary is considering or has decided to receive a non-covered post-acute service or other non-covered associated service or supply, the hospital must notify the beneficiary that the service would not be covered by Medicare.

(ii) If the hospital is discharging a beneficiary to a SNF prior to the occurrence of a 3 day hospital stay, and the beneficiary is being transferred to or is considering a SNF that would not qualify under the SNF 3-day waiver in § 512.610, the hospital must notify the beneficiary in accordance with paragraph (b)(6)(i) of this section that the beneficiary will be responsible for costs associated with that stay except those which would be covered by Medicare Part B during a non-covered inpatient SNF stay.

(7) Lists of beneficiaries that receive notifications must be retained and provided access to CMS, or its designees, in accordance with § 512.110.

§ 512.460 Compliance enforcement.

(a) General. EPM participants must comply with all of the requirements outlined in this part. Except as specifically noted in this part, the regulations under this part must not be construed to affect the applicable payment, coverage, program integrity, or other requirements under this chapter (such as those in parts 412 and 482 of this chapter).

(b) Failure to comply. (1) CMS may take one or more of the remedial actions set forth in paragraph (b)(2) of this section if an EPM participant or its related EPM collaborators, collaboration agents , or downstream collaboration agents does any of the following:

(i) Fails to comply with any requirements of this part or is identified as noncompliant through monitoring by HHS (including CMS and OIG) of the applicable model, including but not limited to any of the following:

(A) Avoiding potentially high cost or high severity patients.

(B) Targeting potentially low cost or low severity patients.

(C) Failing to provide medically appropriate services or systematically engaging in the over or under delivery of appropriate care.

(D) Failing to provide beneficiaries with complete and accurate information, including required notices.

(E) Failing to allow beneficiary choice of medically necessary options, including non-surgical options.

(F) Failing to follow the requirements related to sharing arrangements.

(ii) Has signed a sharing arrangement, distribution arrangement, or downstream distribution arrangement that is noncompliant with the requirements of this part.

(iii) Takes any action that threatens the health or safety of patients.

(iv) Avoids at-risk Medicare beneficiaries, as this term is defined in § 425.20.

(v) Avoids patients on the basis of payer status.

(vi) Is subject to sanctions or final actions of an accrediting organization or Federal, state, or local government agency that could lead to the inability to comply with the requirements and provisions of this part.

(vii) Takes any action that CMS determines for program integrity reasons is not in the best interests of the applicable episode payment model, or fails to take any action that CMS determines for program integrity reasons should have been taken to further the best interests of EPM.

(viii) Is subject to action by HHS (including OIG and CMS) or the Department of Justice to redress an allegation of fraud or significant misconduct, including intervening in a False Claims Act qui tam matter, issuing a pre-demand or demand letter under a civil sanction authority, or similar actions.

(ix) Is subject to action involving violations of the physician self-referral law, civil monetary penalties law, Federal anti-kickback statute, antitrust laws, or any other applicable Medicare laws, rules, or regulations that are relevant to EPM.

(2) Remedial actions include the following:

(i) Issuing a warning letter to the EPM participant.

(ii) Requiring the EPM participant to develop a corrective action plan, commonly referred to as a CAP.

(iii) Reducing or eliminating the EPM participant's reconciliation payment.

(iv) Reducing or eliminating the EPM participant's CR incentive payment.

(v) Requiring the EPM participant to terminate a sharing arrangement with an EPM collaborator and prohibit further engagement by the EPM participant in sharing arrangements with the EPM collaborator.

(vi) Terminating the EPM participant's participation in the EPM. Where a participant is terminated from an EPM, the EPM participant will remain liable for all negative NPRA generated from episodes of care that occurred prior to termination.

(3) CMS may add 25 percent to a repayment amount on an EPM participant's reconciliation report if all of the following conditions are true:

(i) CMS has required a corrective action plan from the EPM participant.

(ii) The EPM participant owes a repayment amount to CMS.

(iii) The EPM participant fails to timely comply with the corrective action plan or is noncompliant with the EPM's requirements.

Subpart F—Financial Arrangements and Beneficiary Incentives

§ 512.500 Sharing arrangements under the EPM.

(a) General. (1) An EPM participant may enter into a sharing arrangement with an EPM collaborator to make a gainsharing payment, or to receive an alignment payment, or both. An EPM participant must not make a gainsharing payment or receive an alignment payment except in accordance with a sharing arrangement.

(2) A sharing arrangement must comply with the provisions of this section and all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.

(3) The EPM participant must develop, maintain, and use a set of written policies for selecting individuals and entities to be EPM collaborators. These policies must contain criteria related to, and inclusive of, the quality of care delivered by the potential EPM collaborator. The selection criteria cannot be based directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the EPM participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent.

(4) If an EPM participant enters into a sharing arrangement, its compliance program must include oversight of sharing arrangements and compliance with the applicable requirements of the EPM.

(b) Requirements. (1) A sharing arrangement must be in writing and signed by the parties, and entered into before care is furnished to EPM beneficiaries under the sharing arrangement.

(2) Participation in a sharing arrangement must be voluntary and without penalty for nonparticipation.

(3) The sharing arrangement must require the EPM collaborator and its employees, contractors (including collaboration agents), and subcontractors (including downstream collaboration agents) to comply with the following:

(i) The applicable provisions of this part (including requirements regarding beneficiary notifications, access to records, record retention, and participation in any evaluation, monitoring, compliance, and enforcement activities performed by CMS or its designees);

(ii) All applicable Medicare provider enrollment requirements at § 424.500 of this chapter, including having a valid and active TIN or NPI, during the term of the sharing arrangement; and

(iii) All other applicable laws and regulations.

(4) The sharing arrangement must require the EPM collaborator to have a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the EPM.

(5) The sharing arrangement must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care.

(6) The board or other governing body of the EPM participant must have responsibility for overseeing the EPM participant's participation in the EPM, its arrangements with EPM collaborators, its payment of gainsharing payments, its receipt of alignment payments, and its use of beneficiary incentives in the EPM.

(7) The written agreement memorializing a sharing arrangement must specify the following:

(i) The purpose and scope of the sharing arrangement.

(ii) The identities and obligations of the parties, including specified EPM activities and other services to be performed by the parties under the sharing arrangement;

(iii) The date of the sharing arrangement.

(iv) Management and staffing information, including type of personnel or contractors that will be primarily responsible for carrying out EPM activities.

(v) The financial or economic terms for payment, including the following:

(A) Eligibility criteria for a gainsharing payment.

(B) Eligibility criteria for an alignment payment.

(C) Frequency of gainsharing or alignment payment.

(D) Methodology and accounting formula for determining the amount of a gainsharing payment that is substantially based on quality of care and the provision of EPM activities.

(E) Methodology and accounting formula for determining the amount of an alignment payment.

(8) The sharing arrangement must not—

(i) Induce the EPM participant, EPM collaborator, or any employees, contractors, or subcontractors of the EPM participant or EPM collaborator to reduce or limit medically necessary services to any Medicare beneficiary; or

(ii) Restrict the ability of an EPM collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies, and treatments.

(c) Gainsharing payment, alignment payment, and internal cost savings conditions and restrictions. (1) Gainsharing payments, if any, must —

(i) Be derived solely from reconciliation payments, or internal cost savings, or both;

(ii) Be distributed on an annual basis (not more than once per calendar year);

(iii) Not be a loan, advance payment, or payment for referrals or other business; and

(iv) Be clearly identified as a gainsharing payment at the time it is paid.

(2)(i) To be eligible to receive a gainsharing payment, an EPM collaborator must meet quality of care criteria for the performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment. The quality of care criteria must be established by the EPM participant and directly related to EPM episodes.

(ii) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, an EPM collaborator other than a PGP or an ACO must have directly furnished a billable item or service to an EPM beneficiary during an EPM episode that occurred in the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount.

(iii) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, an EPM collaborator that is a PGP must meet the following criteria:

(A) The PGP must have billed for an item or service that was rendered by one or more members of the PGP to an EPM beneficiary during an EPM episode that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount; and

(B) The PGP must have contributed to EPM activities and been clinically involved in the care of EPM beneficiaries during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount. For example, a PGP might have been clinically involved in the care of EPM beneficiaries by--

(1) Providing care coordination services to EPM beneficiaries during and/or after inpatient admission;

(2) Engaging with an EPM participant in care redesign strategies, and actually performing a role in implementing such strategies, that are designed to improve the quality of care for EPM episodes and reduce EPM episode spending; or

(3) In coordination with other providers and suppliers (such as members of the PGP, the EPM participant, and post-acute care providers), implementing strategies designed to address and manage the comorbidities of EPM beneficiaries.

(iv) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, an EPM collaborator that is an ACO must meet the following criteria:

(A) The ACO must have had an ACO provider/supplier that directly furnished, or an ACO participant that billed for, an item or service that was rendered to an EPM beneficiary during an EPM episode that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount; and

(B) The ACO must have contributed to EPM activities and been clinically involved in the care of EPM beneficiaries during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment or was assessed a repayment amount. For example, an ACO might be have been clinically involved in the care of EPM beneficiaries by--

(1) Providing care coordination services to EPM beneficiaries during and/or after inpatient admission;

(2) Engaging with an EPM participant in care redesign strategies, and actually performing a role in implementing such strategies, that are designed to improve the quality of care and reduce spending for EPM episodes; or

(3) In coordination with providers and suppliers (such as ACO participants, ACO providers/suppliers, the EPM participant, and post-acute care providers), implementing strategies designed to address and manage the comorbidities of EPM beneficiaries.

(3)(i) The methodology for accruing, calculating and verifying internal cost savings must be transparent, measurable, and verifiable in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book).

(ii) The methodology used to calculate internal cost savings must reflect the actual, internal cost savings achieved by the EPM participant through the documented implementation of EPM activities identified by the EPM participant and must exclude:

(A) Any savings realized by any individual or entity that is not the EPM participant; and

(B) “Paper” savings from accounting conventions or past investment in fixed costs.

(4) The total amount of a gainsharing payment for a performance year paid to certain individuals and entities that are EPM collaborators must not exceed the following:

(i) In the case of an EPM collaborator who is a physician or nonphysician practitioner, 50 percent of the Medicare-approved amounts under the PFS for items and services furnished by that physician or nonphysician practitioner to the EPM participant's EPM beneficiaries during EPM episodes that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being made.

(ii) In the case of an EPM collaborator that is a PGP, 50 percent of the Medicare-approved amounts under the PFS for items and services billed by the PGP and furnished to the EPM participant's EPM beneficiaries by members of the PGP during EPM episodes that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being made.

(5) The amount of any gainsharing payments must be determined in accordance with a methodology that is substantially based on quality of care and the provision of EPM activities. The methodology may take into account the amount of such EPM activities provided by an EPM collaborator relative to other EPM collaborators.

(6) For a performance year, the aggregate amount of all gainsharing payments that are derived from a reconciliation payment must not exceed the amount of the reconciliation payment the EPM participant receives from CMS.

(7) No entity or individual, whether a party to a sharing arrangement or not, may condition the opportunity to make or receive gainsharing payments or to make or receive alignment payments on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the EPM participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent.

(8) An EPM participant must not make a gainsharing payment to an EPM collaborator that is subject to any action for noncompliance with this part or the fraud and abuse laws, or for the provision of substandard care in EPM episodes or other integrity problems.

(9) The sharing arrangement must require the EPM participant to recoup any gainsharing payment that contained funds derived from a CMS overpayment on a reconciliation report or was based on the submission of false or fraudulent data.

(10) Alignment payments from an EPM collaborator to an EPM participant may be made at any interval that is agreed upon by both parties, and must not be—

(i) Issued, distributed, or paid prior to the calculation by CMS of a repayment amount reflected in a reconciliation report;

(ii) Loans, advance payments, or payments for referrals or other business; or

(iii) Assessed by an EPM participant if it does not owe a repayment amount.

(11) The EPM participant must not receive any amounts under a sharing arrangement from an EPM collaborator that are not alignment payments.

(12) For a performance year, the aggregate amount of all alignment payments received by the EPM participant must not exceed 50 percent of the EPM participant's repayment amount.

(13) The aggregate amount of all alignment payments from an EPM collaborator to the EPM participant may not be greater than--

(i) With respect to an EPM collaborator other than an ACO, 25 percent of the EPM participant's repayment amount; or

(ii) With respect to an EPM collaborator that is an ACO, 50 percent of the EPM participant's repayment amount.

(14) The methodology for determining alignment payments must not directly account for the volume or value of past or anticipated referrals or business otherwise generated by, between or among the EPM participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent.

(15) All gainsharing payments and any alignment payments must be administered by the EPM participant in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book).

(16) All gainsharing payments and alignment payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(d) Documentation requirements. (1) The EPM participant must do all of the following:

(i) Document the sharing arrangement contemporaneously with the establishment of the arrangement.

(ii) Maintain accurate current and historical lists of all EPM collaborators, including EPM collaborator names and addresses.

(A) Update such lists on at least a quarterly basis.

(B) Publicly report the current and historical lists of EPM collaborators on a webpage on the EPM participant's website.

(iii) Maintain and require each EPM collaborator to maintain contemporaneous documentation with respect to the payment or receipt of any gainsharing payment or alignment payment that includes at a minimum all of the following:

(A) Nature of the payment (gainsharing payment or alignment payment).

(B) Identity of the parties making and receiving the payment.

(C) Date of the payment.

(D) Amount of the payment.

(E) Date and amount of any recoupment of all or a portion of an EPM collaborator's gainsharing payment.

(F) Explanation for each recoupment, such as whether the EPM collaborator received a gainsharing payment that contained funds derived from a CMS overpayment on a reconciliation report, or was based on the submission of false or fraudulent data.

(2) The EPM participant must keep records of the following:

(i) Its process for determining and verifying its potential and current EPM collaborators' eligibility to participate in Medicare.

(ii) Its plan to track internal cost savings.

(iii) Information on the accounting systems used to track internal cost savings.

(iv) A description of current health information technology, including systems to track reconciliation payments and internal cost savings.

(v) Its plan to track gainsharing payments and alignment payments.

(3) The EPM participant must retain and provide access to, and must require each EPM collaborator to retain and provide access to, the required documentation in accordance with § 512.110.

§ 512.505 Distribution arrangements under the EPM.

(a) General. (1) A PGP or ACO that has entered into a sharing arrangement with an EPM participant may distribute all or a portion of any gainsharing payment it receives from the EPM participant only in accordance with a distribution arrangement.

(2) All distribution arrangements must comply with the provisions of this section and all other applicable laws and regulations, including the fraud and abuse laws.

(b) Requirements. (1) All distribution arrangements must be in writing and signed by the parties, contain the date of the agreement, and be entered into before care is furnished to EPM beneficiaries under the distribution arrangement.

(2) Participation in a distribution arrangement must be voluntary and without penalty for nonparticipation.

(3) The distribution arrangement must require the collaboration agent to comply with all applicable laws and regulations.

(4) The opportunity to make or receive a distribution payment must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the EPM participant, any EPM collaborator, any collaboration

agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent.

(5) The amount of any distribution payments from an ACO must be determined in accordance with a methodology that is substantially based on quality of care and the provision EPM activities and that may take into account the amount of such EPM activities provided by a collaboration agent relative to other collaboration agents.

(6) The amount of any distribution payments from a PGP to a member must be determined either in a manner that complies with §411.352(g) of this chapter or in accordance with a methodology that is substantially based on quality of care and the provision EPM activities and that may take into account the amount of such EPM activities provided by a collaboration agent relative to other collaboration agents.

(7) Except for a distribution payment from a PGP to a PGP member that complies with §411.352(g), a collaboration agent is eligible to receive a distribution payment only if the collaboration agent furnished or billed for an item or service rendered to an EPM beneficiary during an EPM episode that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed.

(8) Except for a distribution payment from a PGP to a PGP member that complies with §411.352(g), the total amount of distribution payments for a performance year paid to a collaboration agent must not exceed the following:

(i) In the case of a collaboration agent that is physician or nonphysician practitioner, 50 percent of the total Medicare-approved amounts under the PFS for items and services furnished by the collaboration agent to the EPM participant's EPM beneficiaries during EPM episodes that

occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed.

(ii) In the case of a collaboration agent that is a PGP, 50 percent of the total Medicare-approved amounts under the PFS for items and services billed by the PGP for items and services furnished by members of the PGP to the EPM participant's EPM beneficiaries during EPM episodes that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed.

(9) With respect to the distribution of any gainsharing payment received by a PGP or ACO, the total amount of all distribution payments must not exceed the amount of the gainsharing payment received by the EPM collaborator from the EPM participant.

(10) All distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(11) The collaboration agent must retain the ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

(12) The distribution arrangement must not—

(i) Induce the collaboration agent to reduce or limit medically necessary items and services to any Medicare beneficiary; or

(ii) Reward the provision of items and services that are medically unnecessary.

(13) The EPM collaborator must maintain contemporaneous documentation regarding distribution arrangements in accordance with § 512.110, including the following:

(i) The relevant written agreements.

(ii) The date and amount of any distribution payment(s);

(iii) The identity of each collaboration agent that received a distribution payment; and

(iv) A description of the methodology and accounting formula for determining the amount of any distribution payment.

(14) The EPM collaborator may not enter into a distribution arrangement with any individual or entity that has a sharing arrangement with the same EPM participant.

(15) The EPM collaborator must retain and provide access to, and must require collaboration agents to retain and provide access to, the required documentation in accordance with § 512.110.

§ 512.510 Downstream distribution arrangements under the EPM.

(a) General. (1) An ACO participant that is a PGP and that has entered into a distribution arrangement with an EPM collaborator that is an ACO may distribute all or a portion of any distribution payment it receives from the EPM collaborator only in accordance with a downstream distribution arrangement.

(2) All downstream distribution arrangements must comply with the provisions of this section and all applicable laws and regulations, including the fraud and abuse laws.

(b) Requirements. (1) All downstream distribution arrangements must be in writing and signed by the parties, contain the date of the agreement, and be entered into before care is furnished to EPM beneficiaries under the downstream distribution arrangement.

(2) Participation in a downstream distribution arrangement must be voluntary and without penalty for nonparticipation.

(3) The downstream distribution arrangement must require the downstream collaboration agent to comply with all applicable laws and regulations.

(4) The opportunity to make or receive a downstream distribution payment must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the EPM participant, any EPM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with an EPM participant, EPM collaborator, collaboration agent, or downstream collaboration agent.

(5) The amount of any downstream distribution payment must be determined either in a manner that complies with §411.352(g) of this chapter or in accordance with a methodology that is substantially based on the quality of care and the provision of EPM activities and that may take into account the amount of such EPM activities provided by a downstream collaboration agent relative to other downstream collaboration agents.

(6) Except for a downstream distribution payment that complies with §411.352(g), a downstream collaboration agent is eligible to receive a downstream distribution payment only if the PGP billed for an item or service furnished by the downstream collaboration agent to an EPM beneficiary during an EPM episode that occurred during the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprise the gainsharing payment from which the ACO made the distribution payment to the PGP that is an ACO participant.

(7) Except for a downstream distribution payment that complies with §411.352(g), the total amount of downstream distribution payments for a performance year paid to a downstream collaboration agent must not exceed 50 percent of the total Medicare-approved amounts under the PFS for services billed by the PGP and furnished by the downstream collaboration agent to the EPM participant's EPM beneficiaries during EPM episodes that occurred during the same

performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment from which the ACO made the distribution payment to the PGP that is an ACO participant.

(8) The total amount of all downstream distribution payments made to downstream collaboration agents must not exceed the amount of the distribution payment received by the PGP from the ACO.

(9) All downstream distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(10) The downstream collaboration agent must retain his or her ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

(11) The downstream distribution arrangement must not—

(i) Induce the downstream collaboration agent to reduce or limit medically necessary services to any Medicare beneficiary; or

(ii) Reward the provision of items and services that are medically unnecessary.

(12) The PGP must maintain contemporaneous documentation regarding downstream distribution arrangements in accordance with § 512.110, including the following:

(i) The relevant written agreements.

(ii) The date and amount of any downstream distribution payment.

(iii) The identity of each downstream collaboration agent that received a downstream distribution payment;.

(iv) A description of the methodology and accounting formula for determining the amount of any downstream distribution payment.

(13) The PGP may not enter into a downstream distribution arrangement with any PGP member who has--

(i) A sharing arrangement with an EPM participant; or

(ii) A distribution arrangement with the ACO the PGP is a participant in.

(14) The PGP must retain and provide access to, and must require downstream collaboration agents to retain and provide access to, the required documentation in accordance with § 512.110.

§ 512.520 Enforcement authority under the EPM.

(a) OIG authority. OIG authority is not limited or restricted by the provisions of the EPM, including the authority to audit, evaluate, investigate, or inspect the EPM participant, EPM collaborators, or any other person or entity or their records, data, or information, without limitation.

(b) Other authorities. None of the provisions of the EPM limits or restricts the authority of any other government agency permitted by law to audit, evaluate, investigate, or inspect the EPM participant, EPM collaborators, or any other person or entity or their records, data, or information, without limitation.

§ 512.525 Beneficiary engagement incentives under the EPM.

(a) General. EPM participants may choose to provide in-kind patient engagement incentives to beneficiaries in an EPM episode, subject to the following conditions:

(1) The incentive must be provided directly by the EPM participant or by an agent of the EPM participant under the EPM participant's direction and control to the EPM beneficiary during an EPM episode.

(2) The item or service provided must be reasonably connected to medical care provided to an EPM beneficiary during an EPM episode.

(3) The item or service must be a preventive care item or service or an item or service that advances a clinical goal, as listed in paragraph (c) of this section, for a beneficiary in an EPM episode by engaging the beneficiary in better managing his or her own health.

(4) The item or service must not be tied to the receipt of items or services outside the EPM episode.

(5) The item or service must not be tied to the receipt of items or services from a particular provider or supplier.

(6) The availability of the items or services must not be advertised or promoted except that a beneficiary may be made aware of the availability of the items or services at the time the beneficiary could reasonably benefit from them.

(7) The cost of the items or services must not be shifted to another federal health care program, as defined at section 1128B(f) of the Act.

(b) Technology provided to an EPM beneficiary. Beneficiary engagement incentives involving technology are subject to the following additional conditions:

(1) Items or services involving technology provided to a beneficiary may not exceed $1,000 in retail value for any one beneficiary in any one EPM episode.

(2) Items or services involving technology provided to a beneficiary must be the minimum necessary to advance a clinical goal, as listed in paragraph (c) of this section, for a beneficiary in an EPM episode.

(3) Items of technology exceeding $100 in retail value must—

(i) Remain the property of the EPM participant; and

(ii) Be retrieved from the beneficiary at the end of the EPM episode. The EPM participant must document all retrieval attempts, including the ultimate date of retrieval. Documented, diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement.

(c) Clinical goals of the EPM. The following are the clinical goals of the EPM, which may be advanced through beneficiary incentives:

(1) Beneficiary adherence to drug regimens.

(2) Beneficiary adherence to a care plan.

(3) Reduction of readmissions and complications resulting from treatment for the EPM clinical condition.

(4) Management of chronic diseases and conditions that may be affected by treatment for the EPM clinical condition.

(d) Documentation of beneficiary engagement incentives. (1) EPM participants must maintain documentation of items and services furnished as beneficiary engagement incentives that exceed $25 in retail value.

(2) The documentation established contemporaneously with the provision of the items and services must include at least the following:

(i) The date the incentive is provided.

(ii) The identity of the beneficiary to whom the item or service was provided.

(3) The documentation regarding items of technology exceeding $100 in retail must also include contemporaneous documentation of any attempt to retrieve technology at the end of an EPM episode as described in paragraph (b)(3) of this section.

(4) The EPM participant must retain and provide access to the required documentation in accordance with § 512.110.

Subpart G—Waivers

§ 512.600 Waiver of direct supervision requirement for certain post-discharge home visits.

(a) General. CMS waives the requirement in § 410.26(b)(5) of this chapter that services and supplies furnished incident to a physician's service must be furnished under the direct supervision of the physician (or other practitioner) to permit home visits as specified in this section. The services furnished under this waiver are not considered to be "hospital services," even when furnished by the clinical staff of the hospital.

(b) General supervision of qualified personnel. The waiver of the direct supervision requirement in § 410.26(b)(5) of this chapter applies only in the following circumstances:

(1) The home visit is furnished during the episode to a beneficiary who has been discharged from an anchor hospitalization.

(2) The home visit is furnished at the beneficiary's home or place of residence.

(3) The beneficiary does not qualify for home health services under sections 1835(a) and 1814(a) of the Act at the time of any such home visit.

(4) The visit is furnished by clinical staff under the general supervision of a physician or non-physician practitioner. Clinical staff are individuals who work under the supervision of a physician or other qualified health care professional, and who are allowed by law, regulation, and facility policy to perform or assist in the performance of a specific professional service, but do not individually report that professional service.

(5) The number of visits that are furnished to the beneficiary during –

(i) An AMI episode, is up to 13 post-discharge home visits;

(ii) A CABG episode, is up to 9 post-discharge home visits; and

(iii) A SHFFT episode, is up to 9 post-discharge home visits.

(c) Payment. Up to the maximum post-discharge home visits for a specific EPM episode, as described in paragraph (b)(5) of this section, may be billed under Part B by the physician or non-physician practitioner or by the participant hospital to which the supervising physician has reassigned his or her billing rights.

(d) Other requirements. All other Medicare rules for coverage and payment of services incident to a physician's service continue to apply.

§ 512.605 Waiver of certain telehealth requirements.

(a) Waiver of the geographic site requirements. Except for the geographic site requirements for a face-to-face encounter for home health certification, CMS waives the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act for episodes being tested in an EPM, but only for services that--

(1) May be furnished via telehealth under existing requirements; and

(2) Are included in the episode in accordance with § 512.210.

(b) Waiver of the originating site requirements. Except for the originating site requirements for a face-to-face encounter for home health certification, CMS waives the originating site requirements under section 1834(m)(4)(C)(ii)(I) through (VIII) of the Act for episodes being tested in an EPM to permit a telehealth visit to originate in the beneficiary's home or place of residence, but only for services that—

(1) May be furnished via telehealth under existing requirements; and

(2) Are included in an EPM episode in accordance with § 512.210.

(c) Waiver of selected payment provisions. (1) CMS waives the payment requirements under section 1834(m)(2)(A) so that the facility fee normally paid by Medicare to an originating site for a telehealth service is not paid if the service is originated in the beneficiary's home or place of residence.

(2) CMS waives the payment requirements under section 1834(m)(2)(B) to allow the distant site payment for telehealth home visit HCPCS codes unique to this model to more accurately reflect the resources involved in furnishing these services in the home by basing payment upon the comparable office visit relative value units for work and malpractice under the Physician Fee Schedule.

(d) Other requirements. All other requirements for Medicare coverage and payment of telehealth services continue to apply, including the list of specific services approved to be furnished by telehealth.

§ 512.610 Waiver of SNF 3-day rule.

(a) Applicability of the SNF 3-day rule waiver. CMS determines that the SNF 3-day rule is –

(1) Waived for the AMI model,

(2) Not waived for the CABG model, and

(3) Not waived for the SHFFT model.

(b) Waiver of the SNF 3-day rule. For episodes being tested in those EPMs where the SNF 3-day rule is waived under paragraph (a) of this section, CMS waives the SNF 3-day rule for coverage of a SNF stay for episodes that begin on or after April 1, 2018, for an EPM beneficiary following the anchor hospitalization, but only if the SNF is identified on the

applicable calendar quarter list of qualified SNFs at the time of EPM beneficiary admission to the SNF.

(1) CMS determines the qualified SNFs for each calendar quarter based on a review of the most recent rolling 12 months of overall star ratings on the Five-Star Quality Rating System for SNFs on the Nursing Home Compare website. 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 website the list of qualified SNFs in advance of the calendar quarter and the waiver only applies for a beneficiary who has been discharged from an anchor hospitalization if the SNF is included on the applicable calendar quarter list for the date of the beneficiary's admission to the SNF.

(c) Financial liability for uncovered SNF services. CMS will determine the financial liability for uncovered SNF services if, subsequent to an EPM hospital applying the SNF 3-day rule waiver under this section, an EPM hospital incorrectly applies the SNF 3-day rule waiver.

(1) If the EPM hospital discharges a beneficiary to a SNF that is not a qualified SNF under paragraph (b) of this section and provides the beneficiary with a discharge planning notice, as described at § 512.450(b)(6), to the beneficiary at the time of discharge to a SNF then the SNF coverage requirements apply and the beneficiary may be financially liable for uncovered SNF services.

(2) The EPM hospital will be financially liable for the SNF stay and the SNF must not bill the beneficiary for the costs of the uncovered SNF services furnished during the SNF stay if, subsequent to an EPM hospital applying the SNF 3-day rule waiver under this section, CMS determines the EPM hospital discharges a beneficiary --

(i) To a SNF that is not a qualified SNF under paragraph (b) of this section and the EPM hospital does not provide the beneficiary with a discharge planning notice, as described at § 512.450(b)(6)

(ii) That is in an EPM where the SNF 3-day rule waiver is not applicable under paragraph (a) of this section; or

(iii) During an episode that begins prior to April 1, 2018, where the SNF 3-day rule waiver is not applicable under paragraph (b) of this section.

(d) Other requirements. All other Medicare rules for coverage and payment of Part A-covered SNF services continue to apply.

§ 512.615 Waiver of certain post-operative billing restrictions.

(a) Waiver to permit certain services to be billed separately during the 90-day post-operative global surgical period. CMS waives the billing requirements for global surgeries to allow the separate billing of certain post-discharge home visits described under § 512.600, including those related to recovery from the surgery, as described in paragraph (b) of this section, for episodes being tested in an EPM.

(b) Services to which the waiver applies. Up to the maximum post-discharge home visits for a specific EPM episode, as described in § 512.600(b)(5), including those related to recovery from the surgery, per EPM episode may be billed separately under Medicare Part B by the physician or non-physician practitioner, or by the participant hospital to which the physician or non-physician practitioner has reassigned his or her billing rights.

(c) Other requirements. All other Medicare rules for global surgery billing during the 90-day post-operative period continue to apply.

§ 512.620 Waiver of deductible and coinsurance that otherwise apply to reconciliation payments or repayments.

(a) Waiver of deductible and coinsurance. CMS waives the requirements of sections 1813 and 1833(a) of the Act for Medicare Part A and Part B payment systems only to the extent necessary to make reconciliation payments or receive repayments based on the NPRA that reflect the episode payment methodology under the final payment model for EPM participant hospitals.

(b) Reconciliation payments or repayments. Reconciliation payments or repayments do not affect the beneficiary cost-sharing amounts for the Medicare Part A and Part B services provided under an EPM.

§ 512.630 Waiver of physician definition for furnishing cardiac rehabilitation and intensive cardiac rehabilitation services to an EPM beneficiary.

(a) General. Section 410.49 of this chapter requires cardiac rehabilitation (CR) and intensive cardiac rehabilitation (ICR) services to be furnished under the direction of a physician as defined in § 410.49(a) of this chapter.

(b) Waiver of the physician definition. For a provider or supplier of CR and ICR services to an EPM beneficiary during an AMI and CABG episode, as defined in § 512.2, CMS waives the physician definition to allow the functions of supervising physician, prescribing exercise, and establishing, reviewing, and signing an individualized treatment plan for CR and ICR services to be furnished under the direction of –

(1) A physician, as defined in section 1861(r)(1) of the Act, or

(2) A qualified nonphysician practitioner, as defined by CMS.

(c) Other definitions and requirements. All other definitions and requirements in § 410.49 of this chapter related to a physician or supervising physician continue to apply.

Subpart H—CR Incentive Payment Model for EPM and Medicare Fee-for-Service Participants

§ 512.700 Basis and scope.

(a) Basis. This subpart implements the cardiac rehabilitation and intensive cardiac rehabilitation (CR) incentive payment model under section 1115A of the Act.

(b) Scope. This subpart sets forth:

(1) The participants in the CR incentive payment model;

(2) The CR/ICR services that count toward CR incentive payments;

(3) The methodology for determining CR incentive payments;

(4) Provisions for FFS-CR participants that are not EPM participants.

§ 512.703 CR incentive payment model participants.

(a) Selection of CR MSAs. The MSAs eligible for selection for AMI and CABG models will be classified into one of up to ten groups based on their historic utilization of CR/ICR services. Within each group, EPM-CR and FFS-CR MSAs will be randomly selected. The number of EPM-CRs to be selected within each group will be distributed proportionately between the groups based on the assignment of the 98 EPM MSAs. The same number of FFS-MSAs will then be drawn from each group.

(b) Hospitals eligible for CR incentive payments. (1) Hospitals that are AMI and CABG model participants located in the EPM-CR MSAs.

(2) FFS-CR Participants. Hospitals located in the FFS-CR MSAs that would meet all requirements in § 512.100(b) to be an AMI or CABG model participant if the hospital were located in an MSA selected for the AMI and CABG models.

§ 512.705 CR/ICR services that count towards CR incentive payments.

(a) Identification of CR/ICR services. CR/ICR services are identified by the HCPCS codes for CR/ICR services included in the CMS change request that implements the National Coverage Determination in the CR performance year.

(b) CR participant eligibility for CR incentive payment. (1) For EPM-CR participants, CR/ICR services paid by Medicare to any provider or supplier for AMI and CABG model beneficiaries during AMI and CABG model episodes result in eligibility for CR incentive payments.

(2) For FFS-CR participants, CR/ICR services paid by Medicare to any provider or supplier for beneficiaries during AMI care periods and CABG care periods that would meet the requirements to be AMI and CABG model episodes in accordance with all provisions in subpart

B if the FFS-CR participant were an EPM participant result in eligibility for CR incentive payments.

(c) Overlap between AMI care periods and CABG care periods with AMI and CABG model episodes. (1) An AMI care period or CABG care period does not begin if the beneficiary is in an AMI or CABG model episode when the AMI care period or CABG care period would otherwise begin.

(2) An AMI care period or CABG care period is canceled if at any time during the AMI care period or CABG care period the beneficiary initiates an AMI or CABG model episode.

(d) CR incentive payment time period. All AMI and CABG model episodes and AMI care periods and CABG care periods begin on or after July 1, 2017 and end on or before December 31, 2021.

§ 512.710 Determination of CR incentive payments.

(a) General. CMS provides a CR incentive payment for each CR performance year to each EPM-CR participant and FFS-CR participant based on CR/ICR services paid by Medicare to any provider or supplier for beneficiaries in AMI and CABG model episodes or AMI and CABG care periods, respectively. CMS makes CR incentive payments from the Medicare Part B Trust Fund to CR participants, and also submits beneficiary-specific CR amounts to the CMS Master Database Management System. The initial level of the per-service CR incentive amount is $25 per CR/ICR service for each of up to 11 CR/ICR services paid for by Medicare. For those CR/ICR services in an AMI or CABG model episode or AMI care period or CABG care period that exceed 11, the per-service CR incentive amount increases to $175 per CR/ICR service for each additional CR/ICR service paid for by Medicare.

(b) Determination of CR incentive payment. At the same time that CMS carries out the determination of NPRA and reconciliation process for an EPM performance year as specified in § 512.305 for EPM participants, CMS also determines each CR participant's CR incentive payment for the CR performance year according to the following:

(1) CR amount when the CR service count is less than 12. CMS determines the CR amount for a beneficiary in an AMI or CABG model episode or AMI care period or CABG care period with a CR service count less than 12 by multiplying the CR service count by $25.

(2) CR amount when the CR service count is 12 or more. CMS determines the CR amount for a beneficiary in an AMI or CABG model episode or AMI care period or CABG care period with a CR service count of 12 or more as the sum of $275 ($25 multiplied by 11 for the first 11 CR/ICR services paid for by Medicare) and $175 multiplied by the difference between the CR service count and 11.

(3) CR incentive payment. CMS sums the CR amounts determined in paragraphs (b)(1) and (2) of this section across the CR participant's beneficiaries in AMI and CABG model episodes or AMI care periods and CABG care periods for a given CR performance year to determine the CR incentive payment for the CR performance year.

(c) Relation of CR incentive payments to reconciliation and Medicare repayments under EPMs. CR incentive payments to EPM-CR participants determined under §512.710(b) are exclusive of reconciliation payments and Medicare repayment amounts determined under § 512.305(d).

(d) Relation of CR incentive payments to sharing arrangements for EPM-CR participants. CR incentive payments under §512.710(b) are not eligible for and may not be distributed under sharing arrangements specified in § 512.500.

(e) Exclusion of CR incentive payments when updating quality-adjusted target prices for EPM-CR participants. CR incentive payments under § 512.710(b) are excluded when updating quality-adjusted target prices for EPM performance years 3 through 5.

(f) CR incentive payment report. At the same time CMS issues the reconciliation report as specified in § 512.305(f) to EPM participants, CMS issues each EPM-CR participant and each FFS-CR participant a CR incentive payment report for the CR performance year. Each report contains the following:

(1) The number of AMI and CABG model episodes or AMI care periods and CABG care periods attributed to the CR participant in which Medicare paid for 11 or fewer CR/ICR services for a beneficiary during the CR performance year, if any.

(2) The total number of CR/ICR services Medicare paid for during AMI and CABG model episodes or AMI care periods and CABG care periods identified in paragraph (f)(1) of this section.

(3) The amount of the CR incentive payment attributable to the AMI and CABG model episodes or AMI care periods and CABG care periods identified in paragraph (f)(1) of this section.

(4) The number of AMI and CABG model episodes or AMI care periods and CABG care periods attributed to the CR participant in which Medicare paid for 12 or more CR/ICR services for a beneficiary during the CR performance year, if any.

(5) The total number of CR/ICR services Medicare paid for during AMI and CABG model episodes or AMI care periods and CABG care periods identified in paragraph (f)(4) of this section.

(6) The amount of the CR incentive payment attributable to the AMI and CABG model episodes or AMI care periods and CABG care periods identified in paragraph (f)(4) of this section.

(7) The total amount of the CR incentive payment.

(g) Timing of CR incentive payments. CMS makes CR incentive payments on a retrospective basis subject to the following:

(1) For EPM-CR participants, CMS makes the CR incentive payment, if any, concurrently with EPM reconciliation payments or repayment amounts assessed for a specific EPM and CR performance year, subject to the appeals process for EPM participants in § 512.310.

(2) For FFS-CR participants, CMS makes the CR incentive payments, if any, at the same time as for EPM-CR participants, subject to the provisions in § 512.720.

Provisions for FFS-CR Participants

§ 512.715 Access to records and retention for FFS-CR participants.

FFS-CR participants and any other individuals or entities providing items or services to a FFS-CR beneficiary must do all of the following:

(a) Allow the Government, including CMS, OIG, HHS and the Comptroller General or their designees, scheduled and unscheduled access to all books, contracts, records, documents, and other evidence (including data related to CR/ICR service utilization and payments, billings, and the documentation required under § 512.740(b)) sufficient to enable the audit, evaluation, inspection, or investigation of the following:

(1) The individual's or entity's compliance with CR incentive payment model requirements.

(2) The obligation to repay any CR incentive payments owed to CMS.

(b) Maintain all such books, contracts, records, documents, and other evidence for a period of 10 years from the last day of the FFS-CR participant's participation in the CR incentive payment model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

(1) CMS determines a particular record or group of records should be retained for a longer period and notifies the FFS-CR participant at least 30 calendar days before the disposition date; or

(2) There has been a dispute or allegation of fraud or similar fault against the FFS-CR participant or any other individual or entity providing items or services to a FFS-CR beneficiary, in which case the records must be maintained for 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

§ 512.720 Appeals process for FFS-CR participants.

(a) Notice of calculation error (first level of appeal). Subject to the limitations on review in subpart H of this part, if a FFS-CR participant wishes to dispute calculations involving a matter related to a CR incentive payment, the FFS-CR participant is required to provide written notice of the error, in a form and manner specified by CMS.

(1) Unless the FFS-CR participant provides such notice, CMS deems final the applicable CR incentive payment report 45 calendar days after the applicable CR incentive payment report is issued and proceeds with the payment as applicable.

(2) If CMS receives a notice of a calculation error within 45 calendar days of the issuance of the applicable CR incentive payment report, CMS responds in writing within 30 calendar days to either confirm that there was an error in the calculation or verify that the

calculation is correct, although CMS reserves the right to an extension upon written notice to the FFS-CR participant.

(3) Only FFS-CR participants may use notice of calculation error process described in this part.

(b) Dispute resolution process (second level of appeal). (1) If the FFS-CR participant is dissatisfied with CMS's response to the notice of a calculation error, the FFS-CR participant may request a reconsideration review in a form and manner as specified by CMS.

(2) The reconsideration request must provide a detailed explanation of the basis for the dispute and include supporting documentation for the FFS-CR participant’s assertion that CMS or its representatives did not accurately calculate the CR incentive payment in accordance with subpart H of this part.

(3) If CMS does not receive a request for reconsideration from the FFS-CR participant within 10 calendar days of the issue date of CMS's response to the FFS-CR participant’s notice of calculation error, then CMS's response to the calculation error is deemed final and CMS proceeds with the applicable processes, as described in subpart H of this part.

(4) The CMS reconsideration official notifies the FFS-CR participant in writing within 15 calendar days of receiving the FFS-CR participant's review request of the following:

(i) The date, time, and location of the review.

(ii) The issues in dispute.

(iii) The review procedures.

(iv) The procedures (including format and deadlines) for submission of evidence.

(5) The CMS reconsideration official takes all reasonable efforts to schedule the review to occur no later than 30 days after the date of receipt of the notification.

(6) The provisions at § 425.804(b), (c), and (e) of this chapter are applicable to reviews conducted in accordance with the reconsideration review process for the FFS-CR participant.

(7) The CMS reconsideration official issues a written determination within 30 days of the review. The determination is final and binding.

(8) Only FFS-CR participants may use the dispute resolution process described in this part.

(c) Exception to the notice of calculation error process. If the FFS-CR participant contests a matter that does not involve an issue contained in, or a calculation which contributes to a CR incentive payment report a notice of calculation error is not required. In these instances, if CMS does not receive a request for reconsideration from the FFS-CR participant within 10 calendar days of the notice of the initial determination, the initial determination is deemed final and CMS proceeds with the action indicated in the initial determination.

(d) Notice of FFS-CR participant termination from the CR incentive payment model. If an FFS-CR participant receives notification that it has been terminated from the CR incentive payment model, it must provide a written request for reconsideration to CMS requesting review of the termination within 10 calendar days of the notice. CMS has 30 days to respond to the FFS-CR participant's request for review. If the FFS-CR participant fails to notify CMS, the termination is deemed final.

(e) Limitations on review. In accordance with section 1115A (d) (2) of the Act, there is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

(1) The selection of models for testing or expansion under section 1115A of the Act.

(2) The selection of organizations, sites, or participants to test those models selected.

(3) The elements, parameters, scope, and duration of such models for testing or dissemination.

(4) Determinations regarding budget neutrality under section 1115A (b) (3) of Act.

(5) The termination or modification of the design and implementation of a model under section 1115A (b) (3)(B) of Act.

(6) Decisions to expand the duration and scope of a model under section 1115A(c) of the Act, including the determination that a model is not expected to meet criteria described in paragraph (e)(1) or (2) of this section.

§ 512.725 Data sharing for FFS-CR participants.

(a) General. CMS makes available to FFS-CR participants, through the most appropriate means, data that CMS determines may be useful to FFS-CR participants to do the following:

(1) Determine appropriate ways to increase the coordination of care.

(2) Improve quality.

(3) Enhance efficiencies in the delivery of care.

(4) Otherwise achieve the goals of the model described in this section.

(b) Beneficiary-identifiable data. (1) CMS makes beneficiary-identifiable data available to a FFS-CR participant in accordance with applicable privacy laws and only in response to the FFS-CR participant's request for such data for a beneficiary who has been furnished a billable service by the FFS-CR participant corresponding to the AMI care period or CABG care period definitions.

(2) The minimum data necessary to achieve the goals of the CR incentive payment test, as determined by CMS, may be provided under this section as frequently as on a quarterly basis throughout the FFS-CR participant's participation in the CR incentive payment test.

§ 512.730 Compliance enforcement for FFS-CR participants.

(a) General. FFS-CR participants must comply with all of the requirements outlined in this subpart. Except as specifically noted in this subpart, the regulations under this subpart must not be construed to affect the payment, coverage, program integrity, or other requirements (such as those in parts 412 and 482 of this chapter) that apply to providers and suppliers under this chapter.

(b) Failure to comply. (1) CMS may take one or more of the remedial actions set forth in paragraph (b)(2) of this section if a FFS-CR participant does any of the following:

(i) Fails to comply with any requirements of this subpart or is identified as noncompliant through monitoring by HHS (including CMS and OIG) of the CR incentive payment model, including but not limited to the following:

(A) Avoiding potentially high severity patients.

(B) Targeting potentially low severity patients.

(C) Failing to provide medically appropriate services or systematically engaging in the over or under delivery of appropriate care.

(D) Failing to provide beneficiaries with complete and accurate information.

(ii) Takes any action that threatens the health or safety of patients.

(iii) Avoids at risk Medicare beneficiaries, as this term is defined in § 425.20.

(iv) Avoids patients on the basis of payer status.

(v) Is subject to sanctions or final actions of an accrediting organization or Federal, state, or local government agency that could lead to the inability to comply with the requirements and provisions of this subpart.

(vi) Takes any action that CMS determines for program integrity reasons is not in the best interests of the CR incentive payment model, or fails to take any action that CMS determines for program integrity reasons should have been taken to further the best interests of CR incentive payment model.

(viii) Is subject to action by HHS (including OIG and CMS) or the Department of Justice to redress an allegation of fraud or significant misconduct, including intervening in a False Claims Act qui tam matter, issuing a pre demand or demand letter under a civil sanction authority, or similar actions.

(ix) Is subject to action involving violations of the physician self-referral law, civil monetary penalties law, Federal anti-kickback statute, antitrust laws, or any other applicable Medicare laws, rules, or regulations that are relevant to the CR incentive payment model.

(2) Remedial actions include the following:

(i) Issuing a warning letter to the FFS-CR participant.

(ii) Requiring the FFS-CR participant to develop a corrective action plan, commonly referred to as a CAP.

(iii) Reducing or eliminating the FFS-CR participant's CR incentive payment.

(iv) Terminating the FFS-CR participant from the CR incentive payment model.

§ 512.735 Enforcement authority for FFS-CR participants.

(a) OIG authority. OIG authority is not limited or restricted by the provisions of the CR incentive payment model, including the authority to audit, evaluate, investigate, or inspect the FFS-CR participant, or any other person or entity or their records, data, or information, without limitation.

(b) Other authorities. None of the provisions of the CR incentive payment model limits or restricts the authority of any other government agency permitted by law to audit, evaluate, investigate, or inspect the FFS-CR participant or any other person or entity or their records, data, or information, without limitation.

§ 512.740 Beneficiary engagement incentives for FFS-CR participant use.

(a) General. FFS-CR participants may choose to provide transportation to CR/ICR services as in-kind patient engagement incentives under the CR incentive payment model, subject to the following conditions:

(1) The incentive must be provided directly by the FFS-CR participant or by an agent of the FFS-CR participant under the FFS-CR participant's direction and control to the FFS-CR beneficiary during an AMI care period or CABG care period.

(2) Transportation must not be tied to the receipt of items or services other than CR/ICR services during AMI care periods or CABG care periods.

(3) Transportation must not be tied to the receipt of items or services from a particular provider or supplier.

(5) The availability of transportation must not be advertised or promoted except that a beneficiary may be made aware of the availability of transportation at the time the beneficiary could reasonably benefit from it.

(6) The cost of transportation must not be shifted to another federal health care program, as defined at section 1128B(f) of the Act.

(b) Documentation of beneficiary engagement incentives. (1) FFS-CR participants must maintain documentation of transportation furnished as a beneficiary engagement incentive that exceeds $25 in retail value.

(2) The documentation established contemporaneously with the provision of transportation must include at least the following:

(i) The date the incentive is provided.

(ii) The identity of the beneficiary to whom the transportation was provided.

(3) The FFS-CR participant must retain and provide access to the required documentation in accordance with § 512.715.

§ 512.745 Waiver of physician definition for furnishing CR and ICR services to a FFS-CR beneficiary.

(a) General. Section 410.49 of this chapter requires cardiac rehabilitation and intensive cardiac rehabilitation services to be furnished under the direction of a physician as defined in § 410.49(a) of this chapter.

(b) Waiver of the physician definition. For a provider or supplier of CR or ICR services to a FFS-CR beneficiary during an AMI care period or CABG care period, as defined in § 512.2. CMS waives the physician definition to allow the functions of supervising physician, prescribing exercise, and establishing, reviewing, and signing an individualized treatment plan for CR or ICR services to be furnished under the direction of –

(1) A physician, as defined in section 1861(r)(1) of the Act; or

(2) A qualified nonphysician practitioner, as defined by CMS.

(c) Other definitions and requirements. All other definitions and requirements in § 410.49 of this chapter related to a physician or supervising physician continue to apply.

Subparts I-J [Reserved]

Subpart K—Model Termination

§ 512.900 Termination of an episode payment model.

CMS may terminate any episode payment model for reasons including but not limited to:

(a) CMS no longer has the funds to support the applicable model; or

(b) CMS terminates the applicable model in accordance with section 1115A(b)(3)(B) of the Act. As provided by section 1115A(d)(2) of the Act, termination of the model is not subject to administrative or judicial review.

§ 512.905 Termination of the CR Incentive Payment Model.

CMS may terminate the CR incentive payment model for reasons including but not limited to:

(a) CMS no longer has the funds to support the CR incentive payment model; or

(b) CMS terminates the applicable model in accordance with section 1115A(b)(3)(B) of the Act. As provided by section 1115A(d)(2) of the Act, termination of the model is not subject to administrative or judicial review.

Dated: July 19, 2016.

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Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

Dated: July 20, 2016.

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Sylvia M. Burwell,

Secretary,

Department of Health and Human Services.

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