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**PROPOSED RULE: 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)
[CMS-5519-P]**

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I. & II. Executive Summary and Background

CMS proposes to make modifications to the CJR model, create three EPMs for care of AMI, CABG, and SHFFT, and create the CR model using its authority under section 1115A. Selected IPPS hospitals would be required to participate for 5 performance years (July 1, 2017 through December 31, 2021). EPM participants (acute care hospitals) would receive retrospectively bundled payments for episodes of care for patients with conditions that are common in the Medicare population and for which spending exhibits substantial variation (AMI, CABG, and SHFFT). Each episode would include all related care within 90 days of discharge from the initial hospitalization. Reconciliation payments (from CMS to participants) and repayments (from participants to CMS) are conditioned upon meeting quality thresholds and cost targets. Under appropriate agreements, EPM participants may engage in sharing gain, risk, and internal cost savings with various collaborators (e.g., physicians, post-acute care providers). The proposed CR incentive program is also briefly described, under which additional payments for CR and intensive cardiac rehabilitation (ICR) services would be made during the follow-up care of AMI and CABG patients. CR/ICR services can reduce cardiac mortality but are significantly underutilized. CR per session incentive payments would be made to a subset of AMI and CABG participants and to a matched group of IPPS hospitals caring for similar patients and who are not EPM participants.

The proposed rule also expands opportunities for Advanced Alternative Payment Model (APM) participation by eligible professionals (through Track 1 in each of the new EPMs and in the modified CJR), potentially allowing them to achieve Qualifying Participant (QP) status and APM-related payment incentives. The proposed Advanced APM opportunities are structured to meet the requirements of MACRA¹ and the related provisions outlined by CMS in the Quality Payment Program proposed rule.²

Key Terms Defined By CMS in the Proposed Rule

For purposes of understanding the technical discussion, CMS provides these definitions:

- **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.
- **Episode benchmark price** - dollar amount assigned to EPM episodes based on historical EPM-episode data.

¹ Pub.L.114-10, April 16, 2015

² 81 FR 28161 through 28586; this proposed rule describes the Merit-Based Incentive Payment System (MIPS) and the Alternative Payment Model (APM) Incentive program which together constitute the Quality Payment Program.

- **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.
- **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.
- **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.

III. Provisions of the Proposed Regulations

A. Selection of Episodes, Advanced APM Considerations, and Future Directions

1. Selection of Episodes for Episode Payment Models in this Rulemaking and Potential Future Directions

Each of the proposed models would be mandatory, would begin with an IPPS hospital admission in a selected geographic area, and would include care through 90 days post-hospital discharge. To reduce administrative burden and to lessen confusion for hospitals participating in multiple episode models, provisions of the proposed rule mimic those of CJR whenever appropriate. CMS anticipates that the new pay-for-performance EPMs will align financial incentives of all providers and suppliers, leading to improved quality and reduced costs.

SHFFT model. The SHFFT model would be tested in the same hospitals already chosen for the CJR model. SHFFT model historical episodes³ demonstrate high spending for readmissions and high post-acute care usage. Mortality associated with hip fracture is 5-10 percent after one month and nearly 33 percent at one year, so that improved care delivery potentially could save life as well as limb function.

AMI and CABG models. The AMI model would include post-infarction patients treated medically (without revascularization) or revascularized through percutaneous coronary interventions (PCI). This model represents the first Center for Medicare and Medicaid Innovation (CMMI) EPM to include two distinct clinical care pathways for a single condition in one episode. Because revascularization via CABG represents the remaining distinct AMI clinical care pathway, CMS proposes to test the AMI and CABG models at a single set of hospitals. The AMI model would include beneficiaries with AMI as a primary or secondary diagnosis. All beneficiaries in the AMI and CABG models can be presumed to have coronary artery disease (CAD). CMS believes that the AMI and CABG models allow incentivizing CAD-directed care management and care coordination as does the proposed CR incentive payment model (Section VI. of the rule).

³ Historical episodes for AMI, CABG, and SHFFT models were constructed by CMS from Part A and Part B claims data for 2012- 2014.

2. Advanced APM Considerations

No episode-based Medicare payment models were identified as Advanced APMs in the MACRA-related Quality Payment Program proposed rule. In the current proposed rule, CMS outlines two tracks for each of the AMI, CABG, and SHFFT models: Track 1 is structured to meet the Advanced APM criteria while Track 2 is not. Track 1 in all three models bases payment on quality measures endorsed by National Quality Forum (NQF) and includes outcome measures. In each model, Track 1 participants would begin to bear downside risk during performance year 2 sufficient to meet the financial risk criterion (except for certain hospitals that would not meet the criterion until performance year 3). Finally, Track 1 EPM participants would be required to use CEHRT.

EPM Participant Tracks. CMS proposes that all EPM participants decide whether or not to utilize CEHRT. Those choosing to adopt CEHRT would be in Track 1 and would be required to attest to CEHRT use. All other EPM participants would be in Track 2 and CEHRT attestation would not be required of them.

Clinician Financial Arrangements Lists under the EPMs. Advanced APM clinicians may be able to achieve QP status by practicing under financial arrangements that require them to support the cost or quality goals of the APM participants. Physicians and other eligible clinicians may enter into such arrangements as Affiliated Practitioners under the Track 1 EPM option, functioning as EPM collaborators, collaboration agents, or downstream collaboration agents (these terms are defined in Section III.I. of the rule).

In order to make QP determinations about eligible clinicians, CMS proposes to identify such clinicians through an “Affiliated Practitioners list” that would be submitted by each Track 1 EPM participant to CMS. QP status would be assessed by CMS only for clinicians appearing on clinician financial arrangement lists as of December 31 of a given performance period.

3. Future Directions for Physician Payment Models

Refinements to the BPCI Incentive Models. Currently, BPCI initiative models 2, 3, and 4 would not qualify as Advanced APMs, failing to meet the criteria for CEHRT use and for payment based on quality measures. CMS notes that for 2018, CMMI plans to implement a new voluntary payment bundle model whose design would meet Advanced APM criteria.

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

1. & 2. Background and Proposed Definition of Episode Initiator

Episodes would begin with an admission to an IPPS acute care hospital that triggers an AMI, CABG, or SHFFT episode, and hospitals would be the only episode initiators for these EPMs. Restricting initiators to hospitals, CMS believes, is straightforward since patients included in these models require hospital admission for appropriate care delivery. Beneficiaries who are being treated in BPCI episodes are also proposed for exclusion.

Maryland Hospital Exception. CMS proposes to exclude all acute care hospitals in Maryland from the proposed EPMS because of the state's All-Payer Model. Further, payments to Maryland hospitals would be excluded in the regional pricing calculations described in III.D.4. Finally, any future all-payer state models would be similarly excluded.

3. Financial Responsibility for the Episode of Care

CMS proposes to designate hospitals as the only provider type accountable for CMS repayments (if required) and as the entity financially responsible for the episode of care under all three new EPMS because:

- an episode always begins with an acute care hospital stay;
- the beneficiary's recovery begins with the hospital stay;
- hospitals play a central role in care coordination and transitions, and hospital staff members already are involved in discharge planning and post-acute care recommendations;
- most hospitals have infrastructure related to health IT, patient and family education, and care management upon which to build to achieve efficiencies under the EPMS; and
- hospitals are the providers most likely to have sufficient episode cases to justify investing in episode management for the EPMS.

Excepted hospitals (BCPI participants). CMS proposes exceptions for BCPI participants from mandatory hospital participation in geographic areas selected for new EPM testing. Hospitals that are episode initiators for episodes in the risk-bearing phase of BCPI models 2 or 4 would be excluded from new EPM participation for episodes that otherwise would qualify for BCPI coverage. Relatedly, if a physician group practice rather than the admitting hospital serves as initiator during an anchor hospitalization (defined in Section II.D.1.b. of the rule) under BCPI model 2, then the episode would be covered under BCPI and excluded from the relevant proposed EPM. BCPI participating providers would participate in the proposed EPMS for any episodes not otherwise preempted under their BCPI participation. Illustrative scenarios involving BCPI models and EPMS are explained by CMS in the proposed rule (Section III.B.3). More detailed discussion of managing situations in which CMS payment models overlap is provided in Section III.D. of the rule.

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

CMS selected MSAs as the geographic unit of selection. After evaluating other options, CMS concluded that MSAs provide the best balance between small geographic unit market patterns plus limiting potential risks for patient shifting and steerage across areas.

CMS also assessed the potential impacts of running both the CJR model and one or more of the new EPMS in the same geographic area. CMS ultimately decided to implement the SHFFT model in MSAs also selected for CJR, and to implement the AMI and CABG models together but in MSAs selected independently from SHFFT selection.

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

CMS proposes to implement the AMI and CABG models together in the same MSAs which may or may not also be CJR and SHFFT participating MSAs. AMI and CABG model participation would be required of all hospitals that are paid under the IPPS and physically located in a county in selected MSA. A hospital would be determined to be 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. While MSAs are revised periodically, CMS would maintain the same cohort of selected hospitals throughout the 5-year performance period of the EPMs with limited exceptions, described below. CMS would retain the possibility of adding a hospital that is owned or incorporated within one of the selected counties after the selection is made and during model duration. CMS Certification Numbers (CCNs) would be used under the EPMs to administer model related activities including physical location determination. Whether a CCN is located in a selected MSA would be governed by the physical location associated with that CCN at the EPM's start date. Hospitals sharing a CCN across several locations would all be required to participate if the CCN-associated physical address is in a selected MSA (unless excluded for other reasons). Conversely, all hospitals under the same CNN would not participate in the applicable EPM if the CNN-associated physical address is not in a selected MSA, even though some hospitals under that CNN are physically located in a selected MSA.

a. Exclusion of Certain MSAs

CMS analyzed 2014 data in considering to exclude MSAs from AMI/CABG EPM implementation based upon AMI and CABG episode volumes in each MSA. Episodes were attributed to an MSA using initiating hospital CNNs. CMS excluded MSAs with fewer than 75 AMI episodes in a year. This removed 49 MSAs from the potential EPM selection pool. CMS also considered exclusion rules based upon overlap with BPCI. CMS removed MSAs if there were < 75 non-BPCI AMI episodes in the MSA in the reference year. This exclusion removed 26 more MSAs from potential EPM selection. CMS also removed MSAs in which the number of non-BPCI AMI episodes is less than 50 percent of total AMIs, eliminating 13 more MSAs. Finally, CMS examined excluding MSAs based upon degree of overlap between the AMI and CABG EPMs and patients prospectively assigned to ACOs bearing two-sided risk. No MSAs were eliminated from EPM implementation through this screen. Of 384 total MSAs, 294 would remain eligible for selection for AMI/CABG EPM implementation.

b. Proposed Selection Approach

CMS proposes selecting 98 MSAs from the 294 eligible MSAs using simple random selection after analyzing for several MSA characteristics that might warrant subgroup creation (and thus stratified MSA selection) for the AMI/CABG implementation. A stratified random assignment approach was used in CJR implementation to allow oversampling of higher-expense MSAs, as there were wide regional variations in episode prices, especially for post-acute services.

C. Episode Definitions for the EPMs

1. & 2. Background and Overview of Three Proposed EPMs

Episodes for each of the three new proposed models (AMI, CABG, SHFFT) almost always begin with an inpatient, “anchor” hospitalization and extend through 90 days after hospital discharge. The AMI model includes patients defined either by MS-DRGs alone or a PCI MS-DRG combined with an ICD-10-CM AMI diagnosis code in the principal (primary) or secondary diagnosis code position. Beneficiaries in the CABG and SHFFT models are described by MS-DRGs alone.

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

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

AMI (Medical Management and PCI) Model. The proposed AMI EPM is defined by admission for a medical condition having multiple treatment options. As a result, CMS proposes that AMI model beneficiary inclusion is defined by either discharge under an AMI MS-DRG (280-282) – representing medical therapy without revascularization – or discharge under a PCI MS-DRG (246-251) accompanied by a principal or secondary ICD-10-CM diagnosis code of AMI – representing percutaneous revascularization therapy.

In Fiscal Year (FY) 2014, 34 percent of the 395,000 beneficiaries discharged with an AMI principal or secondary diagnosis were discharged under MS-DRGs other than those for AMI or PCI.⁴ When defining historical AMI model episodes, CMS proposes to exclude beneficiaries discharged under PCI MS-DRGs plus an AMI ICD-9-M diagnosis, whenever there is an intracardiac ICD-9-CM procedure code on the IPPS claim. Intracardiac procedures (primarily valve and electrophysiology interventions) have recently been removed from PCI MS-DRGs (245-251) and assigned to new MS-DRGs (273-274). Table 2 (Section III.C.3.a.1. of the rule FR 50830-1) lists the intracardiac ICD-9-CM procedure codes. Table 3 (Section III.C.4.a.(2) of the rule FR 50835) provides specifications for AMI episodes, including ICD-9-CM diagnosis codes for setting the initial AMI model-episode benchmark prices and ICD-10-CM AMI diagnosis codes for use during the model’s proposed performance years. These tables appear in Appendix I and Appendix II of this document.

CABG Model. CMS proposes to apply this model for incentivizing care quality, coordination, and efficiency to beneficiaries treated by CABG irrespective of AMI during the CABG hospitalization. The model thereby would include beneficiaries undergoing elective CABG as well as those with AMI who undergo CABG during their initial treatment for AMI; the latter CABG procedures may be urgent or emergent. Beneficiaries admitted and discharged from an IPPS anchor hospitalization paid under CABG MS-DRGs (231-236) would be included in the CABG model.

⁴ In contrast, the AMI quality measures of the Hospital Inpatient Quality Reporting Program (HIQR) are based upon all beneficiaries with an AMI ICD-CM diagnosis only in the principal position regardless of the concomitant MS-DRG, which is unrestricted.

SHFFT (Excludes Lower Extremity Joint Replacement) Model. The SHFFT model anchor hospitalization is defined by admission for a surgical procedure, so the model is defined by MS-DRGs alone. The most common treatment is hip fixation. CMS proposes to include beneficiaries admitted and discharged from an IPPS anchor hospitalization paid under SHFFT MS-DRGs (480-482) in the SHFFT model.

b. Definition of the Related Services Included in EPM Episodes

General considerations. The proposed definition of related services is based upon the same general principles for all three new EPMs. All Part A and Part B services delivered throughout each episode potentially would be related. Items and services would be excluded only when unrelated to the EPM episode diagnosis and procedures. Exclusion would be based on a clinical rationale that would lead to the same, standard exclusion of those same items and services from all applicable EPM episodes.

Items and services remaining after applying all exclusions would be termed related. Medicare spending for them would be included in setting historical EPM-episode-benchmark prices and in calculating actual EPM episode payments for comparison against the quality-adjusted target price during reconciliation. Unrelated spending would not be counted for price setting or payment calculations. Diagnostic exclusions would apply to historical price setting (ICD-9-CM) and to payment calculations (ICD-10-CM). CMS proposes to apply general principles developed for the CJR model when determining other services proposed for exclusion during the EPM episode:

- Excluding unrelated inpatient hospital admissions by identifying MS-DRGs for exclusion on an EPM-specific basis
- Excluding unrelated Part B services using ICD-CM diagnostic codes on claims by identifying code categories for exclusion on an EPM-specific basis, and
- Identifying unrelated Part B services and readmissions based on BPCI Model 2 exclusion lists applicable to the anchor MS-DRG that initiates the EPM episode, or to the price MS-DRG if it differs from the anchor MS-DRG.⁵

The anchor MS-DRG generally would determine the exclusions list applicable to an EPM episode; lists may vary across episodes and associated diagnoses. When a price MS-DRG (see definition in footnote) applies to an AMI episode that includes a chained anchor hospitalization, the exclusions list from the price MS-DRG applies to the AMI episode.

Complete lists of proposed MS-DRGs for readmissions, and proposed excluded ICD-CM codes for Part B services furnished during EPM episodes after beneficiary discharge from an AMI, CABG, or SHFFT anchor or chained anchor hospitalization, are posted at

⁵ CMS reprises the history of the BPCI Model 2 exclusion lists, notes they have been vetted broadly, and expresses confidence that they are reasonable and workable. There are BPCI Model 2 exclusion lists applicable to every MS-DRG and price MS-DRG for the AMI, CABG, and SHFFT model episodes.

Price MS-DRG: HFMA is waiting to hear back from CMS for a definition.

<https://innovation.cms.gov/initiatives/epm>. CMS plans to update posted exclusion lists at least annually using subregulatory guidance.

Specific considerations. CMS proposes to consider the following to be related, absent any EPM-specific exclusions:

- Services:⁶ physician, inpatient hospital, inpatient psychiatric facility, long-term care hospital, inpatient rehabilitation facility, SNF, home health agency, hospital outpatient, independent outpatient therapy, clinical laboratory, and hospice
- Items: durable medical equipment, Part B drugs, and hospice
- All Part A services furnished after hospital discharge but within the 90 post-discharge day period
- All Part B services with principal diagnosis codes on the associated claims that are
 - Directly related (clinically or by coding conventions) to an EPM episode
 - Related to the safety and/or quality of care furnished during the EPM episode
 - Related to preexisting chronic conditions potentially affected by care furnished during the EPM episode.

CMS proposes the following additional exclusions:

- Hemophilia clotting factors
- New technology add-on payments
- OPPS transitional pass-through payments for medical devices
- Unrelated hospital admissions for MS-DRGs that map to the diagnostic categories of Oncology; Trauma, medical; Chronic disease, surgical; and Acute disease, surgical.
- Chronic conditions rarely affected by the EPM diagnosis, procedure, or post-acute care, and
- Acute conditions not arising from existing EPM-related chronic conditions or from EPM episode complications.

4. EPM Episodes

a. Beneficiary Care Inclusion Criteria and Beginning EPM Episodes

General Care Inclusion Criteria. CMS describes criteria that beneficiaries cared for in the EPMs would need to meet on admission to the anchor or chained anchor hospitalization:

- the beneficiary is enrolled in Medicare Parts A and Part B
- the beneficiary's eligibility for Medicare is not on the basis of end stage renal disease (ESRD)
- the beneficiary is not enrolled in any managed care plan (e.g., Medicare Advantage)
- the beneficiary is not covered under a United Mine Workers of America health care plan
- Medicare is the primary payer
- the beneficiary is not aligned to a Next Generation Accountable Care Organization (ACO) or an ESRD Care Initiative ACO incorporating downside risk

⁶ Inpatient hospital services would include those paid through IPPS operating and capital payments.

- the beneficiary is not under the care of an attending or operating physician (designated on the inpatient hospital claim) who belongs to a group practice that initiates BPCI Model 2 episodes at the EPM participant hospital for what would be the anchor MS-DRG under the EPM
- the beneficiary is not already in any BPCI model episode, and
- the beneficiary is not already in an AMI, CABG, SHFF or CJR episode whose definition does not exclude what would be the anchor MS-DRG under the EPM.

CMS notes that if at any time during the episode the beneficiary fails to meet all of the above criteria, the episode would be canceled.

Special Policies for Hospital Transfers of Beneficiaries with AMI. Implementing the AMI and CABG EPMs requires CMS to address patient transfers in the context of EPM episodes. To do so, CMS outlines a framework within which to consider beneficiary transfers for advanced cardiac care:

- Admission to the first treating hospital without subsequent hospital transfer is termed the *no transfer* scenario.
- Treatment as an outpatient (ED) at the first hospital then transfer to another hospital (inpatient admission) is termed the *outpatient-to-inpatient (o-i) transfer* scenario and the transfer (receiving) hospital is an *o-i transfer hospital*.
- Admission to the first treating hospital with later transfer to another hospital (a second inpatient admission) is termed the *inpatient-to-inpatient (i-i) transfer* scenario and the transfer (receiving) hospital is an *i-i transfer hospital*.

Within this framework, CMS extensively discusses AMI patient transfers in the rule (Section III.C.4.a.(5)), from which highlights are presented below. Questions to be considered when beneficiaries are transferred during AMI care and either the sending or the receiving facility (or both) is an AMI or CABG (or both) model participant, include:

- Whether an EPM episode is initiated and if so by whom
- To which model the episode is properly assigned; and
- Which facility is responsibility for quality and cost attributed?

Table 4 from the proposed rule, reproduced below, summarizes how CMS proposes to answer these questions using the transfer scenario framework.

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

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

CMS proposes an overarching policy in which every AMI or CABG episode would be initiated at the first AMI or CABG model participant to which the beneficiary is admitted. Transfers create “chained anchor hospitalizations” in which price MS-DRGs may be used in making pricing adjustments for episodes in which the initial (sending) treatment facility is held responsible for costs and quality performance throughout the AMI episode.

Pricing adjustments are particularly important when the episode that started at the initial (sending) hospital as an AMI medical episode is reclassified based upon treatment at the transfer (receiving) hospital into a costlier AMI with PCI or CABG episode. CMS also proposes to give high importance to the role of the local hospital and physicians associated with the initial treatment, believing that beneficiaries will receive most of their post-discharge care in their home communities. CMS perceives that by maintaining the initiating EPM hospital as the accountable entity, proper emphasis will be given to coordination of CAD care post-infarct and long-term by the beneficiary’s home community providers.

b. Middle of the EPM Episode (includes episode cancellation)

This section of the proposed rule applies to all three EPMs (AMI, CABG, and SHFFT). CMS notes that once an EPM episode begins, it will continue until its end, with rare exceptions. CMS proposes to cancel the episode if the beneficiary:

- Ceases to meet any of the general beneficiary inclusion criteria (except those related to inclusion in other EPM episodes);
- Dies during the anchor *hospitalization*;
- Initiates any BPCI model episode;
- Becomes aligned with a Next Generation ACO or an ESRD Seamless Care Organization (ESCO); or
- Is discharged from a chained anchor hospitalization and the final MS-DRG is not an AMI MS-DRG, PCI MS-DRG, or CABG MS-DRG.^{7, 8}

CMS proposes that when an EPM episode is canceled, services preceding and following the cancellation would instead be paid by Medicare as usual and not be included in any episode spending calculation.

CMS also notes that this beneficiary death cancellation proposal (only for death during the anchor hospitalization) differs from CJR. Under CJR, episode is canceled by beneficiary death at any point during the episode. CMS proposes to calculate actual EPM episode spending and proceed with the spending reconciliation process should a beneficiary die after the initial hospital during the episode timeframe.

Finally, CMS does not propose to cancel an AMI episode altogether, or to cancel the episode plus initiate a CABG episode, in the situation when a beneficiary is readmitted for CABG

⁷ The absence of an AMI ICD-10-CM from one or more claims in a chained anchor hospitalization in an AMI model episode would not preclude use of price MS-DRGs in the reconciliation process for the episode.

⁸ CMS proposes that an AMI episode would not be canceled based on absence of an AMI ICD-10-CM diagnosis on the claim for the final transfer hospitalization of a chained anchor hospitalization, as long as the MS-DRG is under an AMI, PCI, or CABG MS-DRG.

surgery during the 90-day post-discharge period of an AMI episode. In this situation, CMS proposes instead to adjust the AMI episode benchmark price (Section III.D.4.b.(2)(c) of the rule).

c. End of EPM Episodes

AMI (including PCI) and CABG models. CMS proposes that the day of discharge from the anchor hospitalization would count as day 1 of the post-hospital discharge period (as done in the CJR model). In a chained anchor hospitalization, day 1 of the post-discharge period would be the day of discharge from the final hospitalization in the chain.

SHFFT model. CMS believes that SHFFT and CJR model beneficiaries are very similar, and proposes the same 90-day post-discharge period for both models. Based upon CMS analysis of post-acute care patterns after hip fracture treatment, CMS believes that the time for full functional recovery exceeds 60 days.

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

1. Background

a. Overview

Section III.D. of the rule describes proposed policies with respect to the methodology for setting episode prices and paying participants in the AMI, CABG, and SHFFT models. Given the general similarity between the design of the CJR model and these EPMs, CMS plans to use the general payment and pricing parameters used under the CJR model taking into account necessary modifications related to the different clinical conditions. In this section, CMS describes the following proposals:

- PY, 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.

2. Performance Years, Retrospective Episode Payment, and Two-sided Risk EPMs

a. Performance Period

CMS proposes 5 PYs for the EPMs as displayed in Table 5 in the proposed rule (reproduced below). Note that PY 1 is shorter than the other PYs with respect to the length of time over which an episode could occur. PYs 2 through 5 could include episodes that began in a prior year.

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

b. Retrospective Payment Methodology

Consistent with the CJR model, CMS proposes to apply a retrospective payment methodology to the proposed EPMS. 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 system. After the completion of an EPM PY, CMS would group Medicare claims for services into episodes, aggregate payments, assess episode quality and actual payment performance against quality-adjusted target prices, and determine if Medicare will make a payment to the hospital (reconciliation payment) or if the hospital owes money to Medicare (resulting in Medicare repayment).

c. Two-sided Risk Model

CMS proposes to establish two-sided risk for hospitals participating in EPMS. Table 6 (reproduced from proposed rule) shows the timing of the repayment responsibility, as well as the phase-in of the proposed stop-loss limits and the discount percentages. These provisions are discussed in more detail below and in section III.D.7.b and III.D.4.b.(10) of the proposed rule.

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 percent for PY2 (DR) and 5 percent for PY3-PY5.

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

a. Overview

CMS proposes to make certain adjustments to Medicare Part A and Part B payments included in the EPM episode definition: 1) to account for special payment provisions under existing Medicare payment systems; 2) to adjust payment for services that straddle episodes; and 3) to adjust for high payment episodes. CMS discusses the adjustments for overlaps with other Innovation Center models and CMS programs in a separate section (III.D.6)

Each of these areas is discussed below.

b. Special Payment Provisions

Consistent with its approach under the CJR model, CMS proposes to exclude the following special payment provisions in setting EPM-episode benchmark and quality-adjusted target prices and in calculating actual episode payments:

- Hospital Readmissions Reduction Program (HRRP)
- Hospital Value-Based Purchasing (HVBP) Program
- Hospital-Acquired Condition (HAC) Reduction Program
- Hospital Inpatient Quality Reporting Program (IQR) and Outpatient Quality Reporting Program (OQR)
- Medicare Electronic Health Record (EHR) Incentive Program for IPPS and critical access hospitals (CAHs)
- Medicare Disproportionate Share Hospital (DSH) and Uncompensated Care
- Indirect Medical Education (IME)

- Low volume add-on payments
- New technology add-on payments
- Enhanced payments to sole community hospitals (SCHs) or Medicare-dependent hospitals (MDH) based on cost-based hospital-specific rates
- Quality programs affecting IRFs, SNFs, IPFs, HHAs, LTCHs, hospice facilities and ambulatory surgical centers (ASCs)
- Physician quality programs, including the Medicare EHR Incentive Program for Eligible Professionals, the Physician Quality Reporting System (PQRS), and the Physician Value-based Modifier Program
- All special add-on payments for IRFs (rural add-on, low-income percentage (LIP) payments, teaching program payments), HHAs (rural add-on), and SNFs (payments for treating beneficiaries with human immunodeficiency virus (HIV))

To operationalize the exclusions, CMS would apply the CMS Price (Payment) Standardization Detailed Methodology, which is described on the QualityNet website at <http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350>. CMS would also adjust actual episode payments to account for the effects of sequestration.

c. Services that Straddle Episodes

CMS proposes to apply the CJR model methodologies to prorate payments for post-discharge services when Medicare payment for services begin before the start of or continues beyond the end of an EPM episode that extends 90 days post-hospital discharge. Under the CJR model, CMS prorates 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 (80 FR 73333 through 73335). For example, under this approach, proration is based on the percentage of actual length of stay (in days) that falls within the episode window for stays involving non-IPPS inpatient hospitals (for example, CAH) and inpatient PAC providers (for example, SNF, IRF, LTCH, IPF) services. This proposed provisions can be found in §512.300(f).

d. High Payment Episodes

Consistent with its approach under CJR, CMS proposes 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. A high-payment episode would be an episode with payments 2 standard deviations or more above the mean calculated at the regional level. As shown below, CMS proposes to apply and calculate a ceiling separately for each MS-DRG at the regional level for these groupings:

- All SHFFT model episodes
- AMI model episodes anchored by MS-DRGs 280-282 or 246-251 without readmission for CABG MS-DRGs
- CABG model episodes (anchor hospitalization portion), MS-DRGs 231-236
- CABG model episodes (post anchor hospitalization)

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

CMS proposes to apply certain regional level ceilings calculated above to the following model episodes:

- For CABG model episodes (chained anchor hospitalization), CMS proposes to apply the regional level ceiling calculated for the CABG model episodes (anchor hospitalization)
- For CABG model episodes (post chained anchor hospitalization), CMS proposes to apply the regional level ceiling calculated for the CABG model episodes (post anchor hospitalization)
- For AMI model episodes with price MS-DRG 280-282 or 246-251 and with readmission for CABG MS-DRGs, CMS proposes to apply the ceiling separately to the payments during the CABG readmission and all other payments during the episode.
 - CMS proposes to apply the regional level ceiling calculated for the anchor hospitalization portion of a CABG model episode for payments during the CABG readmission.
 - CMS proposes 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 for all other payments during the episode.

e. Treatment of Reconciliation Payments and Medicare Repayments

CMS proposes to include both reconciliation payments and Medicare repayments when calculating historical EPM-episode payments to update EPM-episode benchmark and quality-adjusted target prices. CMS is also proposing to modify its policy for the CJR model to also include reconciliation payment and Medicare repayments when updating target prices in that model (discussed in section V.5 of the proposed rule). CMS also proposes to include BPCI Net Payment Reconciliation Amounts in its calculations when updating EPM-episode benchmark and quality-adjusted target prices.

CMS notes that with respect to CABG model episodes, CMS proposes to allocate EPM reconciliation payments and BPCI Net Reconciliation Payment Amounts proportionally to the anchor hospitalization and post-anchor hospitalization portions of CABG model historical episodes. CMS also proposes 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 hospitalization portion of CABG model episodes that were initiated during the 3 historical years.

4. Episode Price Setting Methodology

a. Overview

CMS proposes 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.

The proposed price-setting methodology incorporates the following features, which are discussed in more detail in sections III.D.4.b through e of the proposed rule.

- 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.
- 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. The specific set of 3 historical years would be updated every other PY.
- Apply Medicare payment system (for example, IPPS, OPSS, IRF PPS, SNF, MPFS.) updates to the historical EPM-episode data. Because different Medicare payment system updates become effective at two different times of the year, CMS 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 PYs. Regions are 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 for 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.

CMS also proposes 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).

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

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

CMS generally proposes to apply the episode pricing methodology that was applied to the CJR model, referred to by CMS as the “standard EPM-episode benchmark price.” In addition, for each EPM participant, CMS proposes to risk stratify and establish special EPM-episode benchmark prices for episodes in different pricing scenarios.⁹

Tables 8 through 10 of the proposed rule (consolidated and reproduced below) summarize the proposed standard pricing methodologies and the adjustments (discussed in the next section) that would occur rule for AMI, CABG, and SHFFT model episodes.

TABLES 8-10: MODEL PRICING SCENARIOS FOR AMI, CABG, and SHFFT

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 (i.e., no inpatient to inpatient transfer)	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

⁹ For purposes of the 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.

AMI MS-DRG or PCI MS-DRG (with AMI diagnosis) anchored AMI episode with chained anchor hospitalization (i.e., an inpatient-to-inpatient transfer) (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. The price assigned the chained anchor hospitalization is the CABG MS-DRG with the highest IPSS weight between the initiating hospital and the transfer hospital.
TABLE 9: CABG MODEL PRICING SCENARIOS	
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 MS-DRG	Episode benchmark price is standard episode benchmark price based on anchor MS-DRG (which is the price MS-DRG)

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

CMS states it has identified several scenarios where certain pricing adjustments could be appropriate.

- Adjustments for Certain AMI Model Episodes with Chained Anchor Hospitalizations
- Adjustments for CABG Model Episodes
- Adjustments for Certain AMI Model Episodes with CABG Readmissions
- Potential Future Approaches to setting Target Prices for AMI and Hip Fracture Episodes

The details of each of these scenarios is discussed in greater detail below.

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

CMS believes it would be appropriate to adjust the AMI model-episode benchmark prices for certain AMI model episodes involving a chained anchor hospitalization as 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. CMS proposes 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 IPSS weight. CMS believes this proposal could minimize potential disincentives to AMI model participants from

transferring patients when different or higher levels of care are needed. Specifically, CMS would 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. CMS provides these scenarios:

- 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, CMS proposes 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 IPSS 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, CMS proposes that the AMI model episode would begin with and be attributed to the first hospital, and to set the price MS-DRG to the CABG MS-DRG in the chained anchor hospitalization with the highest IPSS weight.
- If the price MS-DRG is an AMI or PCI MS-DRG, CMS proposes to set the episode benchmark price as the standard AMI model-episode benchmark price for the price MS-DRG, subject to a possible adjustment for readmission for CABG MS-DRGs, as described in section III.D.4.b.(2)(c) of the proposed rule.
- If the price MS-DRG is a CABG MS-DRG, CMS proposes 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.

(b) Adjustments for CABG Model Episodes

CMS notes that 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).¹⁰ 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).

To address this issue, CMS proposes to set CABG model-episode benchmark prices by splitting historical CABG model-episode expenditures into expenditures that occurred during anchor hospitalizations and expenditures that occurred after discharge from the anchor hospitalizations. 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.

¹⁰ Episodes for CABG model beneficiaries initiated by all U.S. IPSS 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

CMS states that even though CABG readmissions are not excluded from AMI model episodes (because they are clinically-related to the AMI model episode), it proposes to provide an adjusted AMI model-episode benchmark price. The rule establishes 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 a 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, CMS proposes 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. In the event of any other readmission other than CABG during an AMI episode, the usual rules of EPM-episode pricing would apply.

(3) Three Years of Historical Data

As was the case for the CJR model, CMS proposes to use 3 years of historical EPM episodes for calculating EPM-episode benchmark prices and to update the set of 3 historical years every other year.

- January 1, 2013 and December 31, 2015 for PYs 1 and 2;
- January 1, 2015 and December 31, 2017 for PYs 3 and 4; and
- January 1, 2017 and December 31, 2019 for PY 5.

(4) Trending of Historical Data to the Most Recent Year

To mitigate the effects of Medicare payment system updates and changes in national utilization practice patterns within the 3 years of historical episodes, CMS proposes to update the older two historical years using national trend factors. This is the same approach used for the CJR model. Specifically, CMS proposes 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).

To trend historical payments to the most recent year in an historical window, CMS 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. For example, for SHFFT model episodes for MS-DRG 480, CMS 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. Likewise, CMS 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. CMS would repeat this process for each pricing scenario listed above

(5) Update Historical Episode Payments to Account for Ongoing Payment System updates

CMS proposes to update the historical episode payments to reflect ongoing payment system updates for these programs: IPPS, IRF PPS, SNF PPS, PFS, HHA, and other services. Under its proposal, CMS would apply the same methodology developed for the CJR model to incorporate Medicare payment updates.

As noted, CMS calculates target prices separately for episodes initiated between January 1 and September 30 versus October 1 and December 31 of each PY to account for calendar year versus fiscal year program updates. The target price in effect as of the day an episode is initiated is the target price for the entire episode.

Corresponding to the different target prices, a different set of update factors is calculated for January 1 through September 30 versus October 1 through December 31 episodes each PY. The six update factors reflecting each of the six programs are EPM-participant hospital-specific and are combined to create a single update factor by weighting and summing each of the six update percentages according to the proportion of Medicare payments each of the six components represents in the EPM participant's historical EPM episodes. If, for example, 50 percent of an EPM participant's episode payments were for inpatient acute care services, then the update factor for acute care services would have more influence on the weighted update factor than a service, such as physician services that accounted for 15 percent of episode payments. The weighted update factors are applied to the historical EPM-participant hospital-specific average payments.

Region-specific factors are calculated in the same manner as the EPM hospital-specific update factors. Rather than using historical episodes attributed to a specific hospital, region-specific update factors are based on all historical EPM episodes initiated at any IPPS hospital within the region with historical EPM episodes. This is regardless of whether or not the MSAs in which the hospitals are located were selected for inclusion in the models.

(6) Blend Hospital-specific and Regional Historical Data

CMS proposes 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 in the same region.

The blend proportions are shown in the table below:

Year	Blend Proportion
PYs 1 and 2 (2017 and 2018)	Two-thirds of the EPM-participant hospital-specific episode payments and one-third of the regional EPM-episode payments
PY 3 (2019)	One-third of the EPM-participant hospital-specific episode payments and two-thirds of the regional EPM-episode payments
PYs 4 and 5 (2020 and 2021)	Based fully on regional historical EPM-episode payments

Consistent with the methodology for the CJR model, CMS proposes two exceptions. First, CMS proposes to use only regional EPM-episode payments to calculate benchmark prices for EPM participants with low historic EPM-episode volume. The number of episodes considered low volume for each model is shown in the table below:

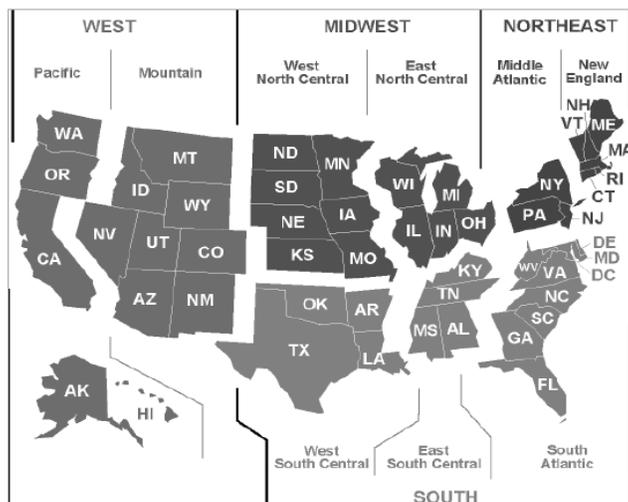
Model	Low volume threshold (in total across 3 historical years)
SHFFT Model	Fewer than 50 SHFFT model episodes
AMI model episodes anchored by MS-DRGs 280-282	Fewer than 75 of these AMI model episodes
AMI model episodes anchored by PCI MS-DRGs 246-251	Fewer than 125 of these AMI model episodes
CABG model episodes	Fewer than 50 CABG model episodes

Second, CMS proposes 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 that episode payments would be determined based on its predecessor(s), as in the CJR model (80 FR 73544).

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

As CMS does for the CJR model, CMS proposes to define “region” as one of the nine U.S. Census divisions, as shown in Figure 1 below.

FIGURE 1: U.S. CENSUS DIVISIONS



CMS clarifies that under its proposal 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. CMS states that it will attribute an MSA to the U.S. Census division in which the majority of people in the MSA resides.

(8) Normalize for Provider-Specific Wage Adjustment Variations

CMS proposes to use the following algorithm to create a wage index normalization factor: $(0.7 * \text{IPPS wage index} + 0.3)$. The proposed rule observes that 0.7 approximates the labor share in IPPS, IRF PPS, SNF PPS, and HHA Medicare payments.

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

CMS proposes to generally follow the process from the CJR model to calculate severity factors (referred to as anchor factors in the CJR final rule), in order to have sufficient episode volume to set stable EPM-episode benchmark and quality-adjusted target prices. CMS uses the term “severity factors” instead of “anchor factors” to avoid confusion when discussing calculations pertaining to expenditures that occurred during the anchor hospitalization and after the anchor hospitalization in the CABG model episodes.

SHFFT Model Episodes

CMS proposes 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. The two severity factors for this model, which would have the same value for all participant hospitals, would be calculated and used as follows:

- i. CMS proposes to calculate severity factors for episodes with price MS-DRGs 480 and 482 as follows:

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

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

The national average would be based on SHFFT model episodes attributed to any IPPS hospital.

- ii. For each SHFFT model participant, CMS would calculate a hospital weight using the formula below, 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 for the hospitals and severity factors from the first step:

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

- iii. For each hospital, CMS would calculate a hospital-specific average episode payment 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).

Similar to how case-mix indices are used, 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.

CMS states that it would calculate region-specific weights and region-specific pooled historical average payments following the same steps.

In the final step of the calculation of episode target prices, 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. CMS would then apply the relevant discount factor resulting in the SHFFT model quality-adjusted target prices for episodes with price MS-DRGs 480-482.

AMI Model Episodes

CMS proposes to follow a comparable computational process for the AMI model episodes with the following four modifications.

- i. Group episodes with price MS-DRGs 280-282 separately from episodes with price MS-DRGs 246-251 for the calculations and make the following calculations:
- ii. Calculate severity factors for episodes with price MS-DRGs 280-282 as follows:

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

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

- iii. For each AMI model participants, calculate hospital-specific weights and region-specific weights for episodes with price MS-DRGs 280-282 as follows:

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

- iv. Calculate five severity factors for episodes with price MS-DRG 246-251. For example, the MS-DRG 246 severity factor equals the following:

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

Repeat for MS-DRG 247-250, where MS-DRG 251 remains the denominator in each calculation.

- v. CMS proposes to calculate hospital-specific weights and region-specific weights for episodes with price MS-DRG 246-251 as --

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

After blending historical and regional pooled episode payments for episodes with price MS-DRGs 280-282, CMS would “unpool” the blended pooled calculations 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.

Similarly, after blending historical and regional pooled episode payments for episodes with price MS-DRGs 246-251, CMS would “unpool” the blended pooled calculations by setting the episode benchmark price for price MS-DRG 251 to the resulting calculation, and by multiplying the resulting calculation by the severity factors to produce the episode benchmark prices for price MS-DRGs 246-250.

CMS would then apply the relevant discount factor that would result in the quality-adjusted target prices for price MS-DRGs 280-282 and 246-251.

CABG Model

For episodes in the CABG model with price MS-DRGs in 231-236, CMS proposes to apply 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.

CABG Model: Anchor Hospitalization Portion

- i. CMS proposes to calculate anchor hospitalization severity factors for price MS-DRGs 231-235. For example, the MS-DRG 231 anchor severity factor calculation is shown below. CMS would repeat to calculate the anchor severity factors for MS-DRG 232-235, where MS-DRG 236 remains the denominator in each calculation.

$$\begin{aligned}
 & \text{MS – DRG 231 anchor hosp. severity factor} \\
 & = \frac{\text{Natl. avg. MS – DRG 231 anchor hosp. spend}}{\text{Natl. avg. MS – DRG 236 anchor hosp. spend}}
 \end{aligned}$$

- ii. CMS proposes to calculate hospital-specific weights and region-specific weights for the anchor hospitalization portion of CABG model episodes as the following:

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

- iii. 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.

CABG Model: Post-Anchor Hospitalization Portion

CMS proposes that the post-anchor hospitalization portion of CABG model episodes would be 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).

- i. Specifically, CMS proposes to calculate post-anchor hospitalization severity factors as follows:

$$\begin{aligned} & \text{w/AMI and MS – DRG w/MCC post – anchor hosp.severity factor} \\ &= \frac{\text{Natl.avg. w/AMI and MS – DRG w/MCC post – anchor hosp.spend}}{\text{Natl.avg. w/o AMI and MS – DRG w/o MCC post – anchor hosp.spend}} \end{aligned}$$

$$\begin{aligned} & \text{w/AMI and MS – DRG w/o MCC post – anchor hosp.severity factor} \\ &= \frac{\text{Natl.avg. w/AMI and MS – DRG w/o MCC post – anchor hosp.spend}}{\text{Natl.avg. w/o AMI and MS – DRG w/o MCC post – anchor hosp.spend}} \end{aligned}$$

$$\begin{aligned} & \text{w/o AMI and MS – DRG w/MCC post – anchor hosp.severity factor} \\ &= \frac{\text{Natl.avg. w/o AMI and MS – DRG w/ MCC post – anchor hosp.spend}}{\text{Natl.avg. w/o AMI and MS – DRG w/o MCC post – anchor hosp.spend}} \end{aligned}$$

- ii. CMS also proposes to calculate hospital-specific weights and region-specific weights for the post-anchor hospitalization portion of CABG model episodes as follows:

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

- iii. 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 price MS-DRGs 231-235.
- iv. CMS proposes 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 would result in the quality-adjusted target prices for CABG model episodes.

CMS states that for episodes in the AMI model with CABG readmissions, CMS proposes to perform no additional blending of hospital-specific and regional-specific episode payments.

The proposals to combine episodes to set stable benchmark and quality-adjusted target prices are included in §512.300(c)(13).

(10) Effective Discount factors

In setting the episode target price – the spending level for which EPM participants would be fully, or partly, accountable for a performance period – CMS proposes to apply a 3 percent effective discount factor to calculate the quality-adjusted target prices for EPM participants in the below acceptable and acceptable quality categories. For EPM participants in good and excellent categories, the discount factor would be 2 percent and 1.5 percent, respectively. Given the proposed phase-in of repayment responsibility (no repayment responsibility in PY 1 and only part of PY 2, EPM participants would owe Medicare less than would otherwise result from this calculation. Tables 20 through 28 in the proposed rule (Sec III.E.1) provide further illustration of the discount percentages that would apply for reconciliation payment and Medicare repayments over the 5 EPM PYs. These proposed provisions are included in §512.300(d).

5. Process for Reconciliation

a. Net Payment Reconciliation Amount (NPRA)

With respect to the process for reconciliation, CMS proposes that each EPM participant's actual episode payments would be compared to its quality-adjusted target prices. An EPM participant could have multiple quality-adjusted target prices for EPM episodes ending in a given PY, 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 PY when the EPM episode was initiated;

- when the EPM episode was initiated within a given PY (January 1 through September 30 of the PY, October 1 through December 31 of the PY, October 1 through December 31 of the prior PY);
- and the potential effective discount factors.

CMS would determine the applicable target price for *each episode*, and the difference between each EPM episode's actual payment and that target price (calculated as target price minus the EPM actual episode payment). These episode calculations would be aggregated for all EPM episodes for an EPM participant within the PY. The aggregate result is referred to as the Net Payment Reconciliation Amount (NPRA).

CMS proposes to not include any reconciliation payments or repayments to Medicare under the EPMs for a given PY when calculating actual episode spending and, therefore the NPRA for a subsequent year. CMS provides the following 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 PY 1, that \$10,000 reconciliation payment amount would not be included in the PY 2 calculations of actual EPM-episode payments.

b. Payment Reconciliation

CMS proposes to reconcile an EPM participant's actual episode payments against the quality-adjusted target price 2 months after the end of the PY. It would calculate the NPRA based on claims submitted by March 1 following the end of the PY and make a reconciliation payment or initiate repayment from hospitals responsible for repayment, as applicable, within the 2nd quarter of following year.

CMS also proposes to calculate the prior PY's episode spending and NPRA a second time during the following PY's reconciliation process in order to account for final claims run-out (i.e., calendar year claims submitted after March 1) and any canceled EPM episodes due to overlap with other CMS payment models. The subsequent reconciliation calculation will occur approximately 14 months after the end of the prior PY. If the re-calculation produces a result other than zero, then this amount would be applied to the NPRA for the subsequent PY (as well as the post-episode spending and ACO overlap calculation) to determine the payment Medicare would make to the EPM participant or such participant's repayment amount. CMS would also apply the stop-loss and stop-gain limits to the calculations in aggregate for that PY (the initial reconciliation and the subsequent calculation) to ensure the amount does not exceed these limits.

Table 12 (reproduced below) 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 (Not responsible for pmts to CMS)	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 1, 2021	Q2 2021
Year 4	Episodes ending January 1, 2020 through December 31, 2020	March 1, 2021	Q2 2021	March 1, 2022	Q2 2022
Year 5	Episodes ending January 1, 2021 through December 31, 2021	March 1, 2022	Q2 2022	March 1, 2023	Q2 2023

6. Adjustments for Overlaps with Other Innovation Center Models and CMS Programs

a. Overview

CMS identified 3 overlap situations that it addresses: provider overlap, beneficiary overlap, and payment reconciliation issues. First, provider overlap can occur when a hospital in a geographic area selected for the AMI, CABG, or SHFFT model is also participating in BPCI for the same episode. Second, beneficiary overlap can occur where a Medicare beneficiary receives care that could potentially be counted under more than one episode or total cost of care payment model. Third, CMS addresses payment reconciliation payment policy related to overlap with non-ACO CMS models and programs.

b. Provider Overlap

(1) BPCI Participant Hospitals in Geographic Areas Selected for EPMs

CMS notes that 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. This is more likely to occur because 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.

In cases of provider overlap, CMS proposes that 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. In other words, the BPCI model takes precedent. If a BPCI hospital in an EPM-selected area withdraws from BPCI episodes anchored by EPM-MS-DRGs, then the BPCI hospital would participate in these EPMs.

(2) BPCI Physician Group Practice (PGP) Episodes Initiators in Hospitals Participating in EPMs

CMS addresses a provider overlap situation where a physician in a BPCI PGP treats a Medicare beneficiary in a hospital participating in one or more EPMs. In this case, CMS proposes 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, CMS will cancel or never initiate the EPM episode. CMS provides several examples in the proposed rule. This provision is at §512.230(g).

c. Beneficiary Overlap

(1) Beneficiary Overlap with BPCI

CMS addresses instances where a different model's episode could initiate during an ongoing EPM episode. CMS proposes 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. CMS notes that given the current scheduled end date for the BPCI, CMS proposes to give precedence to episodes covered under BPCI Models 2, 3 and 4 initiated on or before September 30, 2018.

(2) Beneficiary Overlap with the CJR Model and other EPMs

With respect to beneficiary overlap with the CJR model and other EPMs, CMS proposes a 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. CMS believes that this policy would establish an operationally straightforward policy for future EPMs

and align with its stated goal of encouraging more accountable care. CMS provides a few illustrative examples:

- 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 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.

This policy is at § 512.230(i).

(3) Beneficiary Overlap with Shared Savings Models and Programs

CMS notes that it expects 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. As with CJR, CMS proposes to attribute savings achieved during an EPM episode to the EPM participant, and include EPM reconciliation payments for ACO-aligned beneficiaries as ACO expenditures.

CMS proposes 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. CMS does not propose to exclude beneficiaries aligned to Shared Savings Program ACOs in Tracks 1, 2, or 3 at this time.

CMS proposes that under EPMs, it 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 MSSP 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. CMS would not make an adjustment when a beneficiary is aligned to an ACO in which the hospital is not participating

CMS notes that its proposed policy 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. CMS notes that it may revisit this policy through future rulemaking.

d. Payment Reconciliation of Overlap with non-ACO CMS Models and Programs

CMS specifically excludes these Innovation Center models from AMI, CABG, and SHFFT episodes:

- Oncology Care Model (OCM): episode-based payment initiated by chemotherapy treatment, a service generally reported with ICD-9-CM (or their ICD-10-CM equivalents) codes that are specifically excluded.
- Medicare Care Choices Model: palliative care for beneficiaries with a terminal illness means the PBPM payments would pay for services that are clinically unrelated to EPM episodes.

7. Limits or Adjustments to EPM Participants' Financial Responsibility

a. Limit on Actual EPM-Episode Payment Contribution to Repayment Amounts and Reconciliation Payments

(1) Limit on Actual EPM-Episode Payment Contribution to Repayment Amounts

To provide additional protection to participant hospitals from owing large repayment amounts to Medicare, CMS proposes to establish the same stop-loss limits that were adopted for the CJR model, except they would begin in the second rather than the first quarter of PY 2.

The stop loss limits for each PY is shown in the table below:

Year	Stop-loss Limit
PY 2 (DR) (beginning second quarter)	5%
PY 3	10%
PYs 4 and 5	20%

(2) Limitation on Reconciliation Payments

CMS proposes a parallel limit on the amount it would pay to a hospital as reconciliation payments based on the NPRA. CMS proposes symmetrical stop-gain limits of 5 percent in PYs 1 and 2, 10 percent in PY 3 and 20 percent in PY 4 and 5 for each EPM. This provision is included in §512.305(c)(2)(iii)(B).

b. Additional Protections for Certain EPM Participants

(1) Proposed Policies for Certain EPM Participants to Further Limit Repayment Responsibility

CMS is proposing additional protections for rural hospitals, SCHs, Medicare Dependent Hospitals (MDHs), and Rural Referral Centers (RRCs). CMS proposes 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 PY 2 (DR)—specifically, 3 percent in PY 2 (DR), and 5 percent for PYs 3 through 5 for each EPM.

c. Application of Stop-Gain and Stop-Loss Limits

CMS proposes, to establish 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. Thus, considering the above example, the stop-loss limit for CJR model episodes in PY 4 would be 20 percent for the hospital's CJR model episodes, while the stop-loss limit for SHFFT model episodes for PY 3 would be 10 percent.

d. EPM Participant Responsibility for Increased Post-Episode Payments

To address a possible incentive to withhold or delay medically necessary care until after an episode ends to reduce actual episode payments, CMS proposes to calculate, for each PY, the total Medicare Parts A and B expenditures in the 30-day period following completion of each episode for all services covered under Medicare Parts A and B, regardless of whether or not the services are included in the proposed EPM episode definition. This is consistent with BPCI Model 2 and the CJR model. The proposed calculation would include prorated payments for services that extend beyond the 30-day period following completion of each EPM episode, such as home health services (section III.D.3.c. above).

CMS would identify whether the average 30-day post-episode spending for an EPM participant in any given PY is greater than three standard deviations above the regional average 30-day post-episode spending, based on the 30-day post-episode spending for episodes attributed to all regional hospitals participating in the EPM in the same region as the EPM participant.

CMS proposes that, if the hospital's average post-episode spending exceeds this threshold, the participant hospital would repay Medicare for the amount that exceeds such threshold.

8. Appeal Procedures

a. Notice of Calculation Error (first level appeal)

CMS proposes a calculation error process for EPM participants to contest payment- or reconciliation-related matters. An EPM participant would need to review its Reconciliation Report and payment report for a PY, and provide written notice to CMS of any error in the report through a calculation error form specified by CMS within 45 calendar days of the Reconciliation Report issuance date. Failure to timely submit the calculation error form will also result in the loss of appeal rights on matters contained in that report, including (but not limited to) the following:

1. The calculation of the reconciliation amount or repayment amount reflected in the reconciliation report;
2. The calculation of the CR incentive payments as reflected in the CR incentive payment report;
3. The calculation of NPRA;
4. The calculation of the percentiles of quality measure performance to determine eligibility to receive a reconciliation payment; and
5. The successful reporting of voluntary PRO THA/TKA data to adjust the reconciliation payment.

If CMS receives a notification of a calculation error within the 45-day period, CMS states it will respond within 30 calendar days to either confirm that there was an error in the calculation or verify that the calculation is correct. Only EPM participants may use the notice of calculation error process.

b. Dispute Resolution Process (second level of appeal)

For payment matters, the participant must submit a timely calculation error form for any matters related to payment. Reconsideration review is on-the-record (i.e., limited to review of briefs and evidence). The CMS reconsideration official is supposed to “make reasonable efforts” to send the EPM participant a Scheduling Notice¹¹ within 15 days of receipt of the review request and to issue a written determination within 30 days of review. That determination would be final and binding.

c. Exception to the Notice of Calculation Error Process and Notice of Termination

For reconsideration review requests that are not related to payment matters, CMS proposes to require a timely submitted request for review. Under the proposed rule if CMS does not receive a request for reconsideration from the participating hospital within 10 calendar days of the notice of the initial determination, the initial determination is deemed final and CMS will proceed with the action indicated in the initial determination. The procedures for the Scheduling Notice and written determination are the same as described above.

d. Limitations on review

CMS proposes that there is no administrative and judicial review in §512.310 (e) in accordance with section 1115A (d) (2) of the Act for the following activities:

- 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.

E. EPM quality measures, public display, and use of quality measures in the EPM payment Methodology

1. Selection of Proposed Quality Measures for the EPMs

¹¹ A Scheduling Notice should include the date and time of the review (which should be no later than 30 days after the date of the Scheduling Notice) and a description of the issues in dispute, the review procedures, and the evidence submission requirements.

The proposed EPM measures explicitly address both outcomes and patient experience. Factors in their selection include familiarity to EPM participants, utility for hospitals participating in multiple EPMS, and potential for encouraging care collaboration among providers. CMS proposes three required measures plus one voluntarily reported measure 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 (NQF submitted) (AMI Excess Days)
- HCAHPS Survey (NQF #0166), and
- Voluntary Hybrid Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #2473) (Hybrid AMI Mortality data submission).

CMS proposes two required 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), and
- HCAHPS Survey (NQF #0166).

CMS proposes two required and one voluntarily reported measures for the SHFFT model:

- Hospital-level Risk-Standardized Complication Rate (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).

2. Proposed Use of Quality Measures in the EPM Payment Methodologies

For each EPMS, CMS proposes an EPM *composite quality score* linking quality to payment. This score includes a composite *performance* score plus an *improvement* score; the performance component is more heavily-weighted. This methodology is similar to that used in the CJR model, Shared Savings Program, the Hospital Value-Based Purchasing Program (HVBP), and the Hospital Acquired Conditions Reduction Program (HACRP).

CMS proposes during reconciliation to reference individual EPM participant's most recent results to the national performance percentile distributions of measure results for subsection (d) IPPS hospitals meeting preset patient case or survey count minimums. CMS would apply this approach to the proposed measures that are NQF-endorsed, for which minimum reporting thresholds are detailed in Table 13 of the proposed rule. Low volume EPM participants, new hospitals, and participants whose measure values are suppressed by CMS due to errors in the data are assigned to the 50th performance percentile.

CMS proposes adding into the EPM-specific composite quality score up to 10 percent of the measure's maximum value for participants demonstrating substantial improvement year-over-

year; voluntary measures are excluded. EPM composite quality scores would be capped at 20 points. For the AMI and CABG models, improvement is defined as any year-over-year improvement in a participant's own measure point estimates if the participant falls into the top 10 percent of participants based on the national distribution of measure *improvement*. For the SHFFT model, CMS first proposes defining *improvement* as a year-over-year gain of 2 deciles or more referenced to the relevant national distributions. CMS also proposes to award up to 10 percent of the maximum measure performance scores on both proposed measures, capping the SHFFT composite quality score at 20 points.

CMS proposes to encourage voluntary measure data submission with eligibility for additional composite quality score points, thereby fostering the continued development of these measures. CMS notes that data submitted by SHFFT participants also would be credited under the CJR model, eliminating duplicate submissions.

For each EPM model, CMS proposes to assign a composite quality score and proposes that the SHFFT and CJR scores (based upon the same measures) would be identical. Narrative descriptions and Tables 14-19 provide measure performance weights and individual measure scoring (referenced to national distributions).

For incorporation into quality-adjusted target prices, CMS proposes a maximum effective discount factor for all EPM participants of 3.0 percent. CMS provides detailed narrative and tabular descriptions (Tables 20-28) of the pay-for-performance (P4P) methodology applicable to each EPM. CMS proposes four quality categories for each model based upon their respective composite quality scores: "Below Acceptable", "Acceptable", "Good", and "Excellent". Three tables are provided for each model that relate quality categories to reconciliation payment eligibility, effective discount factor for reconciliation payment, and discount factors for repayment amounts. Multiple tables are required to account for the phased-in repayment responsibility assumption by EPM participants. Discount factors are termed "applicable" until responsibility phase-in is complete and then termed "effective". The proposed SHFFT model discount factors would also apply to the CJR model.

3. Details on Quality Measures for the EPMS

Tables 30-34 summarize the proposed quality measure performance periods arranged by model and by measure. The use of a 3-year rolling performance period for several proposed measures means that reconciliation payments for some years may be based on measures with a performance period that precedes the effective date of the model. No discussion is included regarding potential risk adjustment or stratification of hospital performance to account for variation in sociodemographic factors. Risk adjustment commonly employs a hierarchical logistic regression model that includes age, sex, comorbidities, and case mix as variables. Voluntary measures would not be publicly reported.

AMI Model. Participant performance will not be reported for hospitals with fewer than 25 index admissions in the 3-year measurement period. Measure index hospitalizations overlap variably with anchor/chained anchor hospitalizations. The voluntary measure incorporates five core clinical elements (age, initial heart rate and blood pressure, and initial troponin and creatinine

levels) that are used in risk-adjustment. The voluntary measure will be included in scoring only if valid data are submitted on 50 percent of qualifying admissions in the first performance year, rising to 90 percent in years 2 through 5.

CABG Model. Participant performance will not be reported for hospitals with fewer than 25 index admissions in the 3-year measurement period. Measure index hospitalizations overlap variably with anchor/chained anchor hospitalizations. The MORT-30-CABG measure (NQF #2558) cohort includes only patients undergoing “isolated” CABG operations (e.g., without concomitant valve procedures).

SHFFT Model. The MS-DRGs for the anchor/chained anchor hospitalizations will identify beneficiaries who do not overlap with the index hospitalizations used in SHFFT model measures, because SHFFT measures use elective THA/TKA cases as proxies for hip or femur fracture cases. The Hip/Knee Complications measure (NQF #1550) does not capture patients undergoing partial hip arthroplasty surgery for hip fractures. Approximately 50 hospitals testing BPCI lower extremity joint episodes are excluded from the CJR model but would be included in the SHFFT model as proposed. The voluntary measure includes numerous pre- and post-operative variables and data would be submitted to a CMS contractor. Risk adjustment modeling is not yet complete for the voluntary measure. Voluntary measure submission scoring requires capture of 80 percent of eligible patients according to a complex performance period schedule (Table 12). Successful voluntary SHFFT model data submission is also valid for CJR model submission scoring.

a. Measure Used for All EPMs

In this section of the proposed rule, CMS describes the proposed quality measures for each of the new EPMs and measures proposed for voluntary reporting, the performance periods and reporting requirements that would be used for the models, and the public display of model measure results on the Hospital Compare website.

(1) Quality measures and reporting

CMS proposes that data submission for the EPM quality measures be made through existing HIQR Program processes. For hospitals that voluntarily submit data for the Hybrid AMI mortality measure, CMS anticipates data submission processes will be broadly similar to those of the HIQR Program, if technically feasible. Hospitals would be required to submit data elements using either QRDA-1 or a simpler spreadsheet in performance year 1 but for later years, they would be required to use only QRDA-1.

SHFFT Model

Participants may voluntarily provide patient-reported outcomes and limited risk variable data following elective primary THA/TKA. In order to be considered successful in submitting voluntary data, participants would need to submit:

- In year 1 (2017), pre-operative data on primary elective THA/TKA procedures for ≥ 60 percent or ≥ 75 procedures performed between September 1, 2016 through June 30, 2017, unless CMS requests a more limited data set.

- In year 2 (2018), 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 pre-operative data on primary elective THA/TKA procedures for ≥ 70 percent or ≥ 100 of procedures performed between July 1, 2017 and June 30, 2018, unless CMS requests a more limited data set.
- In year 3 (2019), post-operative data on primary elective THA/TKA procedures for ≥ 70 percent or ≥ 100 procedures performed between July 1, 2017 and June 30, 2018; and pre-operative data on primary elective THA/TKA procedures for ≥ 80 percent or ≥ 200 procedures performed between July 1, 2018 and June 30, 2019, unless CMS requests a more limited data set.
- In year 4 (2020), post-operative data on primary elective THA/TKA procedures for ≥ 80 percent or ≥ 200 procedures performed between July 1, 2018 and June 30, 2019; and pre-operative data on primary elective THA/TKA procedures for ≥ 80 percent or ≥ 200 procedures performed between July 1, 2019 and June 30, 2020, unless CMS requests a more limited data set.
- In year 5 (2021), post-operative data on primary elective THA/TKA procedures for ≥ 80 percent or ≥ 200 procedures performed between July 1, 2019 and June 30, 2020; and pre-operative data on primary elective THA/TKA procedures for ≥ 80 percent or ≥ 200 procedures performed between July 1, 2020 and June 30, 2021, unless CMS requests a more limited data set.

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 - 34 of the proposed rule (FR 50910-11) and are duplicated below.

TABLE 31: SUMMARY OF PROPOSED QUALITY MEASURE PERFORMANCE PERIODS BY YEAR OF THE CABG MODEL

Measure Title	Model Performance Year				
	1 st	2 nd	3 rd	4 th	5 th
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.
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 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) *** Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2558)(MORT-30-CABG);

TABLE 32: SUMMARY OF PROPOSED QUALITY MEASURE PERFORMANCE PERIODS BY YEAR OF THE VOLUNTARY DATA SUBMISSION

	Model Performance Year				
	1st	2nd	3rd	4th	5th
Submission of EHR data elements for the Hybrid AMI Mortality Measure	July 1, 2017– August 31, 2017	September 1 2017 – June 30, 2018	July 1 2018 – June 30, 2019	July 1 2019 – June 30, 2020	July 1, 2020 – June 30, 2021
Submission of functional status data for elective primary THA/TKA procedures	September 1, 2016– June 30, 2017	July 1, 2017 – June 30, 2018	July 1, 2018 – June 30, 2019	July 1, 2019 – June 30, 2020	July 1, 2020– June 30, 2021

TABLE 33: SUMMARY OF PROPOSED QUALITY MEASURE PERFORMANCE PERIODS BY YEAR OF THE SHFFT MODEL

Measure title	Model Performance Year				
	1st	2nd	3rd	4th	5th
Hip/Knee Complications*	April 1, 2014– March 31, 2017.	April 1, 2015– March 31, 2018.	April 1, 2016– March 31, 2019.	April 1, 2017– March 31, 2020.	April 1, 2018– March 31, 2021.

*Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550) (Hip/Knee Complications)

TABLE 34: SUMMARY OF PROPOSED QUALITY MEASURE PERFORMANCE PERIODS BY YEAR FOR REQUIRED MEASURES FOR ALL EPMS

Measure Title	Model Performance Year				
	1st	2nd	3rd	4th	5th
HCAHPS*	July 1, 2016– 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)

(2) HCAHPS Scoring.

In scoring the HCAHPS for the EPMS, CMS proposes to use the HCAHPS Linear Mean Roll-up (HLMR) score, used for the calculation of HCAHPS Star Ratings, which were added to Hospital Compare in April 2015. The HLMR summarizes performance for 10 of the 11 publicly reported HCAHPS measures for hospitals with at least 100 completed HCAHPS surveys over a 4-quarter period.

Improvement on the HCAHPS survey measure would be determined from the measure performance period available for the year immediately preceding the EPM model performance year.

F. Compliance Enforcement and Termination of an Episode Payment Model (§512.460)

CMS agency proposes to hold the EPM participant responsible for its own as well as its EPM collaborators' compliance with the EPM requirements. The rationale for this is in part because ACOs and hospitals, including CAHs, are being added as EPM collaborators.

CMS proposes several remedial actions that it may take against any EPM participant where the EPM participant (or EPM collaborator, collaboration agent or downstream collaboration agent) does not comply with applicable requirements. They include the following:

- Sending a warning letter to the EPM participant;
- Requiring a corrective action plan (CAP) developed by EPM participant;
- Reducing or eliminating an EPM participant's reconciliation payment or CR incentive payment;
- Requiring an EPM participant to terminate a sharing arrangement with an EPM collaborator and prohibiting further engagement by the EPM participant in sharing arrangements with the EPM collaborator; and
- Terminating the EPM participant's in the EPM.

CMS proposes that when an EPM participant is terminated from an EPM, the participant will remain liable for all negative NPRA generated from episodes of care that occurred before termination. CMS also intends to share with its program integrity contractors as well as the

Department of Justice any information it collects in relation to termination of a participant from the model.

The list of requirements for which CMS could take one or more remedial actions in the case of noncompliance is expansive. For example, remedial actions could be imposed if an EPM participant (or its related EPM collaborators, collaboration agents or downstream collaboration agents) fails to comply with any applicable requirement of part 512 or is identified as noncompliant because it (i) avoids high cost or high severity patients or targets low cost or low severity patients; (ii) fails to provide medically appropriate services or systematically engages in over- or under-delivery of appropriate care; (iii) fails to provide beneficiaries with complete and accurate information, including required notices; (iv) fails to allow beneficiary choice of medically-necessary options, including non-surgical options; or (v) fails to follow the requirements related to sharing arrangements.

Under its proposal, CMS could also add 25 percent to a repayment amount on an EPM participant's reconciliation report if all of the following criteria apply:

- CMS requires a CAP from the EPM participant.
- The EPM participant owes a repayment amount to CMS.
- The EPM participant fails to timely comply with the CAP or is noncompliant with the EPM's requirements.

CMS also proposes to grant itself the authority to terminate any episode payment model for other reasons, including that the agency no longer has the funds to support the model or the model does not meet the criteria to expand to phase II of a CMMI demonstration.

G. Monitoring and Beneficiary Protection

Beneficiary Choice and Notification

While participation by hospitals in selected geographic areas in the EPMs would be mandatory, CMS proposes to establish that a beneficiary must continue to be able to choose their Medicare providers. Hospitals would not be able to restrict beneficiaries to a list of preferred or recommended providers to the extent that such restriction is in excess of what is allowed under existing rules and law. In addition, participating hospitals would not be able to charge a collaborator a fee to be included on a list of preferred providers.

CMS proposes a number of required notifications and disclosures:

- 1) As part of the discharge planning process, hospitals in EPMs would be required to inform beneficiaries of all Medicare participating post-acute providers with whom they have sharing arrangements.
- 2) *Hospital detailed notification.* At admission or immediately following the decision to schedule a procedure or service resulting in a patient being included in the episode, participating hospitals would be required to provide a notice that includes the elements listed below. The hospital would be required to be able to generate a list of beneficiaries who

receive the notification including the date of receipt for monitoring purposes. The notice would need to explain:

- The model and how it might affect the beneficiary's care;
- That the beneficiary retains his or her freedom to choose their own providers and services;
- How he or she can access their records and claims data, and how they can share access to their electronic health information with caregivers; and
- That all existing Medicare beneficiary protections continue to apply including the ability to report concerns of substandard care to Quality Improvement Organizations and 1-800-MEDICARE.
- The notice must also provide beneficiaries with a list of the providers and suppliers with whom the hospital has a sharing arrangement.

- 3) *Physician, NPP, PGP, Post-Acute Care, Collaborating Hospital, ACO, and Other Provider Notice notice.* A participating hospital would be required to ensure that any collaborating entity (as listed above) provide notice to Medicare beneficiaries regarding the structure of the model and the existence of any cost sharing arrangements they have with the hospital. The notice would be required at the time of a decision to schedule a procedure or service resulting in a patient being included in the episode. (If not feasible, the notice could be provided to the beneficiary or his or her representative as soon as is reasonably practicable but no later than at discharge.) The provider would be required to be able to generate a list of beneficiaries who receive the notification including the date of receipt for monitoring purposes.
- 4) *Discharge Planning Notice.* CMS would require that each participating beneficiary receive a discharge planning notice informing them of any potential financial liability associated with non-covered services. The notice would be required to be provided at the earlier of when such service is recommended or at discharge. If a hospital knows or should have known that a beneficiary is considering using such a service or supply, the hospital would be required to notify the beneficiary that the service would not be covered by Medicare.

H. Access to EPM Records and Record Retention (§512.110)

CMS proposes that EPM participants, EPM collaborators, collaboration agents, downstream collaboration agents, and any other individuals or entities performing EPM activities must allow CMS, OIG, and other appropriate Federal agencies scheduled and unscheduled access to all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the following six categories of information:

- (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 certified electronic health record technology (CEHRT) use requirements.

The minimum period for document retention would be the 10-year period that begins on the later of (i) the last day of the EPM participant's participation in the EPM or (ii) the date of completion of any audit, evaluation, inspection, or investigation. CMS proposes two exceptions to the general 10-year documentation retention rule. First, CMS may require that a particular record be retained for a longer period if it notifies the EPM participant at least 30 calendar days before the disposition date. Second, if there is 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, the records must be maintained for 6 years from the date of any final resolution of the dispute or allegation of fraud or similar fault.

I. EPM Financial Arrangements

Financial Arrangements and Beneficiary Incentives (Subpart F of Part 512)

CMS discusses several key terms related to EPM financial arrangements that are defined in proposed §512.2.

EPM collaborator means one of the following individuals or entities that enter into a sharing arrangement: skilled nursing facility (SNF), home health agency (HHA), long-term care hospital (LTCH), inpatient rehabilitation facility (IRF), physician, nonphysician practitioner (NPP), outpatient therapy provider, and physician group practice (PGP), hospital, CAH, and ACO.

Sharing arrangement would mean a financial arrangement between a participating hospital and an EPM collaborator for the sole purpose of sharing the following: (i) Reconciliation payments, (ii) the participating hospital's internal cost savings; and (iii) the participating hospital's responsibility for repayment to CMS. Gainsharing payments could only be made, and alignment payments could only be collected, by a participating hospital pursuant to a sharing arrangement.

Sharing arrangements under the EPM (§512.500). CMS would require sharing arrangements to be in writing and to comply with all other applicable laws and regulations, including any applicable fraud and abuse laws and payment and coverage requirements. They would be required to include the following:

- A set of written policies describing how individuals and entities are selected to be EPM collaborators including criteria related to, and inclusive of the quality of care of the potential collaborator. The criteria could not be based directly or indirectly on the volume of referrals or business generated by the collaborator or between the collaborator and the EPM participant.
- The compliance program of the EPM would be required to include oversight of sharing arrangements and compliance with any applicable requirements of the EPM.

Requirements for sharing arrangements (§512.500(b)). Participation in any sharing arrangement would be required to be voluntary and there could be no penalties for nonparticipation. The sharing arrangement could not pose a risk to beneficiary access, freedom of choice or quality of

care. The sharing arrangement would need to obligate the parties to comply (and an EPM collaborator to require any of its employees, contractors or designees to comply) with the following:

- Beneficiary notice requirements and record maintenance requirements.
- Requirements to cooperate with HHS site visits and other evaluation, monitoring, oversight and enforcement activities, including access to records and other information.
- All Medicare provider enrollment requirements and all other applicable laws and regulations.
- The EPM collaborator's compliance program.

The board or governing body of the EPM must oversee participation in the EPM, arrangements with collaborators, gainsharing & alignment payments and beneficiary incentives.

CMS would require that a collaborator agreement is entered into before care is furnished to an EPM beneficiary. The agreement would need to specify the purpose and scope of the arrangement, the identities and obligations of the parties, the date of the sharing arrangements, management and staffing information, financial and economic terms for payments including eligibility criteria for a gainsharing or alignment payment; their frequency, methodology and accounting formula for calculating as well as for distribution and verification of those payments. The methodology for gainsharing payment must be substantially based on quality of care.

CMS would prohibit the agreement from inducing a participant collaborator or any employee, contractor or subcontractor to reduce or limit medical necessary services to a beneficiary, or restricting the ability of an EPM collaborator to make decisions in the best interests of patients.

Gainsharing and Alignment Payments (§512.500(c)). CMS establishes the following conditions and restrictions for payments under the EPM models. Under the proposal, *Gainsharing* payments would be required to:

- Be derived solely from reconciliation payments or internal cost savings.
- Not be a loan or payment for referrals or other business generated from the parties.
- Not be an inducement to reduce or limit medically necessary services.
- Be determined using methodologies that use quality criteria directly related to EPM episodes of care.
- Be distributed annually.
- Be able to be recouped if paid to collaborators if they involved funds from a CMS overpayment or were based on the submission of false or fraudulent data.

Gainsharing payments could not be made to a collaborator who is subject to program integrity issues, such as noncompliance actions under the model, fraud or abuse, or providing substandard care. Total Gainsharing payments would be limited to the CMS reconciliation payment amount for the year and, for any individual physician or NPP, could not exceed 50 percent of total approved MPFS payments for services furnished to EPM beneficiaries. A similar 50 percent limit would apply to PGPs.

To receive a *Gainsharing* payments or be required to make an *Alignment* payment CMS proposes that:

- An EPM collaborator must have directly furnished a billable item or service during the EPM episode in the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment.
- An EPM collaborator that is a PGP or an ACO would qualify for a gainsharing payment if the PGP has billed for, or the ACO has had a provider/supplier that furnished or billed for, a service during the EPM episode in the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment. To qualify, a PGP or ACO must be clinically involved in and have a role in implementing quality strategies, for example, by providing care coordination, and implementing strategies to address or manage comorbidities, etc.

Alignment payments, as proposed under this rule:

- Could be made at any interval as agreed on by both parties;
- Could not be made before the Reconciliation Report reflects a negative NPRA; and
- Could not be in the form of a loan, advance, or payment for referrals/other business generated.
- Total payments received by the hospital could not exceed 50 percent of the hospital's repayment amount owed to CMS, and the most a single collaborator that is not an ACO could pay to a single hospital is 25 percent of the repayment amount owed to CMS. For a collaborator that is an ACO that ceiling would be 50 percent of the repayment amount owed to CMS.
- No other payments except for alignment payments could be made under a sharing arrangement from an EPM collaborator to an EPM participant.

All Gainsharing and Alignment payments would be required to be administered in accordance with generally accepted accounting principles (GAAP).

Internal cost savings. CMS proposes that the methodology for accruing, calculating & verifying internal cost savings would be need to be transparent and be administered by the hospital in accordance with GAAP. Those amounts must reflect documented implementation of EPM activities; and could not reflect “paper” savings from accounting conventions or past investment in fixed costs.

CMS notes that it is not proposing to require documentation of cost savings tied to the activities of specific EPM collaborators as is currently required under the CJR bundle. Elsewhere in this rule, CMS is proposing to make a change to the CJR bundle methodology to be consistent with this EPM provision.

Distribution & Downstream Distribution Arrangements under the EPM (§§ 512.505 – 510)

CMS proposes that financial arrangements made between EPM collaborators and other individuals or entities (called “collaboration agents”) be called “distribution arrangements.” Such arrangements are made for the sole purpose of sharing a gainsharing payment received by

an ACO or PGP. Distribution arrangements would be subject to many of the same requirements described above for sharing arrangements. Distribution arrangements would need to be in writing and comply with, and require all collaboration agents to comply with, all applicable laws and regulations. They would be required to be entered into before care is furnished to EPM beneficiaries under the distribution arrangement.

Distributions under those arrangements must:

- Not be conditioned on the volume or value of referrals or business generated by collaborators and participants;
- Not be an inducement to reduce or limit medically necessary services;
- Be determined substantially based on quality of care and the provision of EPM activities;
- For a collaboration agent, based on an item or services furnished or billed for during the EPM episode in the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment; and
- For a physician or NPP, not exceed 50 percent of total approved MPFS payments for services furnished to EPM beneficiaries. A similar 50 percent limit applies to PGPs.

Total gainsharing payments received by a PGP or ACO could not exceed the total amount of the gainsharing payment received by the EPM collaborator from the EPM participant and could

Certain of those rules, denoted by an asterisk above, would include an exception for collaborators who comply with existing §411.352(g), a provision that prohibits physicians in a group practice from being directly or indirectly compensated based on the volume or value of his or her referrals. CMS proposes to incorporate this exception to allow for the flexibility for an individual PGP provider to share in the practice's financial benefit without consideration of the PGP member's *individual* quality of care or provision of services.

The EPM collaborator would be prohibited from entering into a distribution arrangement with an individual or entity that has a sharing agreement with the same EPM participant and must maintain documentation and provide access to written agreements and distribution payments including any documentation requirements in §512.110 (See section H above).

Downstream distribution arrangements are agreements between an EPM collaborator that is an ACO and a PGP that participates in the ACO. Those agreements would be subject to a similar set of requirements as distribution arrangements. They would need to be in writing and comply with all applicable laws and regulations and must be entered into before care is furnished to EPM beneficiaries under the downstream distribution arrangement.

Downstream distributions under those arrangements must:

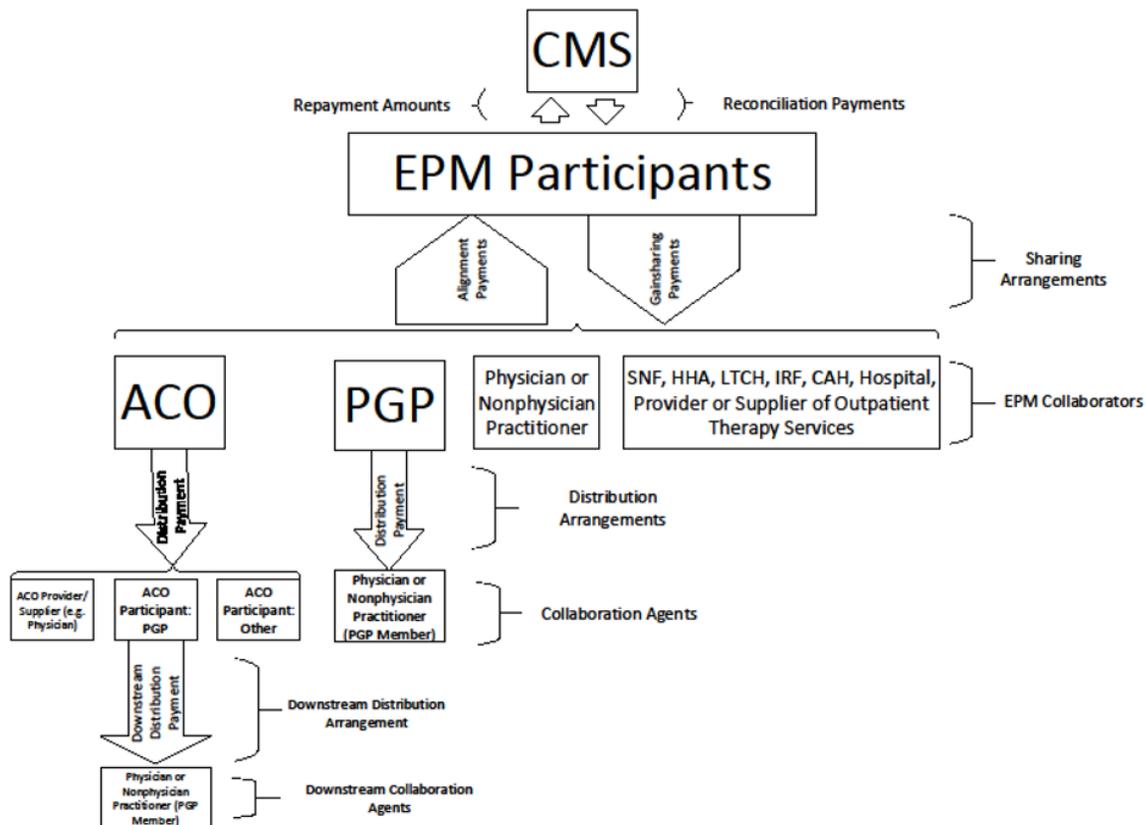
- Not be conditioned on the volume or value of referrals or business generated by collaborators and participants;
- Not be an inducement to reduce or limit medically necessary services;
- Be determined substantially based on quality of care and the provision of EPM activities or alternately;

- Be based on services provided or billed by a downstream collaboration agent during the EPM episode in the same performance year for which the EPM participant accrued the internal cost savings or earned the reconciliation payment; and
- Not exceed 50 percent of total approved MPFS payments for services furnished to EPM beneficiaries; a similar 50 percent limit applies to PGPs.

Total downstream distribution payments could not exceed the total amount of the distribution payment received PGP from the ACO. Certain of those rules, denoted by an asterisk above, would include an exception for collaborators who comply with §411.352(g).

A PGP would be prohibited from entering into a distribution arrangement with another PGP that has a sharing agreement with an EPM participant or a distribution arrangement with the ACO the PGP is a participant in and would be required to maintain the documentation specified in proposed §512.110 (and described in Section H above).

Figure 2: PROPOSED EPM FINANCIAL ARRANGEMENTS



Enforcement authority under the EPM (§512.520).

CMS proposes that the OIG have unlimited authority to audit, evaluate, investigate, or inspect EPM participants and collaborators, and that none of the provisions of the EPM would limit or restrict the authority of other government agencies to do so as permitted by law.

Beneficiary engagement incentives under the EPM (§512.525).

CMS would allow EPM participants to provide in-kind incentives to beneficiaries of EPMs. Incentives would be required to go directly to the EPM beneficiary during the episode, be reasonably connected to medical care provided to an EPM beneficiary during the episode, and be an item or service that advances a clinical goal by engaging the beneficiary in better managing his or her own health. They could not be tied to the receipt of items or services outside the EPM episode or be tied to a particular provider or supplier nor be advertised or promoted. The costs could not be shifted to another federal health care program.

CMS proposes additional conditions for incentives that involve technology. Under the rule, technology incentives could have a retail value of no more than \$1,000 and must be the minimum necessary for advancing the clinical goal. Items or services that have a retail value greater than \$100 would remain the property of the EPM participant and would need to be returned at the end of the episode. The EPM participant would need to document retrieval attempts.

EPM participants would be required to maintain documentation of beneficiary engagement incentives that exceed \$25 in value and as noted above, of any attempt to retrieve technology at the end of an EPM episode. Documentation must include the dates that items or services were furnished as well as the identity of the beneficiary to whom they were provided.

J. Proposed Waivers of Medicare Program Requirements (Subpart G of Part 512)

Post-Discharge Home Visits (§§512.600, 512.615)

CMS proposes to waive the “incident to” rule under §410.26(b)(5) to permit an EPM beneficiary who does not qualify for home health services (e.g., who is not homebound) 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. CMS proposes to permit licensed clinical staff (e.g., nurses) whether they are 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.

Services furnished under the waiver would be billed under the PFS by the physician or nonphysician practitioner, or by the hospital to which the supervising physician has reassigned benefits. CMS notes that where the hospital bills for the post-discharge home visit services, those services would not be considered hospital services even if furnished by clinical staff of the hospital.

The major difference between the CJR waiver and the proposed EPM waiver is that CMS proposes to impose model-specific limits on the number of visits because current model data

show that the average post-acute care LOS may vary or in some cases post-acute care may not be used at all for EPMs. CMS proposes the following model-specific limits on the number of post-discharge home visits:

- AMI Model. A beneficiary in the AMI model could receive up to **13** home visits (i.e., an average of one home visit per week for the entire 90-day AMI episode).
- CABG and SHFFT Models. A beneficiary in the CABG or SHFFT model could receive up to **9** home visits (i.e., an average of one home visit per week for 60 days (two-thirds of the entire 90-day episode)).

Services would be billed with HCPCS code GXXXX12 and paid at approximately \$50 under the PFS; CMS proposes to use standard PFS rate setting methodologies to establish RVUs based on the resources required to furnish the typical service. CMS notes that final RVUs in the 2017 PFS for the proposed new HCPCS code for AMI, CABG, and SHFFT home visits will be included in the EPM final rule. CMS would update values each year to correspond to final values established under the PFS.

CMS proposes to waive current billing rules to permit separate reporting of post-discharge home visits during surgical global periods so the surgeon or other practitioner may furnish and bill for the post-discharge home visits during surgical global periods.

Billing and Payment for Telehealth Services (§512.605)

CMS proposes to waive the geographic site requirements of the Act to permit telehealth services to be furnished to an eligible telehealth individual in his or her home or place of residence. Thus, providers and suppliers would be able to furnish services related to the episode (i.e., AMI, CABG, or SHFFT episode) to EPM beneficiaries via telemedicine for beneficiaries residing in any region. CMS emphasizes that the waiver of the originating site requirement applies only when telehealth services are being furnished in the EPM beneficiary's home or place of residence during the episode.

Telehealth services would include any service on the list of Medicare approved telehealth services and reported on a claim with a principal diagnosis code that is not excluded from the proposed EPM's episode definition, unless the service's HCPCS code descriptor precludes delivering the service in the home or place of residence. CMS proposes to create a specific set of HCPCS G-codes to describe the E/M services furnished to EPM beneficiaries in their homes via telehealth. CMS believes the services would be most similar to services described by the office and other outpatient E/M codes.

CMS would set payment rates for the new telehealth G-codes for E/M services in the patient's home similar to the payment rates for the office/outpatient E/M services; the agency proposes to

12 GXXXX Code Descriptor: 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

include the resource costs typically incurred when services are furnished via telehealth. It would also adopt work and malpractice RVUs associated with the corresponding level of office/outpatient codes as the typical service. CMS would update the values each year to correspond to final values established under the PFS. For EPMs under this waiver, CMS does not propose to include costs of auxiliary licensed clinical staff that would otherwise be incorporated in the practice expense RVUs under the PFS. However, CMS notes that the proposed EPMs include avenues for licensed clinical staff to be in the patient's home through separately paid home visits or home health services. Because of the anticipated complexity of levels 4 and 5 E/M visits, CMS expects 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 occurs, CMS proposes 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.

With respect to home health services paid under the home health prospective payment system (HH PPS), CMS emphasizes that telehealth visits under this model may not substitute for in-person home health visits and that telehealth services by social workers may not be furnished for EPM beneficiaries who are in a home health episode of care (medical social services are home health services and paid for under the HH PPS). By contrast, telehealth services furnished by physicians or other practitioners (i.e., physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, nurse anesthetists, psychologists, and dieticians) may be furnished for EPM beneficiaries who are in a home health episode of care. Finally, CMS does not propose to waive the geographic and originating site limitations under the Act for the face-to-face encounter required as part of the home health certification when that encounter is furnished via telehealth. Thus, 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. CMS believes this is appropriate because the beneficiary would have had a face-to-face encounter with the physician (or nonphysician practitioner) during his or her anchor hospitalization or during a post-acute facility stay prior to discharge directly to home health services.

CMS also clarifies that all telehealth services under the waiver must meet Medicare coverage and payment criteria and that no additional payment would be made to cover set-up costs, technology purchases, training and education, or other related costs. Additionally, CMS would waive the usual facility fee when the service was originated in the beneficiary's home or place of residence. Additionally, beneficiaries could only receive telehealth services under the waiver during the EPM episode.

SNF 3-Day Rule (§512.610)

a. Waiver

CMS proposes to waive the SNF 3-day rule for coverage of a SNF stay following the anchor hospitalization under an EPM where it is clinically appropriate. CMS will not permit use of the waiver until the second performance year which is when hospitals would first be at financial risk for excess spending (episodes beginning on or after April 1, 2018).

CMS also proposes to permit use of this waiver only for discharges to a SNF with an overall rating of three stars or better (on the CMS Five-Star Quality Rating System) based on information publicly available at the time of hospital discharge. Specifically, to be qualified, the SNF must be included in the most recent calendar year quarter on the Nursing Home Compare website and 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. CMS proposes to post on its web site the list of qualified SNFs in advance of each calendar quarter. CMS also notes that there is currently at least one 3-star rated SNF in all 294 MSAs that are eligible for selection for the AMI and CABG models.

CMS will **not permit** the waiver for the CABG model (because of longer geometric mean hospital LOSs of 6.0 to 11.6 days) or for the SHFFT model (because studies show that shorter than average hospital LOSs for hip fracture are associated with higher mortality).

b. Additional Beneficiary Protections under the SNF 3-Day Stay Rule Waiver

CMS believes it must include protections for beneficiaries against financial liability for EPM models for non-covered Part A SNF services that might be directly related to use of the SNF 3-day waiver under the applicable EPM. CMS is concerned with the three following scenarios:

- The EPM participant hospital discharges a beneficiary that is in a specific EPM where the SNF 3-day rule waiver does not apply (e.g., the CABG or SHFFT model).
- 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 3-star quality rating requirement **and** does not provide a discharge planning notice to the beneficiary alerting them of potential financial liability.

CMS is concerned that where the waiver requirements are not met, the claim would be rejected because the beneficiary would not have had a qualifying inpatient hospital stay, meaning that the SNF could charge the EPM beneficiary for non-covered SNF services. In these cases, CMS proposes to hold the EPM participant hospital financially responsible for misusing the waiver in situations where waiver requirements are not met. CMS intends to specify with clarity the requirement for use of the SNF waiver in the EPM final rule. Where CMS determines that the waiver requirements were not met under one or more of the circumstances described above, CMS proposes to apply the following rules:

- CMS would make no payment to the SNF for such services.
- The SNF could not charge the beneficiary for the expenses incurred for such services and the SNF would have to return to the beneficiary any monies collected for such services.
- The hospital would be responsible for the cost of the uncovered SNF services furnished during the SNF stay.

However, where the EPM hospital discharges a beneficiary to a SNF that does not meet the 3-star quality rating requirement and a discharge planning notice **is** provided to the beneficiary alerting him or her of potential financial liability, then the hospital would not be financially liable

for the cost of the SNF stay and the normal rules for coverage of SNF services would apply. Essentially, the discharge notice would absolve the hospital of liability.

Waivers of Medicare Program Rules to Allow Reconciliation Payment or Repayment Actions Resulting from the Net Payment Reconciliation Amount (§512.620)

CMS proposes to waive requirements of sections 1813 and 1833(a) of the Act (relating to deductibles and coinsurance) for 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. CMS clarifies that its 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 beneficiaries and aggregated to determine actual episode spending in the calculation of the NPRA.

New Waiver for Providers and Suppliers of Cardiac Rehabilitation and Intensive Cardiac Rehabilitation Services Furnished to EPM Beneficiaries during an AMI or CABG Episode (§512.630)

CMS proposes to waive the definition of physician to permit certain nonphysician practitioners (viz., physician assistants, nurse practitioners or clinical nurse specialists) to perform the functions of the supervisory physician, prescribe exercise, and establish, review, and sign 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. However, CMS would not permit a nonphysician practitioner to act in the capacity of a medical director under the waiver.

K. Data Sharing (§512.350)

CMS proposes to provide EPM participants in the AMI, CABG, and SHFFT models, upon request, beneficiary-level claims data for the historical period used to calculate episode benchmark and quality-adjusted target prices as well as with ongoing quarterly beneficiary-identifiable claims data. It also proposes to provide EPM participants with aggregate regional data because it intends to incorporate regional pricing in the calculation of benchmark and quality-adjusted target prices.

Beneficiary Claims Data

CMS proposes 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 participation in the model, in accordance with applicable privacy and security laws and established privacy and security protections.

For EPM participants that cannot analyze raw claims data, for both the baseline period and on a quarterly basis during an EPM participant's performance period, CMS proposes 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. This would include the procedure, inpatient stay, and all related

care covered under Parts A and B within the 90-day period after discharge. CMS further proposes that the summary claims data reports would also contain payment information based upon the following categories for each episode initiated under the models: (i) Inpatient, (ii) Outpatient, (iii) Skilled Nursing Facility, (iv) Home Health, (v) Hospice, (vi) Carrier/Part-B, and (vii) Durable Medical Equipment. The data would provide summary spending data (e.g., total average spending for each episode and a breakdown of the episode counts and spending averages by each of the most common categories).

For EPM participants with the capacity to analyze raw claims data, CMS proposes to make available more detailed beneficiary-level information upon request. CMS notes that 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. Further, 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.

Aggregate Regional Data

CMS proposes to provide to an EPM participant, upon request, 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. EPM participants would be provided with aggregate data on the total expenditures during an acute inpatient stay and 90-day post-discharge period for all Medicare FFS beneficiaries who initiated an episode under the proposed episode definitions.

Timing and Period of Baseline Data. CMS proposes to make 3 years of baseline data available to EPM participants upon request and prior to the start of the first episode payment model performance year. CMS proposes 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.

Frequency and Period of Claims Data Updates for Sharing Beneficiary-Identifiable Claims Data During the Performance Period

CMS intends to provide periodically updated beneficiary-identifiable claims data (both summary and beneficiary-level) to EPM participants upon request and subject to the HIPAA Privacy Rule. For the first year of the models (2017), CMS proposes to provide claims data from July 1, 2017 to June 30, 2018 on as frequently as a running quarterly basis, as claims are available. 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.

CMS intends to eventually make these data available more frequently—on a monthly basis if practicable. Under the proposal, EPM participants would only need to make a single initial request to receive data on episode spending rather than multiple periodic requests for data.

Data Considerations with Respect to EPM and CJR Collaborators

CMS acknowledges that its proposal to disclose beneficiary-identifiable data only to EPM participants at financial risk for an AMI, CABG, or SHFFT episode and not with EPM collaborators may present issues for collaborators in assessing their own performance under the

model and the region in which they operate. CMS notes that EPM participants would be able to share data with their EPM collaborators if they are business associates under the HIPAA Privacy Rule.

CMS is also considering whether it would be feasible and appropriate to make additional **non-beneficiary-identifiable** aggregate data publicly available in some manner.

IV. Comprehensive Care for Joint Replacement (CJR) Model

A. Inclusion of Reconciliation and Repayment Amounts when Updating Data for Quality Adjusted Target Prices

Under the CJR final rule, target prices are established for each participant hospital for each performance year. The episode target prices are based on a blend of each participant hospital's hospital-specific and regional episode expenditures. A two-sided risk model is employed in which hospitals meeting or exceeding quality performance thresholds and achieving cost efficiencies relative to CJR target prices receive episode reconciliation payments, while hospitals that exceed their CJR target prices for any of performance years 2 through 5 are responsible for repaying Medicare, with some limitations.

CMS's final rule policy is that reconciliation payments and repayments are excluded when updating quality-adjusted target prices for performance years 3, 4 and 5. Many public comments indicated that excluding these payments from the quality-adjusted target price (now to be called "target-price"), would discourage hospitals from investing in activities that promote coordination of care.

With further consideration, CMS now proposes to include both reconciliation payments and repayments in its calculations when updating quality-adjusted target prices for performance years 3, 4 and 5. Including reconciliation payments would more fully recognize the total costs of care under an episode payment model than would excluding them.

CMS also proposes to include any reconciliation payments and repayment amounts from historical BPCI lower extremity joint replacement (LEJR) episodes initiated at regional hospitals in regional historical episode payments.

B. Quality-Adjusted Target Price

Under the existing regulation, "episode target price" refers to a CJR participant hospital's episode benchmark price incorporating the effective discount factor based on the participant hospital's quality category. CMS proposes to change that term to "quality-adjusted target price." The current term refers to the episode benchmark price with a 3 percent discount applied. Under the revised terminology, the 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 that payment or repayment.

CMS also clarifies that the discount factor included in the quality-adjusted target price based on the quality score is 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. These terminology changes would be implemented in all communications with participant hospitals 60 days after the change is finalized.

C. Reconciliation

1. Hospital Responsibility for Increased Post-Episode Payments

Under the existing regulations, participant hospitals will be responsible for repaying Medicare for post-episode spending that exceeds 3 standard deviations from the regional mean. The amount exceeding 3 standard deviations above the regional mean) is included in a participant hospital's Net Payment Reconciliation Amount (NPRA) for a given performance year. As a result, a hospital's financial responsibility for post-episode spending is subject to the stop-loss and stop-gain limits (see 80 FR 73398).

CMS now proposes to revise this policy. First, CMS proposes to calculate post-episode payments using the same timeframes it uses for the subsequent reconciliation calculation, not when it conducts the initial reconciliation for a performance year as is the current provision (80 FR 73383). Since CMS will begin reconciliation calculations 2 months after the conclusion of a performance year, the current timeframe does not provide sufficient time for the claims run-out needed to set a reliable regional threshold for determining post-episode spending. CMS would assess post-episode spending for the first performance year (episodes beginning and ending between April 1, 2016 and December 31, 2016) when it conducts the reconciliation for the second CJR performance year (2017) in early 2018.

Second, CMS proposes that hospital responsibility for post-episode spending not be subject to the stop-loss and stop-gain limits. Although CMS believes that post-episode spending will be rare, it also believes that where a hospital has post-episode spending, it should be responsible in full for that spending and not reduced as a result of the stop loss limits. 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.

2. ACO Overlap and Subsequent Reconciliation Calculation

CMS proposes to modify the existing language relating to how CMS is 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 Programs or specified ACR models. The existing regulation says that the results of the overlap calculation are to be included in the subsequent reconciliation calculation that occurs 14 months after the conclusion of a performance year.

Under CMS' proposed change, the subsequent reconciliation would 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 would be a separate calculation from the subsequent reconciliation (although both calculations would 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. In this way, the overlap amounts would not be subject to the stop-loss or stop-gain limits that apply to the calculation of the NPRA and subsequent reconciliation calculation. CMS would implement this proposed change when it conducts the subsequent reconciliation calculation for performance year 1 of the model in the first 2 quarters of 2018 and for all performance years thereafter. It notes that it would not impact the performance year 1 NPRA.

D. Use of Quality Measures and the Composite Quality Score

1. Hospitals Included in Quality Performance Distribution

Under the existing CJR regulations, 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. CMS now proposes 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.

2. Quality Improvement Points

Under the finalized CJR model, 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. Two changes are proposed to this, reflected in amendments at §510.315(d). CMS would clarify that, for performance year 1, it would compare the hospital's performance percentile with the corresponding time period in the previous year, not the previous performance year since there is no performance year preceding performance year 1. For performance years 2 through 5, the hospital's performance percentile would still be compared with the previous performance year. CMS also proposes 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.

3. Relationship of Composite Quality Score to Quality Categories

The current regulation calls for CMS to place participant hospitals into one of four quality categories to determine reconciliation payment eligibility and, if applicable, the values of the effective discount percentage at reconciliation. CMS proposes a technical correction that it says will not affect its estimation of savings due to the CJR model because the measure distribution used for the calculations in the CJR final rule was the correct one described in this proposed rule.

If actual episode spending is less than the target price, participant hospitals—

- Would be required to achieve a minimum composite quality score of greater than or equal to 5.0 to be eligible for a reconciliation payment. Those below 5.0 would be assigned to the "Below Acceptable" quality category and would not be eligible for a reconciliation payment.
- With a composite quality score that is greater than or equal to 5.0 and less than 6.9, will be assigned to the "Acceptable" quality category and eligible for a reconciliation payment. These hospitals would not be eligible to receive a reduced effective discount percentage at reconciliation.
- With a composite quality score greater than or equal to 6.9 and less or equal to 15.0, would be assigned to the "Good" quality category and eligible for a reconciliation payment and reduced effective discount percentage.
- With a composite quality score greater than 15.0, would be assigned to the "Excellent" quality category and would be eligible for a reconciliation payment and reduced effective discount percentage.

4. Maximum Composite Quality Score

CMS proposes to award up to 10 percent of the maximum measure performance score on the THA/TKA Complications and HCAHPS Survey measures and to cap the CJR model composite quality score at 20 points. CMS says that this 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.

E. Accounting for Overlap with CMS ACO Models and the Shared Savings Program

CMS now proposes to cancel (or never initiate) a CJR episode for beneficiaries who 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. CMS would 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.

CMS is not proposing to exclude beneficiaries assigned to Shared Savings Program Track 3 ACOs because it intends 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.

CMS also is not proposing to cancel the CJR episode in cases where a beneficiary is in a CJR model and also aligned to a Pioneer ACO, MSSP ACO, or ESCO not participating in downside risk. The final rule policies for accounting for such overlap would continue to apply.

F. 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. CMS proposes to include all CJR collaborators in the requirements for delivery of beneficiary notices and to streamline its current regulations.

1. Physician, Nonphysician Practitioner, Physician Group Practice (PGP), hospitals, ACOs, and CAHs Provision of Notice

CMS would amend §510.405(b)(2), which specifies that a physician who is a CJR collaborator must provide notices to CJR beneficiaries, to include PGP so that there is a distinct notification requirement for PGPs as well as physicians that are CJR collaborators. The intent is to help ensure that beneficiaries are aware of the model and its potential effect on their care.

2. Beneficiary Notification Compliance and Records

CMS would amend §510.405(b)(1) through §510.405(b)(5) and §510.405(b)(7) to require that participant hospitals and CJR collaborators be able to, upon request by CMS, demonstrate compliance with the applicable beneficiary notification requirements. They 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.

G. Financial Arrangements under the CJR Model

CMS now proposes a full replacement for the prior CJR regulations at §510.500 and § 510.505 related to financial arrangements with “CJR collaborators.” The changes are characterized as largely organizational in nature and not changes to policy or requirements. Additionally, CMS proposes new financial arrangement policies and/or requirements for the CJR model that would be effective beginning July 1, 2017, in order to align with the beginning of the first performance year of the proposed EPMs.

1. Definitions Related to Financial Arrangements

a. CMS proposes to allow ACOs (with the limitations discussed later in this section), hospitals, and CAHs to be collaborators. It also proposes to allow participant hospitals to enter into financial arrangements with other hospitals and CAHs that care for CJR beneficiaries

b. Deletion of term “Collaborator Agreements.” To reduce duplicative language and streamline the regulations for financial arrangements between CJR participants and CJR collaborators, CMS would delete “collaborator agreement” in §510.2 and transition the requirements of collaborator agreements to requirements of sharing arrangements.

c. Addition of CJR activities. CMS would further amend §510.2 by adding 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 regulations governing the contents of the written agreement memorializing the sharing arrangement. Activities that would fall under this proposed definition of CJR activities (i.e., those related to promoting accountability for the

quality, cost, and overall care for CJR beneficiaries)¹³ 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.

2. Sharing Arrangements

As noted above, CMS proposes to delete “collaborator agreement” and include all requirements of a financial arrangement between a participant hospital and a CJR collaborator under sharing arrangements. This significant change in terminology leads CMS to propose a complete revision of §510.500.

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 at § 510.500. Under proposed revised paragraph (a)—

- 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.
- A participant hospital must develop, maintain, and use a set of written policies for selecting individuals and entities to be CJR collaborators that contain criteria related to, and inclusive of, the quality of care delivered by the potential CJR collaborator. The 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.

b. Requirements. With CMS’s proposal to delete “collaborator agreement,” the existing requirements under collaborator agreements would now be streamlined under sharing arrangements. CMS provides the following summary of the proposed 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.

¹³ These include managing and coordinating care; encouraging investment in infrastructure, enabling technologies, and redesigned care processes for high quality and efficient service delivery; 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.

- Participation in the arrangement must be voluntary and without penalty for nonparticipation.
- It must require the CJR collaborator and its employees, contractors (including collaboration agents), and subcontractors (including downstream collaboration agents) to comply with the following: the applicable provisions of this part (including requirements regarding beneficiary notifications, access to records, record retention, and participation in any evaluation, monitoring, compliance, and enforcement activities performed by CMS or its designees); all applicable Medicare provider enrollment requirements at §424.500 of this chapter, including having a valid and active TIN or NPI, during the term of the sharing arrangement; and all other applicable laws and regulations.
- It 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.
- It 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 purpose and scope of the sharing arrangement; 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.
- The sharing arrangement must not induce the participant hospital, CJR collaborator, or any employees, contractors, or subcontractors of the participant hospital or CJR collaborator to reduce or limit medically necessary services to any Medicare beneficiary; or restrict the ability of a CJR collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies and treatments.

c. Gainsharing Payment, Alignment Payment and Internal Cost Savings Conditions and Restrictions. CMS places certain conditions and limitations on gainsharing payments, alignment payments and internal cost savings. CMS proposes to amend these limitations and conditions 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.

Under proposed §510.500(c), gainsharing and alignment 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: it 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. Examples of “clinically involved” are provided.
- 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 its documented implementation of CJR activities 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. *With this provision, CMS would be revising current policy that requires the calculation of internal cost savings to be tied to the activities of any specific CJR collaborator (FR 50960-63).*
- The total amount of a gainsharing payment for a performance year paid to a CJR collaborator must not exceed: (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 in 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 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: (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.
- 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: (i) with respect to a CJR collaborator other than an ACO, 25 percent of the participant hospital's repayment amount; and (ii) *with respect to a CJR collaborator that is an ACO, 50 percent of the participant hospital's repayment amount.* (The 50 percent for ACOs would be a change from current policy.)
- 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.

3. Distribution Arrangements

CMS proposes to revise the regulations in §510.505 so as to accommodate its 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. The goal is to avoid confusion for hospitals that are participating in CJR as well as one or more of the proposed EPMs. CMS says that these 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. Under the proposed revisions, certain financial arrangements between CJR collaborators and other individuals or entities called "collaboration agents" are 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, that payment is defined 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.

b. Requirements. CMS would revise paragraph (b)(4) to provide 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 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*.

Under paragraph (b)(5) of the current regulations, 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. CMS proposes to revise this provision to provide a more flexible standard for the determination of the amount of distribution payments from ACOs and PGPs for the same reasons it proposes this standard for the determination of gainsharing payments. Specifically, for ACOs it proposes 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. CMS believes 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.

CMS notes that for distribution payments made by a PGP to PGP members, the requirement that the amount of any distribution payments 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 allowed under existing law. To retain existing flexibility for

distribution payments by a PGP to PGP members, CMS proposes to revise existing paragraphs (b)(4) and (5) 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). (See new paragraph (b)(6)). This change 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. CMS believes that this policy 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. It 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.

Except for a distribution payment from a PGP to a PGP member that complies with §411.352(g), CMS proposes in revised paragraph (b)(8) to continue the current limits on the total amount of distribution payments to physicians, nonphysician practitioners, and PGPs as it proposes 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), the total amount of distribution payments paid for a performance year to the collaboration agent would be limited to 50 percent of the total Medicare-approved amounts under the PFS for items and services furnished by the agent to the hospital's CJR beneficiaries during CJR episodes that occurred during the same performance year for which the hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being distributed. In the case of a collaboration agent that is a PGP, the limit would continue to be 50 percent.

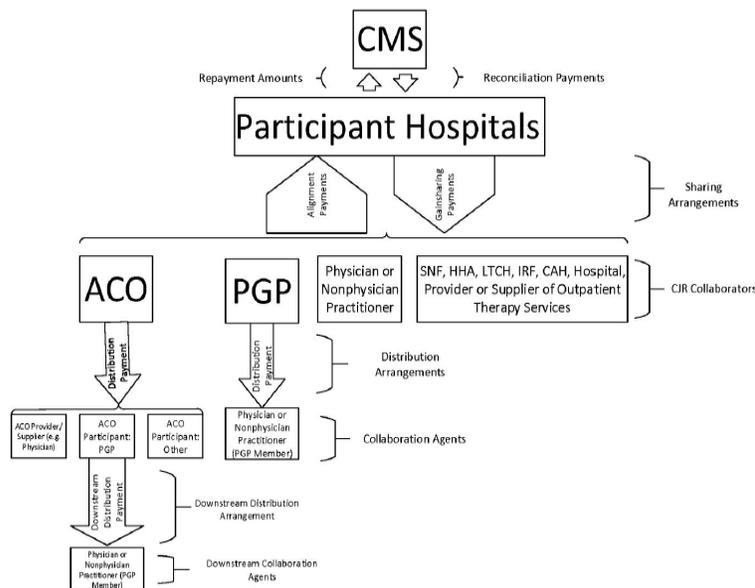
4. Downstream Distribution Arrangements under the CJR Model

a. General. CMS proposes through the addition of new §510.506 that the CJR model allow for certain financial arrangements within an ACO between a PGP and its members. The proposal for downstream distribution arrangements mirror its proposals for the proposed EPMS described in section III.I.6. of this proposed rule. See the EPM Section III (C, D, E, F, G, H, I) of this summary for details.

5. Summary of Proposals for Sharing, Distribution, and Downstream Distribution Arrangements under the CJR model.

The figure reproduced below summarizes CMS' proposals for the defined terms and financial arrangements discussed in Section V.J. of this proposed rule.

Proposed CJR Financial Arrangements



H. Beneficiary Incentives under the CJR Model

Under existing §510.515, participating hospitals (not CJR collaborators) are permitted to provide “in-kind patient engagement incentives” to beneficiaries in CJR episodes for free or below fair market value, with several modifications. CMS proposes numerous amendments to this section for organizational purposes, to more clearly specify its 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. Although CMS retains most existing requirements, its proposed revisions are intended to ensure adequate documentation of beneficiary incentives by participant hospitals and to align with its proposed requirements for the EPMs.

In addition to organizational revisions (e.g., technology provided to a CJR beneficiary is in current paragraph (d) but would move to be paragraph (b)), significant proposed changes include:

- As a program safeguard against misuse of beneficiary incentives under the CJR model, the existing requirements for documentation of beneficiary incentives exceeding \$100 in retail value would also include contemporaneous documentation of any attempt to retrieve the technology at the end of a CJR episode. CMS states in the preamble that documented, diligent, good faith attempts to retrieve items of technology would be deemed to meet the retrieval requirement.
- New paragraph (d)(4) would be added that participant hospitals retain and provide access to required documentation pertaining to beneficiary incentives in accordance with §510.110 (as opposed to existing 610.515(e) of this section, which would be deleted). CMS states that this would promote parallel record retention for all CJR model requirements and further enable successful monitoring efforts by CMS.

I. Access to Records and Record Retention

Participant hospitals, CJR collaborators, collaboration agents, downstream collaboration agents and any other individuals or entities performing CJR activities would be required 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 addition, such documents would have to 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, 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.

CMS also proposes to establish CEHRT use attestation for a CJR participant hospital so that it 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. Thus, it proposes 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. The access to records and record retention requirements provide a program integrity safeguard by allowing CMS to assess the completeness and accuracy of the participant hospital's compliance with the requirements for those submissions.

J. SNF 3-day Waiver Beneficiary Protections

Under existing §510.610 (per the November 2015 CJR final rule), CMS created a waiver of current law to give CJR participating hospitals flexibility to attempt to increase quality and decrease costs for beneficiaries as it relates to their post-hospital stays. Specifically, for SNFs that meet all specified requirements, CMS waives 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. This SNF waiver is only available to hospitals that are active participants in the CJR model. The SNF must meet a quality requirement that it

have 3 stars or higher in 7 of the last 12 months for the beneficiary stay to quality. All other provisions of the statute and regulations regarding Medicare Part A post-hospital extended care services continue to apply.

CMS proposes 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 revised 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 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), the following rules would apply: CMS would not make a payment to the SNF for such services; the SNF could not charge the beneficiary for the expenses incurred for such services; and it would have to return to the beneficiary any monies collected for such services. The hospital would be responsible for the cost of the uncovered SNF stay. In addition, the regulations would be amended to clarify that the SNF 3-day waiver would be available in performance years 2 through 5 for those episodes beginning on or after January 1, 2017.

K. Advanced Alternative Payment Model Considerations

Under this proposed rule, CMS would establish a pathway for participants in the CJR to be considered as participating in an Advanced APM for the purpose of becoming a QP. CMS proposes to establish two tracks for CJR participants. Those CJRs and their participating providers that meet the criteria for participating in an Advanced APM as described under the Quality Payment Program Proposed rule would be on Track 1. Other CJRs and their participants that do not meet such criteria would be on Track 2.

CMS asserts that the existing quality measures for the CJR model meet the criteria under the Quality Payment Proposed rule as described above and include an outcome measure (Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550)(Hip/Knee Complications)). In addition, starting in performance year 2 for episodes ending between January 1, 2017 and December 31, 2017, most participating hospitals will bear downside risk that meets the risk criteria described above. Certain other hospitals subject to special protections – rural hospitals, sole community hospitals, Medicare Dependent Hospitals, and Rural Referral Centers – have a lower stop-loss limit (3 percent in performance year 2) and would, therefore not

meet the risk criteria for that year. Therefore, CMS proposes that those hospitals with special protections would be in Track 2 for performance year 2. CMS also points out that those hospitals with special protections will, in year 3, be subject to a higher stop loss limit (of 5 percent) and so would, beginning with that year, be able to be on Track 1 if the other conditions were met.

With respect to the last criteria – requiring hospital participants to use CEHRT – CMS proposes in new §510.120, that a CJR model may participate in Track 1 for performance years 2 through 5 if they attest in a form and manner as required by CMS to their use of CEHRT to document and communicate clinical care with patients and other health professionals in accordance with 42 CFR 414.1305. Those choosing to require and attest to the use of CEHRT must also provide CMS with a list of clinician financial arrangements on no more than a quarterly basis. The list must provide:

- For collaborating providers, the TIN and NPI for each as well as and the start and end date for the sharing arrangements.
- For each collaboration agent who is a physician or nonphysician provider of a PGP that is a CJR collaborator during the performance year, the TIN of the PGP, 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. A collaboration agent is defined as a PGP member who has entered into a distribution arrangement with the same PGP of which he or she is a member, or an ACO provider/supplier that has entered into a distribution arrangement with the same ACO in which it is participating, and who has not entered into a collaborator agreement with a participating hospital.
- 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 performance year, the TIN of the PGP, 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 and the physician or nonphysician practitioner who is the PGP member.

If there are not individuals who meet the requirements to be reported, the participant hospital must attest as such. Participating hospitals that attest to the use of CEHRT under this section would also be required to maintain documentation of their attestation as well as the clinical financial arrangement lists.

V. Cardiac Rehabilitation Incentive Payment Model

A. Overview of the CR Incentive Payment Model

1. General Design of the CR Incentive Payment Model

Goal. The model is designed to test the cost and quality effects of providing explicit financial incentives to encourage care coordination and increased CR utilization during 90 days after hospital discharge for beneficiaries treated for AMI or undergoing CABG surgery. Specific short and long-term outcome endpoints include mortality, hospitalizations, complications, other clinically relevant events, and Medicare expenditures.

Participants. The payments would be made to hospitals (termed CR participants) for patients admitted for AMI treatment or CABG surgery; over 95 percent of CR/ICR services are provided to Medicare beneficiaries by hospitals. CR participants may also have been selected as AMI and CABG EPM participants (EPM-CR participants) or not (FFS-CR participants). For EPM-CR participants, the incentive for each beneficiary would be given to the hospital to whom cost and quality responsibility has been attributed. For beneficiaries receiving AMI or CABG care through traditional FFS Medicare, incentives would be paid only to hospitals specifically selected to participate in the CR model program.

Payment. Medical literature supports that Medicare beneficiaries completing at least 12 CR sessions have lower mortality rates compared to those completing 1-11 sessions; mortality rates continue to decline with increasing session numbers. Therefore, CMS proposes a two-level, per service, CR incentive amount. The first level is designed to support initial beneficiary CR/ICR engagement, while the second, higher level would reward hospitals for fostering continued engagement above a session utilization benchmark. CMS proposes to make the incentive payments annually on a retrospective basis.

B. CR Incentive Payment Model Participants

CMS recalls that 98 MSAs were selected for mandatory participation in the AMI and CABG EPMs from a pool of 294 eligible MSAs. CMS now proposes to select 45 of the 98 for inclusion in the CR model (termed EPM-CR MSAs), and to select 45 additional MSAs (termed FFS-CR MSAs) for the CR model drawn from the 196 MSAs eligible but not selected for the EPMs. CMS hopes to create four groups well-matched for MSA type: FFS-CR, FFS-non CR, EPM-CR, and EPM-non CR. CMS seeks to balance key characteristics between EPM-CR and EPM-non CR MSAs and to base selection of FFS-CR MSAs on their similarity to randomly selected EPM MSAs.

CMS proposes to start the MSA selection process by classifying the originally eligible 294 MSA into groups based upon CR/ICR service provision metrics within each MSA during the reference year including:

- Percent Starting CR/ICR services – percent of eligible cases who received at least one CR/ICR service
 - CMS is considering dividing MSAs through alternative cut points including percent and percent of this metric
- Percent Completing CR/ICR services – percent of eligible cases who completed 25 or more CR/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 – number who billed for CR/ICR services in the MSA during the reference year
 - CMS is also considering dividing MSAs into those with one versus more than one hospital who billed for CR services.

CMS proposes to use the above four groups above as selection strata to choose CR MSAs through a modified stratified random selection algorithm.

C. CR/IR Services that Count Towards Incentive Payments

CMS proposes using CR/ICR HCPCS service codes submitted on PFS and OPSS claims to identify services counting towards incentive payments. Codes for currently covered services are shown below in Table 37 from the proposed rule, shown below, and the list would be updated by CMS as needed.

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

EPM participant hospitals are eligible to receive CR incentive payments for the full duration of AMI or CABG episodes (throughout the 90-day post-hospital discharge period). EPM participant CR payment eligibility begins once Medicare has paid any CR/ICR provider for delivery of at least one CR service during an AMI or CABG episode to a beneficiary whose episode has been attributed to the EPM participant. At this point, the hospital becomes an EPM-CR participant. To administer the CR incentive program in non-EPM (FFS) hospitals, CMS proposes the concept of an “AMI care period” analogous to the AMI EPM episode. The care period would meet all the requirements to be an AMI model episode if the participating hospital were an EPM participant. Similarly, the FFS counterpart of an EPM CABG episode would be a “CABG care period”. CMS believes the proposed care period definitions would establish comparability between the EPM-CR and EPM-FFS groups for future analysis. Applying the care period concept, a FFS-CR participant hospital would be eligible for CR payments throughout the AMI or CABG care period, and eligibility would begin once Medicare has paid any CR/ICR provider for delivery of at least one CR service during an AMI or CABG care period to a beneficiary whose care period is associated with that FFS hospital.

CMS proposes that AMI/CABG episodes take precedence over AMI/CABG care periods (e.g., an AMI care period would be canceled if a beneficiary began a CABG episode at any time within the care period). To align EPM and CR program performance years, CMS proposes that

all AMI and CABG episodes and all AMI and CABG care periods must begin on or after July 1, 2017 and end on or before December 31, 2021.

D. Determination of CR Incentive Payments

1. Determination of CR Amounts that Sum to Determine a CR Incentive Payment

CR payments would be additive to the usual Medicare payments made to CR/ICR service providers. CMS proposes to tally CR/ICR services using OPPS and PFS claims during the relevant time periods. Payments would be made at the end of each CR performance year from the Part B Trust Fund to CR participants, and beneficiary-specific payment data would be submitted to the CMS Master Database Management (MDM) system.

CMS is proposing a two-level, per service, CR incentive amount. The first (lower) level would support initial beneficiary engagement; the second (higher) level would foster continued adherence above a session utilization benchmark. CMS proposes to set the benchmark at 12 sessions based on evidence linking reduced mortality to increased session completion. CMS describes a “CR amount” as the dollar amount paid to CR/ICR providers during a beneficiary’s EPM episode or non-EPM care period in accordance with the two-level payment structure. A CR participant hospital’s incentive payment would be the sum of the CR amounts for all AMI/CABG beneficiaries attributed to the hospital during a CR performance period. CMS believes that providing a single, summative payment to each CR program hospital at the end of the performance year would explicitly and substantially incentivize the desired CR/ICR services utilization. The single payment would represent the totality of the financial reward to each CR participant during each performance year. CMS proposes to set the CR incentive payments at \$25 per service for each of the first 11 CR/ICR services and \$175 per service thereafter. CMS does not propose to cap the number of services counted toward the CR amount but notes that Medicare program coverage limits already exist.¹⁴ CMS anticipates revisiting the incentive payment levels as experience is gained with the CR incentive payment program.

2. Relation of CR Incentive Payments to EPM Pricing and Payment Policies and Sharing Arrangements for EPM-CR participants

CMS considers CR incentive payments to be distinct from reconciliation payments and repayments involving EPM-CR participants given the different goals and structures of the underlying payment programs. CMS therefore proposes the following:

- CR payment determination and application would be separate from that for reconciliation payments and repayments for EPM-CR participants
- CR incentive payments to EPM-CR participants would not be subject to the EPM limitation on gains

¹⁴ CR program sessions are limited to 2 one-hour sessions per day for up to 36 sessions over up to 36 weeks (with an option for 36 more sessions over an extended time period with MAC approval. For ICR services, the limits are 72 one-hours sessions, up to 6 sessions per day, over a period of up to 18 weeks.

- EPM-CR participants may not include CR incentive payments in their sharing arrangements; sharing with other entities must comply with all existing laws and regulations
- FFS-CR participant payment sharing can be done only under circumstances that comply with all existing laws and regulations, and
- CR incentive payments would be excluded when updating quality-adjusted target prices for EPM-CR participants during EPM performance years 3-5.

3 & 4. CR Incentive Payment Report and Proposed Timing for Making CR Incentive Payments

CMS proposes to issue a performance report annually to each CR participant. The report would be issued to EPM-CR participants at the same time as their reconciliation reports; FFS-CR participant reports would also be issued at this time. CR program performance reports would contain information about each hospital's attributed AMI and CABG EPM episodes or FFS care periods; CR/ICR utilization by beneficiaries including use above and below the 12-session utilization benchmark; CR payment amounts categorized by payment level; and total CR payment amount. CMS notes that participants can request beneficiary-specific data from CMS.

E. Provisions for FFS-CR Participants

1. Access to Records and Retention for FFS-CR participants

CMS proposes setting requirements for FFS-CR participants related to two information categories: compliance with model requirements and the obligation to repay any CR incentive payment owed to CMS. FFS-CR participants would be required to:

- Allow appropriate access by government agencies to all materials necessary for audit, evaluation, inspection or investigation
- Maintain all related materials for 10 years from the participant's last day of CR incentive payment model participation or from the completion date of any audit, evaluation, inspection, or investigation, whichever is later, with two exceptions.¹⁵

2. Appeals Process for FFS-CR Participants

a. Notice of Calculation Error (first level appeal)

CMS proposes the following process for use by a FFS-CR participant who believes their CR incentive payment report and calculation are in error:

- the FFS-CR participant must submit a written notice using a calculation error form to CMS within 45 days of the CR payment report issue date

¹⁵ 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, in which case the records must be maintained for 6 years from the date of any resulting final resolution.

- in the absence of such written notice to CMS, the payment report becomes final
- having received proper notice from the FFS-CR participant, CMS will respond within 30 days, confirming the error or verifying that the calculation is correct
 - CMS may extend its response time upon written notice to the FFS-CR participant.

This process is restricted to use by FFS-CR participants.

b. Dispute Resolution Process (second level of appeal)

CMS proposes a dispute resolution process limited to use by FFS-CR participants. For calculation errors, the dispute resolution process is not available to a FFS-CR participant who did not submit a correct, timely calculation error form. A participant who submitted the form and who is dissatisfied with CMS’s response may request a reconsideration review. The reconsideration request must provide a detailed explanation of and supporting documentation about the calculation error, and the request must be received by CMS within 10 days of the issue date of CMS’s response to the participant’s initial calculation error notice. (CMS’s response becomes final if a reconsideration request is not received within the 10-day period.) Within 15 calendar days of receiving a valid reconsideration request, a CMS reconsideration official notifies the FFS-CR participant in writing of: review meeting time and location, issues in dispute, the review procedures, and procedures for evidence submission. Reasonable efforts would be made to schedule the review to occur no later than 30 days after the receipt of the notification.

c. Exception to the Notice of Calculation Error Process and Notice of Termination

A FFS-CR participant may wish to dispute notification from CMS about an issue unrelated to incentive payment calculation, such as termination from the CR incentive program. In such cases, a calculation error notice is not required, but the FFS-CR participant must submit a written request to CMS for review of the notification within 10 days of the date of notification. Absent a timely review request, the CMS notification becomes final. CMS must respond to the review request within 30 days.

3. Data-Sharing for FFS-CR Participants

a. Data-Sharing with CR Participants

CMS proposes to provide FFS-CR participants with more limited data than that provided to EPM-CR participants (upon request and in keeping with all applicable privacy and security laws and protections) consisting of:

- Inpatient claims -- potential admissions for CABG and AMI MS-DRGs, plus PCI MS-DRGs if paired with an AMI ICD-CM diagnosis as a principal or secondary code, and
- Carrier and Outpatient claims -- CR/ICR services occurring in the 90-day period after discharge for treatment of AMI or for CABG surgery (AMI or CABG “care period”).

CMS proposes to provide the data to FFS-CR participants in either summary or claims-level format, according to requestor preference. For the first CR performance year (2017), CMS

proposes to provide claims data from July 1, 2017 to June 30, 2018 on as frequently as a running quarterly basis. Participants would receive data for up to the current quarter and all of the previous quarters going back to July 1, 2017. Subsequent data would be released as often as quarterly and would include up to 6 quarters of prior data.

4. & 5. Compliance Enforcement for FFS-CR Participants and Termination of the CR Incentive Payment Model and Enforcement Authority for FFS-CR Participants

CMS recalls discussing compliance enforcement proposals for EPMs previously in Section III.F. and now proposes to establish similar provisions for FFS-CR participants. CMS proposes that remedial actions for compliance violations by a FFS-CR participant would include:

- Issuing a warning letter to the FFS-CR participant
- Requiring the FFS-CR participant to develop a corrective action plan
- Reducing or eliminating the FFS-CR participant's CR incentive payment, and
- Terminating the FFS-CR participant from the CR incentive payment model.

CMS perceives that avoiding high severity patients and targeting low severity patients are the primary concerns relevant to FFS-CR participants. CMS also notes that termination of the CR incentive payment model could occur for reasons including insufficient funds to continue, and that model termination is not subject to administrative or judicial review.

6. Beneficiary Engagement Incentives for FFS-CR Participants

CMS believes that providing transportation would help overcome barriers to CR/ICR service utilization and proposes to allow FFS-CR participants the same opportunity to provide transportation as is proposed for the EPM-CR participants. Conditions applying to the provision of a transportation engagement incentive and documenting its use are further discussed in the proposed rule.

7. Waiver of Physician Definition for Providers and Suppliers of CR/ICR Services Furnished to FFS-CR Beneficiaries During an AMI or CABG Care Period

Physician functions currently required in furnishing CR/ICR services are those of medical director, supervising physician, physician exercise prescription, and individualized treatment plan creation and maintenance. For services furnished to CR model beneficiaries, CMS now proposes to waive the definition of physician to permit certain nonphysician practitioners (physician assistants, nurse practitioners or clinical nurse specialists) to perform all of these functions except that of medical director. This waiver would apply to CR/ICR services furnished by any provider or supplier to EPM beneficiaries during AMI or CABG model episodes and to FFS-CR beneficiaries during AMI or CABG care periods.

F. Considerations Regarding Financial Arrangements Under the CR Incentive Payment Model

CMS proposes not to allow EPM-CR participants to include CR incentive payments in their sharing arrangements and that all FFS-CR financial arrangements would be subject to all existing laws, regulations, and payment and coverage requirements. Since over 95 percent of CR/ICR services are furnished in hospital outpatient departments, CMS believes that in most cases the accountable CR participant (EPM or FFS) would implement CR model activities through its own CR program. CMS notes, however, that CR participants might choose to engage with other entities to assist with model activities such as service utilization analysis and beneficiary outreach. Such relationships would focus on the CR model, be narrow in scope, and be based solely upon the degree to which resources of the other entities directly support CR model implementation.

Appendix I. Intracardiac ICD-9-CM Procedure Codes

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

ICD-9-CM Procedure code	ICD-9-CM Procedure code description
35.52	Repair of atrial septal defect with prosthesis, closed technique.
35.96	Percutaneous balloon valvuloplasty.
35.97	Percutaneous mitral valve repair with implant.
37.26	Catheter based invasive electrophysiologic testing.
37.27	Cardiac mapping.
37.34	Excision or destruction of other lesion or tissue of heart, endovascular approach.

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

ICD-9-CM Procedure code	ICD-9-CM Procedure code description
37.36	Excision, destruction, or exclusion of left atrial appendage.
37.90	Insertion of left atrial appendage device.

Appendix II. ICD-9-CM and ICD-10-CM Diagnosis Codes That Initiate AMI Model Episodes

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

ICD-9-CM Diagnosis code	ICD-9-CM Description	ICD-10-CM Diagnosis code	ICD-10-CM Description
410.01	Acute myocardial infarction of anterolateral wall, initial episode of care.	121.09	ST elevation (STEMI) myocardial infarction involving other coronary artery of anterior wall.
		122.0	Subsequent ST elevation (STEMI) myocardial infarction of anterior wall.
410.11	Acute myocardial infarction of other anterior wall, initial episode of care.	121.01	ST elevation (STEMI) myocardial infarction involving left main coronary artery.
		121.02	ST elevation (STEMI) myocardial infarction involving left anterior descending coronary artery.
		121.09	ST elevation (STEMI) myocardial infarction involving other coronary artery of anterior wall.
		122.0	Subsequent ST elevation (STEMI) myocardial infarction of anterior wall.
410.21	Acute myocardial infarction of inferolateral wall, initial episode of care.	121.10	ST elevation (STEMI) myocardial infarction involving other coronary artery of inferior wall.
		122.1	Subsequent ST elevation (STEMI) myocardial infarction of inferior wall.
410.31	Acute myocardial infarction of inferoposterior wall, initial episode of care.	121.11	ST elevation (STEMI) myocardial infarction involving right coronary artery.
		122.1	Subsequent ST elevation (STEMI) myocardial infarction of inferior wall.
410.41	Acute myocardial infarction of other inferior wall, initial episode of care.	121.19	ST elevation (STEMI) myocardial infarction involving other coronary artery of inferior wall.
		122.1	Subsequent ST elevation (STEMI) myocardial infarction of inferior wall.
410.51	Acute myocardial infarction of other lateral wall, initial episode of care.	121.29	ST elevation (STEMI) myocardial infarction involving other sites.
		122.8	Subsequent ST elevation (STEMI) myocardial infarction of other sites.
410.61	True posterior wall infarction, initial episode of care.	121.29	ST elevation (STEMI) myocardial infarction involving other sites.
		122.8	Subsequent ST elevation (STEMI) myocardial infarction of other sites.
410.71	Subendocardial infarction, initial episode of care	121.4	Non-ST elevation (NSTEMI) myocardial infarction.
		122.2	Subsequent non-ST elevation (NSTEMI) myocardial infarction.
410.81	Acute myocardial infarction of other specified sites, initial episode of care.	121.21	ST elevation (STEMI) myocardial infarction involving left circumflex coronary artery.
		121.29	ST elevation (STEMI) myocardial infarction involving other sites.
		122.8	Subsequent ST elevation (STEMI) myocardial infarction of other sites.
410.91	Acute myocardial infarction of unspecified site, initial episode of care.	121.3	ST elevation (STEMI) myocardial infarction of unspecified site.
		122.9	Subsequent ST elevation (STEMI) myocardial infarction of unspecified site.

Appendix III. - Measure Performance Weights and Individual Measure Scoring

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%	Patient Experience/20%.
HCAHPS Survey (NQF #0166)	20%	

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)
≥90 th	10.00	4.00	4.00
≥80 th and <90 th	9.25	3.70	3.70
≥70 th and <80 th	8.50	3.40	3.40
≥60 th and <70 th	7.75	3.10	3.10
≥50 th and <60 th	7.00	2.80	2.80
≥40 th and <50 th	6.25	2.50	2.50

Performance percentile	MORT-30-AMI (points)	AMI excess days (points)	HCAHPS survey (points)
≥30 th and <40 th	5.50	2.20	2.20
<30 th	0.00	0.00	0.00

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%. Patient Experience/25%.
HCAHPS Survey (NQF #0166)	25%	

Appendix III. - Measure Performance Weights and Individual Measure Scoring - Continued

TABLE 17—INDIVIDUAL SCORING FOR TWO REQUIRED CABG QUALITY MEASURES

Performance percentile	MORT-30-CABG (points)	HCAHPS survey (points)
≥90th	15.00	5.00
≥80th and <90th	13.88	4.63
≥70th and <80th	12.75	4.25
≥60th and <70th	11.63	3.88
≥50th and <60th	10.50	3.50
≥40th and <50th	9.38	3.13
≥30th and <40th	8.25	2.75
<30th	0.00	0.00

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%	

TABLE 19—INDIVIDUAL SCORING FOR TWO REQUIRED SHFFT QUALITY MEASURES

Performance percentile	Hip/knee complications (points)	HCAHPS survey quality score (points)
≥90th	10.00	8.00
≥80th and <90th	9.25	7.40
≥70th and <80th	8.50	6.80
≥60th and <70th	7.75	6.20
≥50th and <60th	7.00	5.60
≥40th and <50th	6.25	5.00
≥30th and <40th	5.50	4.40
<30th	0.00	0.00

Appendix IV. Pay-for-Performance Methodology Applicable to EPMs

TABLE 20—PERFORMANCE YEAR 1 AND PERFORMANCE YEAR 2 (NDR): RELATIONSHIP OF AMI MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

AMI model composite quality score	Eligible for reconciliation payment	Effective discount factor for reconciliation payment %	Effective discount factor for repayment amount
<3.6	No	3.0	Not applicable.
>=3.6 and <6.9	Yes	3.0	Not applicable.
>=6.9 and <=14.8	Yes	2.0	Not applicable.
>14.8	Yes	1.5	Not applicable.

TABLE 21—PERFORMANCE YEARS 2 (DR) AND 3: RELATIONSHIP OF AMI MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

AMI model composite quality score	Eligible for reconciliation payment	Effective discount factor for reconciliation payment %	Applicable discount factor for repayment amount*
<3.6	No	3.0	2.0
>=3.6 and <6.9	Yes	3.0	2.0
>=6.9 and <=14.8	Yes	2.0	1.0
>14.8	Yes	1.5	0.5

*The applicable discount factor for the repayment amount only applies in performance years 2 (DR) and 3 when repayment responsibility is being phased-in.

TABLE 22—PERFORMANCE YEARS 4 AND 5: RELATIONSHIP OF AMI MODEL COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT FACTOR EXPERIENCED AT RECONCILIATION

AMI model composite quality score	Eligible for reconciliation payment	Effective discount factor for reconciliation payment	Effective discount factor for repayment amount
<3.6	No	3.0	3.0
>=3.6 and <6.9	Yes	3.0	3.0
>=6.9 and <=14.8	Yes	2.0	2.0
>14.8	Yes	1.5	1.5

Appendix IV. Pay-for-Performance Methodology Applicable to EPMs - Continued

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

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.

Appendix IV. Pay-for-Performance Methodology Applicable to EPMs - Continued

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

Appendix V. Proposed Quality Measure Performance Periods Arranged by Model and Measure

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).

Appendix V. Proposed Quality Measure Performance Periods Arranged by Model and Measure - Continued

TABLE 34—SUMMARY OF PROPOSED QUALITY MEASURE PERFORMANCE PERIODS BY YEAR FOR REQUIRED MEASURES FOR ALL EPMS

Measure title	Model performance year				
	1st	2nd	3rd	4th	5th
HCAHPS*	July 1, 2016–June 30, 2017.	July 1, 2017–June 30, 2018.	July 1, 2018–June 30, 2019.	July 1, 2019–June 30, 2020.	July 1, 2020–June 30, 2021.

*Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey (NQF #0166).