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Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 510

[CMS–5516–P]

RIN 0938–AS64

Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services

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

ACTION: Proposed rule.

SUMMARY: This proposed rule proposes to implement a new Medicare Part A and B payment model under section 1115A of the Social Security Act, called the Comprehensive Care for Joint Replacement (CCJR) model, in which acute care hospitals in certain selected geographic areas will receive retrospective bundled payments for episodes of care for lower extremity joint replacement or reattachment of a lower extremity. All related care within 90 days of hospital discharge from the joint replacement procedures will be included in the episode of care. We believe this model will further our goals in improving the efficiency and quality of care for Medicare beneficiaries for these common medical procedures.

DATES: *Comment period:* To be assured consideration, comments on this proposed rule must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EDT on September 8, 2015.

ADDRESSES: In commenting, please refer to file code CMS–5516–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may (and we encourage you to) submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the ''submit a comment'' tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5516–P, P.O. Box 8013, Baltimore, MD 21244–1850.

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3. *By express or overnight mail.* You may send written comments via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5516–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

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b. For delivery in Baltimore, MD—

Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call the telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

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

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:
Claire Schreiber, *Claire.Schreiber@cms.hhs.gov,* 410–786–8939
Gabriel Scott, *Gabriel.Scott@cms.hhs.gov,* 410–786–3928

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection, generally beginning approximately 3 weeks after publication of the rule, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, on Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. EDT. To schedule an appointment to view public comments, phone 1–800–743–3951.

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Alphabetical List of Acronyms

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

μSA Micropolitan Statistical Area
ACO Accountable Care Organization
ASPE Assistant Secretary for Planning and Evaluation
BPCI Bundled Payments for Care Improvement
CBSA Core-Based Statistical Area
CMS Centers for Medicare & Medicaid Services
CPT Current Procedural Terminology
CCJR Comprehensive Care for Joint Replacement
CSA Combined Statistical Area
DME Durable Medical Equipment
FFS Fee-for-service
HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems
HHA Home health agency
HOPD Hospital outpatient department
HHPPS Home Health Prospective Payment System
HIQR Hospital Inpatient Quality Reporting
HRRP Hospital Readmissions Reductions Program
HRR Hospital Referral Region
HVBP Hospital Value Based Purchasing Program
ICD–9–CM International Classification of Diseases, 9th Revision, Clinical Modification
IPPS Inpatient Prospective Payment System
IPF Inpatient psychiatric facility
IRF Inpatient rehabilitation facility
LEJR Lower extremity joint replacement
LOS Length of stay
LTCH Long term care hospital
LUPA Low Utilization Payment Adjustment

MAC Medicare Administrative Contractor
MCC Major complications or comorbidities
MSA Metropolitan Statistical Area
MS–DRG Medical Severity Diagnosis-Related Group
MP Malpractice
NPP Nonphysician Practitioner
NPRA Net Payment Reconciliation Amount
OPPS Outpatient Prospective Payment System
PAC Post-acute care
SNF Skilled nursing facility
THA Total hip arthroplasty
TKA Total knee arthroplasty

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I. Executive Summary

A. Purpose

The purpose of this proposed rule is to propose the creation and testing of a new payment model called the Comprehensive Care for Joint Replacement (CCJR) Model under the authority of the Center for Medicare and Medicaid Innovation (Innovation Center or CMMI). Section 1115A of the Social Security Act (the Act) authorizes the Innovation Center to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. The intent of the CCJR model is to promote quality and financial accountability for episodes of care surrounding a lower-extremity joint replacement (LEJR) or reattachment of a lower extremity procedure.[1] CCJR will test whether bundled payments to acute care hospitals for LEJR episodes of care will reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. We anticipate the CCJR model being proposed would benefit Medicare beneficiaries by improving the coordination and transition of care, improving the coordination of items and services paid for through Medicare Fee-For-Service (FFS), encouraging more provider investment in infrastructure and redesigned care processes for higher quality and more efficient service delivery, and incentivizing higher value care across the inpatient and post-acute care spectrum spanning the episode of care. We propose to test CCJR for a 5 year performance period, beginning January 1, 2016, and ending December 31, 2020. Under FFS, Medicare makes separate payments to providers and suppliers for the items and services furnished to a beneficiary over the course of treatment (an episode of care). With the amount of payments dependent on the volume of services delivered, providers may not have incentives to invest in quality improvement and care coordination activities. As a result, care may be fragmented, unnecessary, or duplicative.

We have previously used our statutory authority under section 1115A of the Act to test bundled payment models such as the Bundled Payments for Care Improvement (BPCI) initiative. Bundled payments for multiple services in an episode of care hold participating organizations financially accountable for an episode of care. They also allow participants to receive payment in part based on the reduction in expenditures for Medicare arising from their care redesign efforts.

We believe the CCJR model being proposed would further the mission of the Innovation Center and the Secretary's goal of increasingly paying for value and outcomes, rather than for volume,[2] because it would promote the alignment of financial and other incentives for all health care providers caring for a beneficiary during an LEJR episode. In the proposed CCJR model, the acute care hospital that is the site of surgery would be held accountable for spending during the episode of care. Participant hospitals would be afforded the opportunity to earn performance-based payments by appropriately reducing expenditures and meeting certain quality metrics. They would also gain access to data and educational resources to better understand post-acute care and associated spending. Payment approaches that reward providers that assume financial and performance accountability for a particular episode of care create

[1] In this proposed rule, we use the term LEJR to refer to all procedures within the Medicare Severity-Diagnosis Related Groups (MS–DRGs) we propose to select for the model, including reattachment of a lower extremity, as described in section III.B. of this proposed rule.

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

incentives for the implementation and coordination of care redesign between hospitals and other providers.

The proposed model would require the participation of hospitals in multiple geographic areas that might not otherwise participate in the testing of bundled payments for episodes of care for LEJR procedures. Other episode-based, bundled payment models being tested by Centers for Medicare & Medicaid Services (CMS), such as the BPCI initiative, are voluntary in nature. Interested participants must apply to such models to participate. To date, we have not tested an episode payment model with bundled payments in which providers are required to participate. We recognize that realizing the full potential of new payment models will require the engagement of an even broader set of providers than have participated to date, providers who may only be reached when new payment models are applied to an entire class of providers of a service. As such, we are interested in testing and evaluating the impact of a bundled payment approach for LEJR procedures in a variety of circumstances, especially among those hospitals that may not otherwise participate in such a test.

This proposed model would allow CMS to gain experience with making bundled payments to hospitals who have a variety of historic utilization patterns; different roles within their local markets; various volumes of services; different levels of access to financial, community, or other resources; and various levels of population and health provider density including local variations in the availability and use of different categories of post-acute care providers. We believe that by requiring the participation of a large number of hospitals with diverse characteristics, the proposed model would result in a robust data set for evaluation of this bundled payment approach, and would stimulate the rapid development of new evidence-based knowledge. Testing the model in this manner would also allow us to learn more about patterns of inefficient utilization of health care services and how to incentivize the improvement of quality for common LEJR procedure episodes. This learning potentially could inform future Medicare payment policy.

Within this proposed rule we propose a model focused on episodes of care for LEJR procedures. We chose LEJR episodes for the proposed model because as discussed in depth in section III.C. of this proposed rule, these are high-expenditure, high utilization procedures commonly furnished to Medicare beneficiaries,[3] where significant variation in spending for procedures is currently observed. The high volume of episodes and variation in spending for LEJR procedures create a significant opportunity to test and evaluate the proposed model that specifically focuses on a defined set of procedures. Moreover, there is substantial regional variation in post-acute care referral patterns and the intensity of post-acute care provided for LEJR patients, thus resulting in significant variation in post-acute care expenditures across LEJR episodes initiated at different hospitals. The proposed model would enable hospitals to consider the most appropriate post-acute care for their LEJR patients. The proposed model additionally would offer hospitals the opportunity to better understand their own processes with regard to LEJR, as well as the processes of post-acute providers. Finally, while many LEJR procedures are planned, the proposed model would provide a useful opportunity to identify efficiencies both for when providers can plan for LEJR procedures and for when the procedure must be performed urgently.

We note that we seek public comment on the proposals contained in this proposed rule, and also on any alternatives considered as well.

B. Summary of the Major Provisions

1. Model Overview: LEJR Episodes of Care

LEJR procedures are currently paid under the Inpatient Prospective Payment System (IPPS) through one of two Medicare Severity-Diagnosis Related Groups (MS–DRGs): MS–DRG 469 (Major joint replacement or reattachment of lower extremity with Major Complications or Comorbidities (MCC)) or MS–DRG 470 (Major joint replacement or reattachment of lower extremity without MCC). Under the proposed model, as described further in section III.B of this proposed rule, episodes would begin with admission to an acute care hospital for an LEJR procedure that is assigned to MS–DRG 469 or 470 upon beneficiary discharge and paid under the IPPS and would end 90 days after the date of discharge from the acute care hospital. This episode of care definition offers operational simplicity for providers and CMS. The episode would include the LEJR procedure, inpatient stay, and all related care covered under Medicare Parts A and B within the 90 days after discharge, including hospital care, post-acute care, and physician services.

2. Model Scope

We propose that participant hospitals would be the episode initiators and bear financial risk under the proposed CCJR model. In comparison to other health care facilities, hospitals are more likely to have resources that would allow them to appropriately coordinate and manage care throughout the episode, and hospital staff members are already involved in hospital discharge planning and post-acute care recommendations for recovery, key dimensions of high quality and efficient care for the episode. We propose to require all hospitals paid under the IPPS and physically located in selected geographic areas to participate in the CCJR model, with limited exceptions. Eligible beneficiaries who receive care at these hospitals will automatically be included in the model. We propose to select geographic areas through a stratified random sampling methodology within strata based on the following criteria: Historical wage adjusted episode payments and population size. Our proposed geographic area selection process is detailed further in section III.A of this proposed rule.

3. Payment

We propose to test the CCJR model for 5 performance years. During these performance years we propose to continue paying hospitals and other providers according to the usual Medicare FFS payment systems. However, after the completion of a performance year, the Medicare claims payments for services furnished to the beneficiary during the episode, based on claims data, would be combined to calculate an actual episode payment. The actual episode payment is defined as the sum of related Medicare claims payments for items and services furnished to a beneficiary during a CCJR episode. The actual episode payment would then be reconciled against an established CCJR target price, with consideration of additional payment adjustments based on quality performance and post-episode spending. The amount of this calculation, if

[3] For example, Total Hip Arthroplasty and Total Knee Arthroplasty procedures are very high volume LEJR procedures that together represent the largest payments for procedures under Medicare. Suter L, Grady JL, Lin Z et al.: 2013 Measure Updates and Specifications: Elective Primary Total Hip Arthroplasty (THA) And/Or Total Knee Arthroplasty (TKA) All-Cause Unplanned 30-Day Risk-Standardized Readmission Measure (Version 2.0). 2013. *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html;* Bozic KJ, Rubash HE, Sculco TP, Berry DJ., An analysis of Medicare payment policy for total joint arthroplasty. J Arthroplasty. Sep 2008; 23(6 Suppl 1):133–138.

positive, would be paid to the participant hospital. This payment would be called a reconciliation payment. If negative, we would require repayment from the participant hospital. We propose Medicare would require repayment of the difference between the actual episode payments and the CCJR target price from a participant hospital if the CCJR target price is exceeded.

We propose to make reconciliation payments to participant hospitals that achieve quality outcomes and cost efficiencies relative to the established CCJR target prices in all performance years of the model. We also propose to phase in the requirement that participant hospitals whose actual episode payments exceed the applicable CCJR target price pay the difference back to Medicare beginning in performance year 2. Under this proposal, Medicare would not require repayment from hospitals for performance year 1 for actual episode payments that exceed their target price in performance year 1.

We also propose to limit how much a hospital can gain or lose based on its actual episode payments relative to target prices. We also propose additional policies to further limit the risk of high payment cases for all participant hospitals and for special categories of participant hospitals as described in section III.C. of this proposed rule.

4. Similar Previous and Concurrent Models

This proposed model is informed by other models and demonstrations currently and previously conducted by CMS and would explore additional ways to enhance coordination of care and improve the quality of services through bundled payments.

We recently announced the Oncology Care Model (OCM), a new voluntary payment model for physician practices administering chemotherapy. Under OCM, practices will enter into payment arrangements that include financial and performance accountability for episodes of care surrounding chemotherapy administration to cancer patients. We plan to coordinate with other payers to align with OCM in order to facilitate enhanced services and care at participating practices. More information on the OCM can be found on the Innovation Center's Web site at: *http://innovation.cms.gov/initiatives/Oncology-Care/.*

Medicare tested innovative approaches to paying for orthopedic services in the Medicare Acute Care Episode (ACE) demonstration, a prior demonstration, and is currently testing additional approaches under BPCI. Both of these models have also informed the design of the CCJR model.

Under the authority of section 1866C of the Act, we conducted a 3-year demonstration, the Medicare Acute Care Episode (ACE) Demonstration. The demonstration used a prospective global payment for a single episode of care as an alternative approach to payment for service delivery under traditional Medicare FFS. The episode of care was defined as a combination of Part A and Part B services furnished to Medicare FFS beneficiaries during an inpatient hospital stay for any one of a specified set of cardiac and orthopedic MS–DRGs. The MS–DRGs tested included 469 and 470, those proposed for inclusion in the CCJR model. The discounted bundled payments generated an average gross savings to Medicare of $585 per episode for a total of $7.3 million across all episodes (12,501 episodes) or 3.1 percent of the total expected costs for these episodes. After accounting for increased post-acute care costs that were observed at two sites, Medicare saved approximately $4 million, or 1.72 percent of the total expected Medicare spending. More information on the ACE Demonstration can be found on the Innovation Center's Web site at: *http://innovation.cms.gov/initiatives/ACE/.*

We are currently testing the BPCI initiative. The BPCI initiative is comprised of four related payment models, which link payments for multiple services that Medicare beneficiaries receive during an episode of care into a bundled payment. Under the initiative, entities enter into payment arrangements with CMS that include financial and performance accountability for episodes of care. Episodes of care under the BPCI initiative begin with either—(1) an inpatient hospital stay or (2) post-acute care services following a qualifying inpatient hospital stay. The BPCI initiative is evaluating the effects of episode-based payment approaches on patient experience of care, outcomes, and cost of care for Medicare FFS beneficiaries. Each of the four models tests LEJR episodes of care. While final evaluation results for the models within the BPCI initiative are not yet available, we believe that CMS' experiences with BPCI support the design of the CCJR model. Under section 1115A(c) of the Act, the Secretary may, taking into consideration an evaluation conducted under section 1115A(b)(4) of the Act, ''through rulemaking, expand (including implementation on a nationwide basis) the duration and the scope of a model that is being tested under'' the Innovation Center's authority. CCJR is not an expansion of BPCI, and BPCI may be expanded in the future. CMS published a discussion item soliciting public comment on a potential future expansion of one or more of the models within BPCI in the CY2016 IPPS rule, 80 FR 24414 through 24418. CCJR would not be not an expansion or modification of BPCI; nor does it reflect comments received in response to the NPRM for the 2016 IPPS Rule. CCJR is a unique model that tests a broader, different group of hospitals than BPCI. It is necessary to provide CMS with information about testing bundled payments to hospitals that are required to participate in an alternative payment model. For a discussion of why we are requiring hospitals to participate in the CCJR model, see section III.A of this proposed rule.

The CCJR model's design was informed to a large degree by our experience with BPCI Model 2. BPCI's Model 2 is a voluntary episode payment model in which a qualifying acute care hospitalization initiates a 30, 60 or 90 day episode of care. The episode of care includes the inpatient stay in an acute care hospital and all related services covered under Medicare Parts A and B during the episode, including post-acute care services. More information on BPCI Model 2 can be found on the Innovation Center's Web site at: *http://innovation.cms.gov/initiatives/BPCI-Model-2/.*

Further information of why elements of the OCM, the ACE Demonstration, and BPCI Model 2 were incorporated into the design of the CCJR model is discussed later in this proposed rule.

5. Overlap With Ongoing CMS Efforts

We propose to exclude from participation in CCJR certain hospitals participating in the risk-bearing phase of BPCI Models 2 and 4 for LEJR episodes, as well as acute care hospitals participating in BPCI Model 1. We propose not to exclude beneficiaries in CCJR model episodes from being included in other Innovation Center models or CMS programs, such as the Medicare Shared Savings Program, as detailed later in this proposed rule. We propose to account for overlap, that is, where CCJR beneficiaries are also included in other models and programs to ensure the financial policies of CCJR are maintained and results and spending reductions are attributed to the correct model or program.

6. Quality Measures and Reporting Requirements

We are proposing to adopt three hospital-level quality of care measures for the CCJR model. Those measures

include a complication measure, readmission measure, and a patient experience survey measure. We propose to use these measures to test the success of the model in achieving its goals under section 1115A of the Act and to monitor for beneficiary safety. We intend to publicly report this information on the Hospital Compare Web site. Additionally, we are proposing and requesting public feedback on possible voluntary submission of data to support the development of a hospital-level measure of patient-reported outcomes following an elective Primary Total Hip (THA) or Total Knee Arthroplasty (TKA).

7. Data Sharing Process

We propose to share data with participant hospitals upon request throughout the performance period of the CCJR model to the extent permitted by the HIPAA Privacy Rule and other applicable law. We propose to share upon request both raw claims-level data and claims summary data by service line with participants. This approach would allow participant hospitals without prior experience analyzing claims to use summary data to receive useful information, while allowing those participant hospitals who prefer raw claims-level data the opportunity to analyze claims. We propose to provide hospitals with up to 3 years of retrospective claims data upon request that will be used to develop their target price, as described in section III.C of this proposed rule. In accordance with the HIPAA Privacy Rule, we would limit the content of this data set to the minimum data necessary for the participant hospital to conduct quality assessment and improvement activities and effectively coordinate care of its patient population.

8. Beneficiary Protections

Under the CCJR model, beneficiaries retain the right to obtain health services from any individual or organization qualified to participate in the Medicare program. Under the CCJR model, eligible beneficiaries who receive services from a participant hospital would not have the option to opt out of inclusion in the model. We propose to require participant hospitals to supply beneficiaries with written information regarding the design and implications of this model as well as their rights under Medicare, including their right to use their provider of choice. We will also make a robust effort to reach out to beneficiaries and their advocates to help them understand the CCJR model.

We also propose to use our existing authority, if necessary, to audit participant hospitals if claims analysis indicates an inappropriate change in delivered services. Beneficiary protections are discussed in greater depth in section III.E. of this proposed rule.

9. Financial Arrangements and Program Policy Waivers

We propose to hold participant hospitals financially responsible for CCJR LEJR episodes as participants in the model as discussed in section III.C.10.a. of this proposed rule. Specifically, only these hospital participants would be directly subject to the requirements of this proposed rule for the CCJR model. Participant hospitals would be responsible for ensuring that other providers and suppliers collaborating with the hospital on LEJR episode care redesign are in compliance with the terms and conditions of the model.

Several of the proposed Medicare program policy waivers outline the conditions under which skilled nursing facilities (SNFs) and physicians could furnish and bill for certain services furnished to CCJR beneficiaries where current Medicare programs rules would not permit such billing. We draw the attention of SNFs and physicians to these proposals that are included in section III.C.10.b.(5). of this proposed rule.

C. Summary of Economic Effects

As shown in our impact analysis, we expect the proposed model to result in savings to Medicare of $153 million over the 5 years of the model. More specifically, in performance year 1 of the model, we estimate a Medicare cost of approximately $23 million, as we have proposed that hospitals will not be subject to downside risk in the first year of the model. As we introduce downside risk beginning in performance year 2 of the model, we estimate Medicare savings of approximately $29 million. In performance year 3 of the model, we estimate Medicare savings of $43 million. In performance years 4 and 5 of the model, as we have proposed to move from target episode pricing that is based on a hospital's experience to target pricing based on regional experience, we estimate Medicare savings of $50 million and $53 million, respectively.

Additionally, hospitals must meet or exceed specific thresholds on performance on certain quality of care measures in order to be eligible for a reconciliation payment and as the performance threshold increases in performance years 4 through 5, we estimate additional savings. As a result, we estimate the net savings to Medicare to be $153 million over the 5 years of the model. We anticipate there would be a broader focus on care coordination and quality improvement for LEJR episodes among hospitals and other providers within the Medicare program that would lead to both increased efficiency in the provision of care and improved quality of the care provided to beneficiaries.

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

II. Background

This proposed rule proposes the implementation of a new innovative health care payment model under the authority of section 1115A of the Act. Under the model, called the CCJR model, acute care hospitals in certain selected geographic areas will receive bundled payments for episodes of care where the diagnosis at discharge includes a lower extremity joint replacement or reattachment of a lower extremity that was furnished by the hospital. We are proposing that the bundled payment will be paid retrospectively through a reconciliation process; hospitals and other providers and suppliers will continue to submit claims and receive payment via the usual Medicare FFS payment systems. All related care covered under Medicare Part A and Part B within 90 days after the date of hospital discharge from the joint replacement procedure will be included in the episode of care. We believe this model will further our goals of improving the efficiency and quality of care for Medicare beneficiaries for these common medical procedures.

III. Provisions of the Proposed Rule

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

1. Background

The CCJR model is different from BPCI because it would require participation of all hospitals (with limited exceptions) throughout selected geographic areas, which would result in a model that includes varying hospital types. However, a discussion of BPCI is relevant because its design informs and supports the proposed CCJR model. The BPCI model is voluntary, and under that model we pay a bundled payment for an episode of care only to entities that have

elected to participate in the model. We are interested in testing and evaluating the impact of an episode payment approach for LEJRs in a variety of other circumstances, including among those hospitals that have not chosen to voluntarily participate because we have not tested bundled payments for these hospitals previously. This would allow CMS and participants to gain experience testing and evaluating episode-based payment for LEJR procedures furnished by hospitals with a variety of historic utilization patterns; roles within their local markets; volume of services provided; access to financial, community, or other resources; and population and health care provider density. Most importantly, participation of hospitals in selected geographic areas will allow CMS to test bundled payments without introducing selection bias such as the selection bias inherent in the BPCI model due to self-selected participation.

2. Proposed Definition of Episode Initiator

In BPCI Model 2, LEJR episode initiators are either acute care hospitals where the LEJR procedure is performed or physician group practices whose physician members are the admitting or operating physician for the hospital stay. Thus, under BPCI, it is possible that only some Medicare cases that could potentially be included in an LEJR episode at a specific hospital are actually being tested in BPCI. For example, if the hospital itself is not participating as an episode initiator under BPCI, yet some physicians who admit patients to the hospital are members of physician group practices participating in BPCI, not all of the hospital's possible LEJR episodes are tested and paid under BPCI.

Under the proposed CCJR model, as described further in section III.B of this proposed rule, episodes would begin with admission to an acute care hospital for an LEJR procedure that is paid under the IPPS through Medical Severity Diagnosis-Related Group (MS–DRG) 469 (Major joint replacement or reattachment of lower extremity with MCC) or 470 (Major joint replacement or reattachment of lower extremity without MCC) and end 90 days after the date of discharge from the hospital. For the CCJR model, we propose that hospitals would be the only episode initiators. For purposes of CCJR, the term ''hospital'' means a hospital as defined in section 1886(d)(1)(B) of the Act. This statutory definition of hospital includes only acute care hospitals paid under the IPPS. Under this proposal, all acute care hospitals in Maryland would be excluded from CCJR. The state of Maryland entered into an agreement with CMS, effective January 1, 2014, to participate in CMS' new Maryland All-Payer Model. In order to implement the Maryland All-Payer Model, CMS waived certain requirements of the Act, and the corresponding implementing regulations, as set forth in the agreement between CMS and Maryland. Specifically, under the Maryland All-Payer Model, Maryland acute care hospitals are not paid under the IPPS or OPPS but rather are paid under rates set by the state. Following the model's performance period, Maryland will transition to a new model that incorporates the full spectrum of care, not just hospital services. As such, with respect to Maryland hospitals, CMS intends to test and develop new payment and delivery approaches that can incorporate non-hospital services in a manner that accounts for Maryland's unique hospital rate setting system and permit Maryland to develop its own strategy to incentivize higher quality and more efficient care across clinical situations within and beyond hospitals, including but not limited to LEJR episodes of care. We are proposing that payments to Maryland hospitals would be excluded in the regional pricing calculations as described in section III.C.4 of this proposed rule. We seek comment on this proposal and whether there are potential approaches for including Maryland acute care hospitals in CCJR. In addition, we seek comment on whether Maryland hospitals should be included in CCJR in the future upon any termination of the Maryland All-Payer Model.

We propose to designate IPPS hospitals as the episode initiators to ensure that all Medicare FFS LEJR services furnished by participant hospitals in selected geographic areas to beneficiaries who do not meet the exclusion criteria specified in section III.B.3 of this proposed rule and are not BPCI episodes that we are proposing to exclude as outlined in this section and also in section III.C.7 of this proposed rule are included in the CCJR model. We are proposing certain exceptions to the inclusion of hospitals in the CCJR Model, as discussed in section III.C. of this proposed rule. Given that our proposal to initiate the LEJR episode begins with an admission to a hospital paid under the IPPS that results in a discharge assigned to MS–DRG 469 or 470, we believe that utilizing the hospital as the episode initiator is a straightforward approach for this model because the hospital furnishes the LEJR procedure. In addition, we are interested in testing a broad model in a number of hospitals under the CCJR model in order to examine results from a more generalized payment model. Thus, we believe it is important that, in a model where hospital participation is not voluntary, all Medicare FFS LEJR episodes that begin at the participant hospital in a selected geographic area are included in the model for beneficiaries that do not meet the exclusion criteria specified in section III.B.3 of this proposed rule and are not BPCI episodes that we are proposing to exclude as outlined in this section and also in section III.C.7 of this proposed rule. This is best achieved if the hospital is the episode initiator. Finally, as described in the following sections that present our proposed approach to geographic area selection, this geographic area selection approach relies upon our definition of hospitals as the entities that initiate episodes. We seek comment on our proposal to define the episode initiator as the hospital under CCJR.

3. Financial Responsibility for the Episode of Care

BPCI Model 2 participants that have entered into agreements with CMS to bear financial responsibility for an episode of care include acute care hospitals paid under the IPPS, health systems, physician-hospital organizations, physician group practices, and non-provider business entities that act as conveners by coordinating multiple health care providers' participation in the model. Thus, our evaluation of BPCI Model 2 will yield information about how results for LEJR episodes may differ based on differences in which party bears financial responsibility for the episode of care.

For the CCJR model, we propose to make hospitals financially responsible for the episode of care for several reasons. We recognize that ideally all of the providers involved in the continuum of care for Medicare beneficiaries in a 90-day post-discharge LEJR episode would work together to determine the best structure for managing the LEJR episode, develop an efficient process that leads to high quality care, track information across the episode about quality and Medicare expenditures, and align financial incentives using a variety of approaches, including gainsharing. However, because the proposed CCJR model is testing a more generalizable model by including hospitals that might not participate in a voluntary model and includes episodes initiated at a wide variety of hospitals, we believe it is

most appropriate to identify a single type of provider to bear financial responsibility for making repayment to CMS under the model.

Hospitals play a central role in coordinating episode-related care and ensuring smooth transitions for beneficiaries undergoing LEJR procedures. Moreover, the episode always begins with an acute care hospital stay, IPPS payments for LEJRs comprise about 50 percent of Medicare payments for a 90-day episode, and the beneficiary's recovery from surgery begins during the hospital stay. Most hospitals already have some infrastructure related to health information technology, patient and family education, and care management and discharge planning. This includes post-acute care (PAC) coordination infrastructure and resources such as case managers, which hospitals can build upon to achieve efficiencies under this episode payment model. Many hospitals also have recently heightened their focus on aligning their efforts with those of community providers to provide an improved continuum of care due to the incentives under other CMS models and programs, including Accountable Care Organization (ACO) initiatives such as the Medicare Shared Savings Program (MSSP), and the Hospital Readmissions Reduction Program (HRRP), establishing a base for augmenting these efforts under the CCJR model.

In view of our proposal that hospitals be the episode initiators under this model, we believe that hospitals are more likely than other providers to have an adequate number of episode cases to justify an investment in episode management for this model. We also believe that hospitals are most likely to have access to resources that would allow them to appropriately manage and coordinate care throughout the LEJR episode. Finally, the hospital staff is already involved in discharge planning and placement recommendations for Medicare beneficiaries, and more efficient PAC service delivery provides substantial opportunities for improving quality and reducing costs under CCJR.

We considered requiring treating physicians (orthopedic surgeons or others) or their associated physician group practices, if applicable, to be financially responsible for the episode of care under the CCJR Model. We expect that every Medicare beneficiary discharged with a diagnosis grouped under MS–DRG 469 or 470 would have an operating physician and an admitting physician for the hospital stay. However, the services of providers other than the hospital where the acute care hospital stay for the LEJR procedure (hereinafter ''the anchor hospitalization'') occurs would not necessarily be furnished in every LEJR episode. For example, that physicians of different specialties play varying roles in managing patients during an acute care hospitalization for a surgical procedure and during the recovery period, depending on the hospital and community practice patterns and the clinical condition of the beneficiary and could not be assumed to be included in every LEJR episode. This variability would make requiring a particular physician or physician group practice to be financially responsible for a given episode very challenging.

If we were to assign financial responsibility to the operating physician, it is likely that there would be significant variation in the number of relevant episodes that could be assigned to an individual person. Where the physician was included in a physician group practice, episodes could be aggregated to this group level but this would not be possible for all cases and would likely still have low volume concerns. We believe that the small sample sizes accruing to individual physician and physician group practices would make systematic care redesign inefficient and more burdensome, given that we are proposing to test all episodes occurring at hospitals selected for participation for beneficiaries that do not meet the exclusion criteria specified in section III.B.3 of this proposed rule and are not BPCI episodes that we are proposing to exclude as outlined in this section and also in section III.C.7 of this proposed rule.

Finally, we note that although the BPCI initiative includes the possibility of a physician group practice as a type of initiating participant, the physician groups electing to participate in BPCI have done so because their practice structure supports care redesign and other infrastructure necessary to bear financial responsibility for episodes and is not necessarily representative of the typical group practice. In addition, most of the physician group practices in BPCI are not bearing financial responsibility, but are participating in BPCI as partners with convener organizations (discussed later in this section), which enter into agreements with CMS, on behalf of health care providers such as physician group practices, through which they accept financial responsibility for the episode of care. The infrastructure necessary to accept financial responsibility for episodes is not present across all physician group practices, and thus we do not believe it would be appropriate to designate physician group practices to bear the financial responsibility for making repayments to CMS under the proposed CCJR model. We seek comment on our proposal to require the hospital to bear the financial responsibility for the episodes of care under CCJR.

We are proposing that hospitals will bear the financial responsibility for LEJR episodes of care under CCJR. However, because there are LEJR episodes currently being tested in BPCI Model 1, 2, 3 or 4, we believe that participation in CCJR should not be required if it would disrupt testing of LEJR episodes already underway in BPCI models. Therefore, we are proposing that IPPS hospitals located in an area selected for the model that are active Model 1 BPCI participant hospitals as of July 1, 2015 or episode initiators for LEJR episodes in the risk-bearing phase of Model 2 or 4 of BPCI as of July 1, 2015, would be excluded from participating in CCJR during the time that their qualifying episodes are included in one of the BPCI models. Likewise, we are proposing that if the participant hospital is not an episode initiator for LEJR episodes under BPCI Model 2, then LEJR episodes initiated by other providers or suppliers under BPCI Model 2 or 3 (where the surgery takes place at the participant hospital) would be excluded from CCJR. Otherwise qualifying LEJR episodes (that is, those that are not part of a Model 3 BPCI LEJR episode or a Model 2 physician group practice-initiated LEJR episode) at the participant hospital would be included in CCJR.

While we propose that the participant hospital be financially responsible for the episode of care under CCJR, we also believe that effective care redesign for LEJR episodes requires meaningful collaboration among acute care hospitals, PAC providers, physicians, and other providers and suppliers within communities to achieve the highest value care for Medicare beneficiaries. We believe it may be essential for key providers to be aligned and engaged, financially and otherwise, with the hospitals, with the potential to share financial responsibility with those hospitals. We note that all relationships between and among providers and suppliers must comply with all relevant laws and regulations, including the fraud and abuse laws and all Medicare payment and coverage requirements unless otherwise specified further later in this section and in section III.C.10 of this proposed rule. Depending on a hospital's current degree of clinical integration, new and different contractual relationships among hospitals and other health care

providers may be important, although not necessarily required, for CCJR model success in a community. We acknowledge that financial incentives for other providers may be important aspects of the model in order for hospitals to partner with these providers and incentivize certain strategies to improve episode efficiency.

In the BPCI initiative, participants have entered a variety of relationships with entities above the hospital level. Some of these relationships are ones where the financial risk is borne by the entity other than the hospital, such as a parent organization (known as awardee conveners) and others have managerial or other responsibility relationships with other organizations (known as facilitator conveners) but financial responsibility remains with the episode initiator . We acknowledge the important role that conveners play in the BPCI initiative with regard to providing infrastructure support to hospitals and other entities initiating episodes in BPCI. The convener relationship (where another entity assumes financial responsibility) may take numerous forms, including contractual (such as a separate for-profit company that agrees to take on a hospital's financial risk in the hopes of achieving financial gain through better management of the episodes) and through ownership (such as when risk is borne at a corporate level within a hospital chain).

However, we are proposing that for the CCJR model, we would hold only the participant hospitals financially responsible for the episode of care. This is consistent with the goal of evaluating the impact of bundled payment and care redesign across a broad spectrum of hospitals with varying levels of infrastructure and experience in entering into risk-based reimbursement arrangements. If conveners were included as participants in CCJR, we may not gain the knowledge of how a variety of hospitals can succeed in relationship with CMS in which they bear financial risk for the episode of care. We acknowledge that CCJR hospitals may wish to enter into relationships with other entities in order to manage the episode of care or distribute risk. We do not intend to restrict the ability of hospitals to enter into administrative or risk sharing arrangements related to this model. We refer readers to section III.C.10 of this proposed rule for further discussion of model design elements that may outline financial arrangements between participant hospitals and other providers and suppliers.

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

In determining which hospitals to include in the CCJR model, we considered whether the model should be limited to hospitals where a high volume of LEJRs are performed, which would result in a more narrow test on the effects of an episode-based payment, or whether to include all hospitals in particular geographic areas, which would result in testing the effects of an episode-based payment approach more broadly across an accountable care community seeking to coordinate care longitudinally across settings. Selecting certain hospitals where a high volume of LEJRs are performed may allow for fewer hospitals to be selected as model participants, but still result in a sufficient number of CCJR episodes to evaluate the success of the model. However, there would be more potential for behavioral changes that could include patient shifting and steering between hospitals in a given geographic area that could impact the test. Additionally, this approach would provide less information on testing episode payments for LEJR procedures across a wide variety of hospitals with different characteristics. Selecting geographic areas and including all IPPS hospitals in those areas not otherwise excluded due to BPCI overlap as previously described and in section III.C.7 of this proposed rule as model participants would help to minimize the risk of participant hospitals shifting higher cost cases out of the CCJR model. Moreover, in selecting geographic areas we could choose certain characteristics, stratify geographic areas according to these characteristics, and randomly select geographic areas from within each stratum. Such a stratified random sampling method based on geographic area would allow us to observe the experiences of hospitals with various characteristics, such as variations in size, profit status, and episode utilization patterns, and examine whether these characteristics impact the effect of the model on patient outcomes and Medicare expenditures within episodes of care. Stratification would also substantially reduce the extent to which the selected hospitals will differ from non-selected hospitals on the characteristics used for stratification, which would improve the statistical power of the subsequent model evaluation, improving our ability to reach conclusions about the model's effects on episode costs and the quality of patient care. Therefore, given the authority in section 1115A(a)(5) of the Act, which allows the Secretary to elect to limit testing of a model to certain geographic areas, we propose to use a stratified random sampling method to select geographic areas and require all hospitals paid under the IPPS in those areas to participate in the CCJR model and be financially responsible for the cost of the episode, with certain exceptions as previously discussed and in sections III.B.3 and III.C.7 of this proposed rule.

a. Overview and Options for Geographic Area Selection

In determining the geographic unit for the geographic area selection for this model, we considered using a stratified random sampling methodology to select (1) certain counties based on their Core-Based Statistical Area (CBSA) status, (2) certain zip codes based on their Hospital Referral Regions (HRR) status or (3) certain states. We address each geographic unit in turn.

We considered selecting certain counties based on their CBSA status. The general concept of a CBSA is that of a core area containing a substantial population nucleus, together with adjacent communities having a high degree of economic and social integration within that core. Counties are designated as part of a CBSA when the county or counties or equivalent entities are associated with at least one core (urbanized area or urban cluster) of at least 10,000 in population, plus adjacent counties having a high degree of social and economic integration with the core as measured through commuting ties with the counties associated with the core. There are 929 CBSAs currently used for geographic wage adjustment purposes across Medicare payment systems.[4] The 929 CBSAs include 388 Metropolitan Statistical Areas (MSAs), which have an urban core population of at least 50,000, and the 541 Micropolitan Statistical Areas (μSA), which have an urban core population of at least 10,000 but less than 50,000. CBSAs may be further combined into a Combined Statistical Area (CSA) which consists of two or more adjacent CBSAs (MSAs or μSAs or both) with substantial employment interchange. Counties not classified as a CBSA are typically categorized and examined at a state level.

[4] As stated in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27552) and final rule (78 FR 50586), on February 28, 2013, OMB issued OMB Bulletin No. 13–01, which established revised delineations for MSAs, μSAs, and CSAs, and provided guidance on the use of the delineations of these statistical areas. A copy of this bulletin may be obtained at *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf.*

The choice of a geographical unit based on CBSA status could mean selection of a CBSA, an MSA, or a CSA. We propose basing the selection on an MSA, which we will discuss later in this section.

In determining which geographic areas will be potentially subject to selection, we focused on MSAs, which is a subcategory within CBSA characterized by counties associated with an urban core population of at least 50,000. It is our intention at this time that counties not in an MSA would not be subject to the selection process. These counties not subject to selection would include the μSA counties and the counties without a core urban area of at least 10,000. These areas are largely rural areas and have a limited number of qualifying LEJR cases. Relatively few of these areas would be able to qualify for inclusion based on the minimum number of LEJR episodes in year requirement discussed later in this section.

We considered, but ultimately decided against, using CSA designation instead of MSAs as a potential unit of selection. Under this scenario, we would look at how OMB classifies counties. We would first assess whether a county has been identified as belonging to a CSA, a unit which consists of adjacent MSAs or μSAs or both. If the county was not in a CSA, we would determine if it was in an MSA that is not part of a larger CSA. Counties not associated with a CSA or an MSA would be unclassified and excluded from selection. These unclassified areas would include the counties in a state that were either not a CBSA (no core area of at least 10,000) or associated with a μSA (core area of between 10,000 and 50,000) but unaffiliated with a CSA.

Whether to select on the basis of CSA/MSAs or just on MSAs was influenced by a number of factors including an assessment with respect to the anticipated degree to which LEJR patients would be willing to travel for their initial hospitalization, the extent to which surgeons are expected to have admitting privileges in multiple hospitals located in different MSAs and considerations related to the degree to which we desire to include hospitals within μSAs that are part of a larger CSA. It was believed that the anticipated risk for patient shifting and steering between MSAs within a CSA was not severe enough to warrant selecting CSAs. However, for these same reasons, we believe that selecting complete MSAs is preferable to selecting metropolitan divisions of MSAs for inclusion in the CCJR model. We use the metropolitan divisions to set wage indices for its prospective payment systems. Of the 388 MSAs, there are 11 MSAs that contain multiple metropolitan divisions. For example, the Boston-Cambridge-Newton, MA–NH MSA is divided into the following metropolitan divisions:

- Boston, MA.
- Cambridge-Newton-Framingham, MA.
- Rockingham County-Strafford County, NH.

The Seattle-Tacoma-Bellevue, WA MSA is divided into the following metropolitan divisions:

- Seattle-Bellevue-Everett, WA.
- Tacoma-Lakewood, WA.

We propose selecting entire MSAs rather than sub-divisions within an MSA.

We next considered selecting hospital referral regions (HRRs). HRRs represent regional health care markets for tertiary medical care. There are 306 HRRs with at least one city where both major cardiovascular surgical procedures and neurosurgery are performed. HRRs are defined by determining where the majority of patients were referred for major cardiovascular surgical procedures and for neurosurgery.[5] Compared to MSAs, HRRs are classified based on where the majority of beneficiaries within a zip code receive their hospital services for selected tertiary types of care. The resulting HRRs represent the degree to which people travel for tertiary care that generally requires the services of a major referral center and not the size of the referral network for more routine services, such as knee and hip arthroplasty procedures. In addition, because HRRs are defined based on referrals for cardiovascular surgical procedures and neurosurgery, they may not reflect referrals for orthopedic procedures. Therefore, we believe that MSAs as a geographic unit are preferable over HRRs for this model.

We also considered selecting states for the CCJR model. However, we concluded that MSAs as a geographic unit are preferable over states for the CCJR model. As mentioned in section III.A.4.b of this proposed rule, we anticipate that hospitals that would otherwise be required to participate in the CCJR model would be excluded from the model because their relevant LEJR episodes are already being tested in BPCI. If we were to select states as the geographic unit, there is a potential that an entire state would need to be excluded because a large proportion of hospitals in that state are episode initiators of LEJR episodes in BPCI. In contrast, if we excluded a specific MSA due to BPCI participation, as discussed in the next section, we could still select another MSA within that same state. Likewise, if we chose states as the geographic unit, we would automatically include hospitals in all rural areas within the state selected. If MSAs are selected for the geographic unit, we anticipate that fewer small rural hospitals would be included in the model. Using a unit of selection smaller than a state would allow for a more deliberate choice about the extent of inclusion of rural or small population areas. Selecting states rather than MSAs would also greatly reduce the number of independent geographic areas subject to selection under the model, which would decrease the statistical power of the model evaluation. Finally, MSAs straddle state lines where providers and Medicare beneficiaries can easily cross these boundaries for health care. Choosing states as the geographic unit would potentially divide a hospital market and set up a greater potential for patient shifting and steering to different hospitals under the model. The decision that the MSA-level analysis was more analytically appropriate was based on the specifics of this model and not meant to imply that other levels of selection would not be appropriate in a different model such as the proposed Home Health Value Based Purchasing (HHVBP) model.

For the reasons previously discussed, we propose to require participation in the CCJR model of all hospitals, with limited exceptions as previously discussed in section III.A.2.of this proposed rule, paid under the IPPS that are physically located in a county in an MSA selected through a stratified random sampling methodology, outlined in section III.A.3.b in this proposed rule, to test and evaluate the effects of an episode-based payment approach for an LEJR episodes. We propose to determine that a hospital is located in an area selected if the hospital is physically located within the boundary of any of the counties in that MSA as of the date the selection is made. Although MSAs are revised periodically, with additional counties added or removed from certain MSAs, we propose to maintain the same cohort of selected hospitals throughout the 5 year performance period of the model with limited exceptions as described later in this section. Thus, we propose not to add hospitals to the model if after the start of the model new counties are added to one of the selected MSAs or

[5] The Dartmouth Atlas of Healthcare, *http://www.dartmouthatlas.org/data/region/*. Accessed on April 9, 2015.

remove hospitals from the model if counties are removed from one of the selected MSAs. We believe that this approach will best maintain the consistency of the participants in the model, which is crucial for our ability to evaluate the results of the model. However, we retain the possibility of adding a hospital that is opened or incorporated within one of the selected counties after the selection is made and during the period of performance. (See section III.C.of this proposed rule for discussion of how target prices will be determined for such hospitals.) Although we considered including hospitals in a given MSA based on whether the hospitals were classified into the MSA for IPPS wage index purposes, this process would be more complicated, and we could not find any compelling reasons favoring this approach. For example, we assign hospitals to metro divisions of MSAs when those divisions exist. See our previous discussion of this issue. In addition, there is the IPPS process of geographic reclassification by which a hospital's wage index value or standardized payment amount is based on a county other than the one where the hospital is located. For the purpose of this model, it is simpler and more straightforward to use the hospital's physical location as the basis of assignment to a geographic unit. This decision would have no impact on a hospital's payment under the IPPS. We seek comment on our proposal to include participant hospitals for the CCJR model based on the physical location of the hospital in one of the counties included in a selected MSA.

b. MSA Selection Methodology

We propose to select the MSAs to include in the CCJR model by stratifying all of the MSAs nationwide according to certain characteristics.

(1) Exclusion of Certain MSAs

Prior to assigning an MSA to a selection stratum, we examined whether the MSA met specific proposed exclusion criteria. MSAs were evaluated sequentially using the following 4 exclusion criteria: First, MSAs in which fewer than 400 LEJR episodes (determined as we propose to determine episodes included in this model, as discussed in section III.B.2) occurred from July 1, 2013 through June 30, 2014 were removed from possible selection. The use of the 400 LEJR cases in a year was based on a simple one-sided power calculation to assess the number of episodes that would be needed to detect a 5 percent reduction in episode expenditures. Accordingly, cases in hospitals paid under either the critical access hospital (CAH) methodology or the Maryland All-Payer Model are not included in the count of eligible episodes. This criterion removed 156 MSAs from possible selection.

Second, MSAs were removed from possible selection if there were fewer than 400 non-BPCI LEJR episodes in the MSA in the reference year. For the purposes of this exclusion, the number of BPCI episodes was estimated as the number of potentially eligible cases during the reference year that occurred in acute care hospitals participating in BPCI Model 1, or in phase 2 of BPCI Models 2 or 4 as of July 1, 2015 and the number of LEJRs in 2013 and 2014 associated with these hospitals was examined. This criterion removed an additional 24 MSAs from potential selection.

Third, MSAs were also excluded from possible selection if the MSA was dominated by BPCI Models 1, 2, 3, or 4 episodes to such a degree that it would impair the ability of participants in either the CCJR model or the BPCI models to succeed in the objectives of the initiative or impair the ability to set accurate and fair prices. We anticipate that some degree of overlap in the two programs will be mutually helpful for both models. There are two steps to this exclusion. First, we looked at the number of LEJR episodes at BPCI Model 1, 2 or 4 initiating hospitals and second, the number of LEJR episodes among BPCI Model 3 SNF and HHA episode initiators. We set the first cut off for this exclusion if, within an MSA, more than 50 percent of otherwise qualifying proposed CCJR episodes were in Phase 2 of BPCI Model 2 or 4 with hospital initiators. We set the second cut off for BPCI Model 3, based on if either SNF or HHA BPCI Model 3 initiating providers accounted for more than 50 percent of LEJR referrals to that provider type, the MSA would be eliminated from the possibility of selection. As a result of this third criterion, 4 additional MSAs were removed from possible selection. No MSAs were excluded based on Skilled Nursing Facility (SNF) or Health Home Agency (HHA) participation in Model 3.

Finally, MSAs were removed if, after applying the previous 3 criteria they remained eligible for selection, but more than 50 percent of estimated eligible episodes during the reference year were not paid under the IPPS system. Please refer to the appenda for this proposed rule for the status of each MSA based on these exclusion criteria, available at *http://innovation.cms.gov/initiatives/ccjr/*. After applying these four exclusions, 196 MSAs remained to be stratified for purposes of our proposed selection methodology.

(2) Proposed Selection Strata

Numerous variables were considered as potential strata for classifying MSAs included in the model. However, our proposal is intended to give priority to transparency and understandability of the strata. We propose creating selection strata based on the following two dimensions: MSA average wage-adjusted historic LEJR episode payments and MSA population size.

(a) MSA Average Wage-adjusted Historic LEJR Episode Payments.

We were interested in being able to classify and divide MSAs according to their typical patterns of care associated with LEJR episodes. As a straightforward measure of LEJR patterns of care, we selected the mean MSA episode payment, as defined in this proposed rule. MSAs vary in their average episode payments. The average episode payments in an area may vary for a variety of reasons including—1) in response to the MS–DRG mix and thus the presence of complicating conditions; 2) readmission rates; 3) practice patterns associated with type of PAC provider(s) treating beneficiaries; 4) variations of payments within those PAC providers, and 5) the presence of any outlier payments.

The measure of both mean episode payments and median episode payments within the MSA was considered. We propose to stratify by mean because it would provide more information on the variation in episode payments at the high end of the range of payments. We are interested in the lower payment areas for the purpose of informing decisions about potential future model expansion. However, the CCJR model is expected to have the greatest impact in areas with higher average episode payments.

The average episode payments used in this analysis were calculated based on the proposed episode definition for CCJR using Medicare claims accessed through the Chronic Conditions Warehouse for 3 years with admission dates from July 1, 2011 through June 30, 2014. Episode payments were wage-adjusted using the FY 2014 hospital wage index contained in the FY 2014 IPPS Final Rule, downloaded at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY-2014-IPPS-Final-Rule-Home-Page-Items/FY-2014-IPPS-Final-Rule-CMS-1599-F-Data-Files.html.* The adjusted payment was calculated by dividing the unadjusted payment by a factor equal to the sum of 0.3 plus the

multiplicative product of 0.7 and the wage index value of the hospital where the LEJR was performed. Episodes in the database with IPPS payments less than $4,000 for the DRG 469 or 470 case were deleted as indicating that the hospital did not receive full payment for the LEJR procedure. We also truncated the episode payment at the 99.9th percentile of the distribution ($135,000) to limit the impact of extreme outliers.

(b) MSA Population Size

The second dimension proposed for the CCJR selection strata is the number of persons in the MSA. In deciding how best to incorporate the dimensions of urban density and availability of medical resources, a variety of measures were considered, including overall population in the included counties, overall population in the core area of the MSA, population over the age of 65 in the MSA, the number of hospital beds and the number of Medicare FFS LEJR procedures in a year. The reason we decided to include this dimension in the strata definition is that these factors are believed to be associated with the availability of resources and variations in practice and referral patterns by the size of the healthcare market. When examined, these alternative measures were all very highly correlated with one another, which allowed the use of one of these measures to be able to substitute for the others in the definition of the stratum. From these alternative approaches, we choose to use MSA population.

In operationalizing this measure, MSAs were classified according to their 2010 census population.

(c) Analysis of Strata

The two proposed domains, MSA population and MSA historic LEJR episode spending, were examined using a K-Means factor analysis. The purpose of this factor analysis was to inform the process of which cut points most meaningfully classify MSAs. Factor analysis attempts to identify and isolate the underlying factors that explain the data using a matrix of associations. Factor analysis is an interdependence technique. Essentially, variables are entered into the model and the factors (or clusters) are identified based on how the input variables correlate to one another. The resulting clusters of MSAs produced by this methodology suggested natural cut points for average episode payments at $25,000 and $28,500. While not intentional, these divisions correspond roughly to the 25th and 75th percentiles of the MSA distribution. Cut points based on these percentiles seemed reasonable from statistical and face validity perspectives in the sense that they created groups that included an adequate number of MSAs and a meaningful range of costs.

As a result of this analysis, we propose to classify MSAs according to their average LEJR episode payment into four categories based the on the 25th, 50th and 75th percentiles of the distribution of the 196 potentially selectable MSAs. This approach ranks the MSAs relative to one another and creates four equally sized groups of 49. The population distribution was divided at the median point for the MSAs eligible for potential selection. This resulted in MSAs being divided into two equal groups of 98. The characteristics of the resulting strata are shown in Table 1.

TABLE 1—SUMMARY POPULATION AND EPISODE PAYMENT STATISTICS BY MSA GROUP

	Payment in lowest quarter	Payment in 2nd lowest quarter	Payment in 3rd lowest quarter	Payment in highest quarter	Total eligilble
MSAs with population less than median:					
Number of Eligible MSAs	33	19	22	24	98
Average of Population	251,899	238,562	268,331	254,154	253,554
Minimum MSA Population	96,275	55,274	106,331	96,024	55,274
Maximum MSA Population	425,790	416,257	424,858	428,185	428,185
Average Episode Payments ($)	$22,994	$25,723	$27,725	$30,444	$26,410
Minimum Episode Payments	$18,440	$24,898	$26,764	$29,091	$18,440
Maximum Episode Payments	$24,846	$26,505	$28,679	$32,544	$32,544
MSAs with population more than median:					
Number of Eligible MSAs	16	30	27	25	98
Average of Population	1,530,083	1,597,870	1,732,525	2,883,966	1,951,987
Minimum MSA Population	464,036	436,712	434,972	439,811	434,972
Maximum MSA Population	4,335,391	5,286,728	12,828,837	19,567,410	19,567,410
Average Episode Payments ($)	$23,192	$25,933	$27,694	$30,291	$27,082
Minimum Episode Payments	$16,504	$25,091	$26,880	$28,724	$16,504
Maximum Episode Payments	$24,819	$26,754	$28,659	$33,072	$33,072
Total Eligible MSAs	49	49	49	49	.....

Note: Population and episode payment means are un-weighted averages of the MSA values within each of the eight MSA groups.

Please refer to the addenda for this proposed rule for information on the non-excluded MSAs, their wage adjusted average LEJR episode spending, their population and their resultant group assignment at: *http://innovation.cms.gov/initiatives/ccjr/*.

(3) Factors Considered but Not Used in Creating Proposed Strata

In addition to the two dimensions we are proposing to use for the selection groups previously discussed, a variety of possible alternative measures and dimensions were considered. Many of these variables are considered to be important but it was believed that it was important to have a fairly straightforward and easily understandable stratum definition. Simplicity, by definition, required that only the most important variables would be used. If a market characteristic under consideration was correlated with one of the chosen dimensions or it was believed that variations in the characteristic could be adequately captured by random selection within the strata, is was not prioritized for inclusion.

Some of the factors considered that we are not proposing as dimensions are—

- Measures associated with variation in practice patterns associated with LEJR episodes. In considering how to operationalize this measure, a number of alternatives were considered including total PAC LEJR payments in

an MSA, percent of LEJR episodes with a SNF claim in an MSA, percent of LEJR episodes with an initial discharge to HHA, percent of LEJR episodes with an IRF claim, and percent of LEJR episodes with claims for two or more types of PAC providers;

- Measures associated with relative market share of providers with respect to LEJR episodes;
- Healthcare supply measures of providers in the MSA including counts of IRF beds, SNF beds, hospital beds, and number of orthopedic surgeons;
- MSA level demographic measures such as; average income, distributions of population by age, gender or race, percent dually eligible, percent of population with specific health conditions or other demographic composition measures; and
- Measures associated with the degree to which a market might be more capable or ready to implement care redesign activities. Examples of market level characteristics that might be associated with anticipated ease of implementation include the MSA-level EHR meaningful use levels, managed care penetration, ACO penetration and experience with other bundling efforts.

It should be noted that, while these measures are proposed to be part of the selection stratus, we acknowledge that these and other market-level factors may be important to the proper understanding of the evaluation of the impact of CCJR. It is the intention that these and other measures will be considered in determining which MSAs are appropriate comparison markets for the evaluation as well as considered for possible subgroup analysis or risk adjustment purposes. The evaluation will include beneficiary, provider, and market level characteristics in how it examines the performance of this proposed model.

(4) Sample Size Calculations and the Number of Selected MSAs

Analyses of the necessary sample size led us to conclude that we need to select 75 MSAs of the 384 MSAs with eligible LEJR episodes to participate in CCJR. The number and method of selection of these 75 MSAs from the 8 proposed groups is addressed in the following section. In coming to the decision to target 75 MSAs, we are proposing a conservative approach. Going below this threshold would jeopardize our ability to be confident in our results and to be able to generalize from the model to the larger national context. We discuss the assumptions and modeling that went into our proposal to test the model in 75 MSAs later in this section.

In calculating the necessary size of the model, a key consideration was to have sufficient power to be able to detect the desired size impact. The larger the anticipated size of the impact, the fewer MSAs we would have to sample in order to observe it. However, a model sized to be able to only detect large impacts runs the risk of not being able to draw conclusions if the size of the change is less than anticipated. The measure of interest used in estimating sample size requirements for the CCJR model was wage-adjusted total episode spending. The data used for the wage-adjusted total episode spending is the 3 year data pull previously described that covers LEJR episodes with admission dates from July 1, 2011 through June 30, 2014. For the purposes of the sample size calculation the impact estimate assumed we wanted to be able to detect a 2 percent reduction in wage adjusted episode spending after 1 year of experience. This amount was chosen because it is the anticipated amount of the discount we propose to apply to target prices in CCJR.

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

A third consideration in the sample size calculation was the appropriate unit of selection and whether it is necessary to base the calculation on the number of MSAs, the number of hospitals, or the number of episodes. As discussed later in this section, we are proposing to base the sample size calculation at the MSA level.

The CCJR model is a nested comparative study, which has two key features. First, the unit of assignment (to treatment and comparison groups) is an identifiable group; such groups are not formed at random, but rather through some physical, social, geographic, or other connection among their members. Second, the units of observation are members of those groups. In such designs, the major analytic problem is that there is an expectation for a positive correlation (intra-class correlation (ICC)) among observations of members of the same group (MSA). That ICC reflects an extra component of variance attributable to the group above and beyond the variance attributable to its members. This extra variation will increase the variance of any aggregate statistic beyond what would be expected with random assignment of beneficiaries or hospitals to the treatment group.

In determining the necessary sample size, we need to take into consideration the degrees of freedom. As part of this process, we examined the number of beneficiaries, the number of hospitals, and the number of MSAs and the level of correlation in episode payments between each level. For example, while each beneficiary has their own episode expenditure level, there are commonalities between those expenditure amounts at the hospital level, based on hospital-specific practice and referral patterns. The number of degrees of freedom needed for any aggregate statistic is related to the number of groups (MSAs or hospitals), not the number of observations (beneficiary episodes). If we were to base the determination of the size of the model on beneficiary episodes where correlation exists, we would have an inflated false positive error rate and would overstate the impact of the model. We empirically examined the level of correlation between beneficiaries and hospitals and between hospitals and MSAs and determined that the correlation was high enough to be of concern and necessitate a MSA level unit of selection.

Using the aforementioned assumptions, a power calculation was run which indicated we would need between 50 and 150 treatment MSAs to be able to reliably detect a 2 percent reduction in payments after 1 year. The lower end of this range assumes the ability of evaluation models to substantially reduce variation through risk adjustment and modeling. We anticipate that we will be able to use the conservative end of this range, but assuming that evaluation modeling can achieve ''best'' results poses a real risk to our ability to draw conclusions. We want to allow for some degree of flexibility and are thus proposing proceeding with 75 MSAs. The 75 MSA

number is at the 25th percentile between the 50 and 150 treatment MSA range. We narrowed the acceptable range to between 50 and 100, based on the assumption that we will be able substantial improve our estimates through modeling, and then chose a number in the middle of this reduced range.

(5) Method of Selecting MSAs

As previously discussed, we are seeking to choose 75 MSAs from our proposed 8 selection groups. We examined and considered a number of possible approaches including equal selection in each of the eight groups, equal selection in the four payment groups, selection proportionate to the number of MSAs in each group, and a number of approaches that differentially weighted the payment categories.

After consideration, it was decided that a methodology that proportionally under-weighted more efficient MSAs and over-weighted more expensive MSAs was the most appropriate approach to fulfilling the overall priorities of this model to increase efficiencies and savings for LEJR cases while maintaining or improving the overall quality of care. This approach would make it less likely for the MSAs in the lowest spending category to be selected for inclusion. We thought this appropriate because the MSAs in the lowest expenditure areas have the least room for possible improvement and are already performing relatively efficiently compared to other geographic areas, which means that experience with the model in these areas may be relatively less valuable for evaluation purposes. At the same time, we believed it was important to include some MSAs in this group in order to assess the performance of this model in this type of circumstance. We also believe it is appropriate for higher payment areas to be disproportionately included because they are most likely to have significant room for improvement in creating efficiencies. We expect more variation in practice patterns among the more expensive areas. There are multiple ways an MSA can be more relatively expensive, including through outlier cases, higher readmission rates, greater utilization of physician services, or through PAC referral patterns. A larger sample of MSAs within the higher payment areas will allow for us to observe the impact of the CCJR model on areas with these various practice patterns in the baseline period.

The proposed method of disproportionate selection between the strata is to choose 30 percent of the MSAs in the two groups in the bottom quarter percentile of the payment distribution, 35 percent of the MSAs in the two groups in the second lowest quartile, 40 percent in the third quartile, and 45 percent in the highest episode payment quartile. This proportion works out to an average of 38 percent overall, which corresponds to 75 selected MSAs out of the 196 eligible. The number of MSAs to be chosen in the eight selection groups is shown in Table 2.

TABLE 2—NUMBER OF MSAS TO BE CHOSEN FROM THE EIGHT SELECTION GROUPS

	Payment in lowest quarter	Payment in 2nd lowest quarter	Payment in 3rd lowest quarter	Payment in highest quarter	Total eligible MSAs
Selection Proportion	30%	35%	40%	45%	
Less Than Median Population (Group #)	(1)	(2)	(3)	(4)	
Number Eligible MSAs	33	19	22	24	98
Proportion x Number	9.9	6.65	8.8	10.8	
Number to be selected from group	10	7	9	11	37
More Than Median Population (Group #)	(5)	(6)	(7)	(8)	
Number Eligible MSAs	16	30	27	25	98
Proportion x Number	4.8	10.5	10.8	11.25	
Number to be selected from group	5	11	11	11	38
Total Eligible MSAs	49	49	49	49	196
Number to be selected	15	18	20	22	75

We selected the proposed MSAs for the CCJR model through random selection. In the proposed method of selection, each MSA was assigned to one of the eight selection groups previously identified. Based on this sampling methodology, SAS Enterprise Guide 7.1 software was used to run a computer algorithm designed to randomly select MSAs from each strata. SAS Enterprise Guide 7.1 and the computer algorithm used to conduct selection represents an industry-standard for generating advanced analytics and provides a rigorous, standardized tool by which to satisfy the requirements of randomized selection. The key SAS commands employed include a ''PROC SURVEYSELECT'' statement coupled with the ''METHOD=SRS'' option used to specify simple random sampling as the sample selection method. A random number seed was generated for each of the eight strata by using eight number seeds corresponding to birthdates and anniversary dates of parties present in the room. The random seeds for stratum one through eight were as follows: 907, 414, 525, 621, 1223, 827, 428, 524. Note that no additional stratification was used in any of the eight groupings so as to produce an equal probability of selection within each of the eight groups. For more information on this procedure and the underlying statistical methodology, please reference SAS support documentation at: *http://support.sas.com/documentation/cdl/en/statug/63033/HTML/default/viewer.htm#statug_surveyselect_sect003.htm/*. We also considered a potential alternative approach to this random selection in which we would generate a starting number within SAS and then choose every third MSA within a group starting at this point until the relevant number of MSAs were chosen. We opted to not utilize this feature for simplicity's sake and alignment with other randomization methodologies used for CMS models.

The selection of an MSA means that all hospitals that are physically located anywhere within the counties that make up the MSA are included. By definition, the entire county is included in an MSA and hospitals that are in the relevant counties will be impacted even if they are not part of the core urban area.

The MSAs selected may change if the methodology changes in response to comments on the proposed methodology. Should the methodology we propose in this rule change as a result of comments received during the rulemaking process, it could result in different areas being selected for the model. In such an event, we would

apply the final methodology and announce the selected MSAs in the final rule. Therefore we seek comment from all interested parties in every MSA on the randomized selection methodology proposed in this section.

In accordance with section 1115A of the Act, we are proposing to codify these proposals in regulation in the new proposed part 510 of the Code of Federal Regulations.

TABLE 3—PROPOSED MSAS INCLUDED IN THE CCJR MODEL

MSA	MSA Name
10420	Akron, OH.
10740	Albuquerque, NM.
11700	Asheville, NC.
12020	Athens-Clarke County, GA.
12420	Austin-Round Rock, TX.
13140	Beaumont-Port Arthur, TX.
13900	Bismarck, ND.
14500	Boulder, CO.
15380	Buffalo-Cheektowaga-Niagara Falls, NY.
16020	Cape Girardeau, MO-IL.
16180	Carson City, NV.
16740	Charlotte-Concord-Gastonia, NC-SC.
17140	Cincinnati, OH-KY-IN.
17820	Colorado Springs, CO.
17860	Columbia, MO.
18580	Corpus Christi, TX.
19500	Decatur, IL.
19740	Denver-Aurora-Lakewood, CO.
20020	Dothan, AL.
20500	Durham-Chapel Hill, NC.
21780	Evansville, IN-KY.
22420	Flint, MI.
22500	Florence, SC.
22660	Fort Collins, CO.
23540	Gainesville, FL.
23580	Gainesville, GA.
24780	Greenville, NC.
25420	Harrisburg-Carlisle, PA.
26300	Hot Springs, AR.
26900	Indianapolis-Carmel-Anderson, IN.
28140	Kansas City, MO-KS.
28660	Killeen-Temple, TX.
29820	Las Vegas-Henderson-Paradise, NV.
30700	Lincoln, NE.
31080	Los Angeles-Long Beach-Anaheim, CA.
31180	Lubbock, TX.
31540	Madison, WI.
32780	Medford, OR.
32820	Memphis, TN-MS-AR.
33100	Miami-Fort Lauderdale-West Palm Beach, FL.
33340	Milwaukee-Waukesha-West Allis, WI.
33700	Modesto, CA.
33740	Monroe, LA.
33860	Montgomery, AL.
34940	Naples-Immokalee-Marco Island, FL.
34980	Nashville-Davidson—Murfreesboro—Franklin, TN.
35300	New Haven-Milford, CT.
35380	New Orleans-Metairie, LA.

TABLE 3—PROPOSED MSAS INCLUDED IN THE CCJR MODEL—Continued

MSA	MSA Name
35620	New York-Newark-Jersey City, NY-NJ-PA.
35980	Norwich-New London, CT.
36260	Ogden-Clearfield, UT.
36420	Oklahoma City, OK.
36740	Orlando-Kissimmee-Sanford, FL.
37860	Pensacola-Ferry Pass-Brent, FL.
38300	Pittsburgh, PA.
38940	Port St. Lucie, FL.
38900	Portland-Vancouver-Hillsboro, OR-WA.
39340	Provo-Orem, UT.
39740	Reading, PA.
40060	Richmond, VA.
40420	Rockford, IL.
40980	Saginaw, MI.
41860	San Francisco-Oakland-Hayward, CA.
42660	Seattle-Tacoma-Bellevue, WA.
42680	Sebastian-Vero Beach, FL.
43780	South Bend-Mishawaka, IN-MI.
41180	St. Louis, MO-IL.
44420	Staunton-Waynesboro, VA.
45300	Tampa-St. Petersburg-Clearwater, FL.
45780	Toledo, OH.
45820	Topeka, KS.
46220	Tuscaloosa, AL.
46340	Tyler, TX.
47260	Virginia Beach-Norfolk-Newport News, VA-NC.
48620	Wichita, KS.

B. Episode Definition for the Comprehensive Care for Joint Replacement (CCJR) Model

1. Background

Coordinated Quality Care-Joint Replacement is an episode payment model, focused on incentivizing health care providers to improve the efficiency and quality of care for an episode of care as experienced by a Medicare beneficiary by bundling payment for services furnished to the beneficiary for an episode of care for a specific clinical condition over a defined period of time. Key policies of such a model include the definition of episodes of care. Episodes of care have two significant dimensions—(1) a clinical dimension that describes what clinical conditions and associated services comprise the episode; and (2) a time dimension that describes the beginning, middle, and end of an episode. We present our proposals for these two dimensions of CCJR episodes in this section.

2. Clinical Dimension of Episodes of Care

a. Definition of the Clinical Conditions Included in the Episode

As discussed previously in section I.A. of this proposed rule, we have identified LEJR episodes, primarily hip and knee replacements, as the focus of this model. We believe that a straightforward approach for hospitals and other providers to identify Medicare beneficiaries in this payment model is important for the care redesign that is required for model success, as well as to operationalize the proposed payment and other model policies.

The vast majority of lower extremity joint replacements (LEJRs) are furnished in the inpatient hospital setting, with a small fraction of partial knee replacements occurring in the hospital outpatient department (HOPD) setting. Most of the Current Procedural Terminology (CPT) codes that physicians report for LEJR are on the hospital Outpatient Prospective Payment System (OPPS) inpatient only list. The CY 2015 OPPS inpatient only list is Addendum E of the CY 2015 Hospital Outpatient Prospective Payment–Final Rule with Comment Period, which is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1613-FC.html*. Thus, under current FFS payment policy, Medicare pays hospitals for the facility services required for LEJR only when those procedures are furnished in the inpatient hospital setting. Therefore, we believe an episode payment model most appropriately focuses around an inpatient hospitalization for these major surgical procedures, as there is little opportunity for shifting the procedures under this model to the outpatient setting.

We note further that LEJRs are paid for under the IPPS through the following two Medicare Severity-Diagnosis Related Groups (MS–DRGs):

- MS–DRG 469 (Major joint replacement or reattachment of lower extremity with Major Complications or Comorbidities (MCC)).
- MS–DRG 470 (Major joint replacement or reattachment of lower extremity without MCC).

Multiple ICD–9–CM procedure codes that describe LEJR procedures and other less common lower extremity procedures group to these MS–DRGs, with their percentage distribution within the IPPS MS–DRGs 469 and 470 for the past 4 years outlined in Table 4.

TABLE 4—DISTRIBUTION OF HOSPITAL CLAIMS FOR PROCEDURE CODES MAPPING TO MS–DRGS 469 AND 470

ICD–9–CM procedure code	Code descriptor	FY 2014 %	FY 2013 %	FY 2012 %	FY 2011 %
81.54	Total knee replacement	57	58	58	58
81.51	Total hip replacement	30	29	29	28
81.52	Partial hip replacement	12	13	13	14
81.56	Total ankle replacement	0	0	0	0
00.85	Resurfacing hip, total, acetabulum and femoral head	0	0	0	0
00.86	Resurfacing hip, partial, femoral head	0	0	0	0
00.87	Resurfacing hip, partial, acetabulum	0	0	0	0
84.27	Lower leg or ankle reattachment	0	N/A	N/A	N/A
84.28	Thigh reattachment	N/A	N/A	N/A	0

Note: Percentages or claim counts with "N/A" had no claims. percentages of 0% represent less than 0.5% of total claims.

Additionally, we note that there are various types of claims-based information available to CMS, hospitals, and other providers, that could be used to identify beneficiaries in the model who receive LEJRs, including the MS–DRGs for the acute care hospitalization for the procedure, the ICD–9–CM procedure code on the hospital claim, or the CPT code(s) reported by the orthopedic surgeon who furnishes the surgical procedure. While we could utilize ICD–9–CM procedure codes or CPT codes to identify beneficiaries included in the model, over 85 percent of procedures that group to MS–DRGs 469 and 470 are hip or knee replacements. Additionally, the hospitals that would be participating in this model receive payment under the IPPS, which is not determined by CPT codes and is based on clinical conditions and procedures that group to MS–DRGs. Finally, our review of the other low volume procedures that group to these same MS–DRGs, aside from total or partial hip and knee replacements, does not suggest that there is significant clinical or financial heterogeneity within these two MS–DRGs such that we would need to define care for included beneficiaries by ICD–9–CM procedure codes.

Therefore, we propose that an episode of care in the CCJR model is triggered by an admission to an acute care hospital stay (hereinafter ''the anchor hospitalization'') paid under MS–DRG 469 or 470 under the IPPS during the model performance period. This approach offers operational simplicity for providers and CMS, and is consistent with the approach taken by the BPCI initiative to identify beneficiaries whose care is included in the LEJR episode for that model. We seek public comments on this proposal to define the clinical conditions that are the target of CCJR.

b. Definition of Related Services Included in the Episode

For purposes of this model, as in BPCI, given the frequent comorbidities experienced by Medicare beneficiaries and the generally elective nature of LEJR, we are interested in testing inclusive episodes to incentivize comprehensive, coordinated patient-centered care for the beneficiary throughout the episode. We propose to exclude only those Medicare items and services furnished during the episode that are unrelated to LEJR procedures based on clinical justification. During our experience with BPCI implementation, we reviewed a number of narrow episode definitions for LEJR episodes that were recommended by BPCI participants and other interested parties during the design phase for this project. We concluded that these narrow definitions commonly exclude many services that may be linked to the LEJR, as LEJR beneficiaries, on average, are at higher risk for more clinical problems than Medicare beneficiaries who have not recently undergone such procedures.

Therefore, we propose that all CCJR episodes, beginning with the admission for the anchor hospitalization under MS–DRG 469 or 470 through the end of the proposed episode, include all items and services paid under Medicare Part A or Part B with the exception of certain exclusions as proposed in this section that are excluded because they are unrelated to the episode. The items and services ultimately included in the episode after the exclusions are applied are called related items and services. As proposed in sections III.C.4 and III.C.6 of this proposed rule, Medicare spending for related items and services would be included in the historical data used to set target prices, as well as in the calculation of actual episode spending that would be compared against the target price to assess the performance of participant hospitals. In contrast, Medicare spending for unrelated items and services (excluded from the episode definition) would not be included in the historical data used to set target prices or in the calculation of actual episode spending.

Related items and services included in CCJR episodes would be the following items and services paid under Medicare Part A or Part B, after the exclusions are applied:

- Physicians' services.
- Inpatient hospital services (including readmissions), with certain exceptions proposed later in this section.
- Inpatient psychiatric facility (IPF) services.
- LTCH services.
- IRF services.
- SNF services.
- HHA services.
- Hospital outpatient services.
- Independent outpatient therapy services.
- Clinical laboratory services.
- Durable medical equipment (DME).
- Part B drugs.
- Hospice.

We note that under our proposed definition of related services included in the episode, the episode could include certain per-member-per-month model payments, as discussed in section III.C of this proposed rule.

We propose to exclude from CCJR drugs that are paid outside of the MS–DRG, specifically hemophilia clotting factors (§ 412.115), identified through HCPCS code, diagnosis code, and revenue center on IPPS claims. Hemophilia clotting factors, in contrast to other drugs that are administered during an inpatient hospital stay and paid through the MS–DRG, are paid separately by Medicare in recognition that clotting factors are costly and essential to appropriate care for certain beneficiaries. Thus, we believe there are no efficiencies to be gained in the variable use of these high cost drugs when particular beneficiaries receive

LEJR procedures who have significantly different medical needs for clotting factors under an episode payment model, so we propose to exclude these high cost drugs from the actual historical episode expenditure data used to set target prices and from the hospital's episode actual spending that is reconciled to the target price. Similarly, we propose to exclude IPPS new technology add-on payments for drugs, technologies, and services from CCJR episodes, excluding them from both the actual historical episode expenditure data used to set target prices and from the hospital's actual episode spending that is reconciled to the target price. This proposal would apply to both the anchor hospital stay and any related readmissions during the episode. New technology add-on payments are made separately and in addition to the MS–DRG payment under the IPPS for specific new drugs technologies, and services that substantially improve the diagnosis or treatment of Medicare beneficiaries and would be inadequately paid otherwise under the MS–DRG system. Medicare pays a marginal cost factor of 50 percent for the costs to hospitals of the new drugs, technologies, or services. We do not believe it would be appropriate for the CCJR model to potentially hamper beneficiaries' access to new technologies that are receiving new technology add-on payments or to burden hospitals who choose to use these new drugs, technologies, or services with concern about these payments counting toward episode actual expenditures. In addition, because new drugs, technologies, or services approved for the add-on payments vary unpredictably over time in their application to specific clinical conditions, we believe we should exclude IPPS new technology add-on payments from CCJR episodes.

We followed a number of general principles in determining other proposed excluded services from the CCJR episodes in order to promote coordinated, high-quality, patient-centered care. Based on the broad nature of these episodes, we propose to identify excluded (unrelated) services rather than included (related) services based on the rationale that all Part A and Part B services furnished during the episode are related to the episode, unless they are unrelated based on clinical justification as described in more detail later in this section. In developing our proposals for exclusions for this model, we believe that no Part A services, other than certain excluded hospital readmissions during the episode as described in this section, furnished post-hospital discharge during the episode should be excluded, as post-hospital discharge Part A services are typically intended to be comprehensive in nature. We also believe that no claims for services with diagnosis codes that are directly related to the LEJR procedure itself (for example, loosening of the joint prosthesis) based on clinical judgment, and taking into consideration coding guidelines, should be excluded. Furthermore, we believe that no claims for diagnoses that are related to the quality and safety of care furnished during the episode, especially the anchor hospitalization under MS–DRG 469 or 470, should be excluded, such as direct complications of post-surgical care during the anchor hospitalization. Examples of diagnoses that would not be excluded on this basis include surgical site infection and venous thromboembolism. Finally, we believe that no claims for services for diagnoses that are related to preexisting chronic conditions such as diabetes, which may be affected by care furnished during the episode, should be excluded. However, severe exacerbations of chronic conditions (for example, some surgical readmissions) that are unlikely to be affected by care furnished during the episode should be excluded; thus, when a beneficiary is admitted to the hospital during the episode for these circumstances, we would not consider it to be a related readmission for purposes of CCJR. We also believe that services for clinical conditions that represent acute clinical conditions not arising from an existing chronic clinical condition or complication of LEJR surgery occurring during an episode of care, which would not be covered by the previous principles about included services, should be excluded.

To operationalize these principles for CCJR, we propose to exclude unrelated inpatient hospital admissions during the episode by identifying MS–DRGs for exclusion. We propose to exclude unrelated Part B services based on the ICD–9–CM diagnosis code (or their ICD–10–CM equivalents when ICD–10–CM codes are implemented) that is the principal diagnosis code reported on claims for services furnished during the episode. More specifically, we propose to exclude specific inpatient hospital admissions and services consistent with the LEJR episode definition (also triggered by MS–DRGs 469 and 470) that is currently used in BPCI Model 2. We note that the list of exclusions was initially developed over 2 years ago for BPCI through a collaborative effort of CMS staff, including physicians from medical and surgical specialties, coding experts, claims processing experts, and health services researchers. The list has been shared with thousands of entities and individuals participating in one or more phases of BPCI, and has undergone refinement over that time in response to stakeholder input about specific diagnoses or MS–DRGs for exclusion, resulting in only minimal changes over the last 2 years. Thus, the BPCI list of exclusions for LEJR procedures has been vetted broadly in the health care community; refined based on input from a wide variety of providers, researchers and other stakeholders; and successfully operationalized in the BPCI models. We are proposing its use in CCJR based on our confidence related to our several of years of experience that this definition is reasonable and workable for LEJR episodes, for both providers and CMS.

With respect to the proposed inpatient hospital admission exclusions for this model, we propose that all medical MS–DRGS for readmissions be included in CCJR episodes as related services, with the exception of oncology and trauma medical MS–DRGs. We propose that admissions for oncology and trauma medical MS–DRGs be excluded from CCJR episodes. Readmissions for medical MS–DRGs are generally linked to the hospitalization for the LEJR procedure as a complication of the illness that led to the surgery, a complication of treatment or interactions with the health care system, or a chronic illness that may have been affected by the course of care. We refer readers to section III.D. of this proposed rule for background and discussion of the complication rate measure proposed for CCJR that includes common medical complications resulting from the aforementioned circumstances following LEJR procedures and that may result in related hospital readmissions. For readmissions for medical MS–DRGs, the selection of the primary diagnosis code is not clear-cut, so we generally believe they all should be included, and we strongly believe that providers should focus on comprehensive care for beneficiaries during episodes. We propose to include all disease-related surgical MS–DRGs for readmissions, such as hip/knee revision, in CCJR episodes. We also propose to include readmissions for all body system-related surgical MS–DRGs as they are generally related to complications of the LEJR procedures. An example of a readmission of this type would be for an inferior vena cava filter placement for

treatment of thromboembolic complications of the LEJR. We propose to exclude hospital admissions for chronic disease surgical MS–DRGs, such as prostatectomy (removal of the prostate gland), as they are unrelated to the clinical condition that led to the LEJR nor would they have been precipitated by the LEJR. Finally, we propose that hospital admissions for acute disease surgical MS–DRGs, such as appendectomy, be excluded because they are highly unlikely to be related to, or precipitated by, LEJR procedures and would not be affected by LEJR episode care redesign.

With respect to the LEJR proposed diagnosis code exclusions for Part B services for this model, we propose that ICD–9–CM codes be excluded or included as a category and as identified by code ranges. We propose that disease-related diagnoses, such as osteoarthritis of the hip or knee, are included. We also propose that body system-related diagnoses are included because they relate to complications that may arise from interactions with the health care system. An example of this would be pressure pre-ulcer skin changes. Additionally, we propose that all common symptom diagnoses are included because providers have significant discretion to select these as principal diagnosis codes. We propose that acute disease diagnoses, such as severe head injury, are excluded. Finally, we propose that chronic disease diagnoses be included or excluded based on specific clinical and coding judgment as described previously with respect to the original development of the exclusions for LEJR episodes under BPCI, taking into consideration whether the condition was likely to have been affected by the LEJR procedure and recovery period and whether substantial services were likely to have been provided for the chronic condition during the episode. Thus, chronic kidney disease and cirrhosis would be included in the episode, but glaucoma and chemotherapy would be excluded.

Exclusions from CCJR episodes are based on care for unrelated clinical conditions represented by MS–DRGs for readmissions during the episode and ICD–9 CM codes for Part B services furnished during the episode after discharge from the anchor hospitalization. The complete lists of proposed excluded MS–DRGs for readmissions and proposed excluded ICD–9–CM codes for Part B services is posted on the CMS Web site at *http://innovation.cms.gov/initiatives/ccjr/.*

We note that as CMS moves to implement ICD–10–CM we will make the CCJR exclusions that would map to the final ICD–9–CM exclusions for CCJR available in the ICD–10–CM format as well. We propose that all Part A and B-covered items and services that would not be excluded based on the exclusions list are included in the episode. Furthermore, we propose to update the exclusions list without rulemaking on an annual basis, at a minimum, to reflect annual changes to ICD–CM coding and annual changes to the MS–DRGs under the IPPS, as well as to address any other issues that are brought to our attention by the public throughout the course of the model test.

We would first develop potential exclusions list revisions of MS–DRGs for readmissions and ICD–9 (or ICD–10, as applicable) diagnosis codes for Part B services based on our assessment against the following standards:

- We would not exclude any items or services that are—

++ Directly related to the LEJR procedure itself (such as loosening of the joint prosthesis) or the quality or safety of LEJR care (such as post-surgical wound infection or venous thromboembolism); and

++ For chronic conditions that may be affected by the LEJR procedure or post-surgical care (such as diabetes). By this we mean that where a beneficiary's underlying chronic condition would be affected by the LEJR procedure, or where the beneficiary's LEJR or post-LEJR care must be managed differently as a result of the chronic condition, then those items and services would be related and would be included in the episode.

- We would exclude items and services for—

++ Chronic conditions that are generally not affected by the LEJR procedure or post-surgical care (such as removal of the prostate). By this we mean that where a beneficiary's underlying chronic condition would not be affected by the LEJR procedure, or where the beneficiary's LEJR or post-LEJR care need not be managed differently as a result of the chronic condition, then those items and services would not be related and would not be included in the episode; and

++ Acute clinical conditions not arising from existing episode-related chronic clinical conditions or complications of LEJR surgery from the episode (such as appendectomy).

We would post the potential revised exclusions, which could include additions to or deletions from the exclusions list, to the CMS Web site to allow for public input on our planned application of these standards, and then adopt changes to the exclusions list with posting to the CMS Web site of the final revised exclusions list after our consideration of the public input.

We seek comment on our proposals for identifying excluded readmissions and Part B-covered items and services, as well as our proposed process for updating the exclusions list.

3. Duration of Episodes of Care

a. Beginning the Episode and Beneficiary Care Inclusion Criteria

While we propose to identify LEJR episodes by an acute care hospitalization for MS–DRG 469 and 470, we recognize that the beneficiary's care for an underlying chronic condition, such as osteoarthritis, which ultimately leads to the surgical procedure, typically begins months to years prior to the surgical procedure. Because of the clinical variability leading up to the joint replacement surgery and the challenge of identifying unrelated services given the multiple chronic conditions experienced by many beneficiaries, we do not propose to begin the episode prior to the anchor hospitalization (that is, the admission that results in a discharge under MS–DRG 469 or 470). We believe the opportunities for care redesign and improved efficiency prior to the inpatient hospital stay are limited for an episode payment model of this type that focuses on a surgical procedure and the associated recovery once the decision to pursue surgery has been made, rather than an episode model that focuses on decision-making and management of a clinical condition itself (such as osteoarthritis).

We propose to begin the episode with an inpatient anchor hospitalization for MS–DRG 469 or MS–DRG 470 in accordance with the methodology described. This proposal to begin the episode upon admission for the anchor hospitalization is consistent with LEJR episode initiation under Model 2 of BPCI. While we are not proposing to begin the episode prior to the inpatient hospital admission, we note that our proposed episode definition includes all services that are already included in the IPPS payment based on established Medicare policies, such as diagnostic services (including clinical diagnostic laboratory tests) and nondiagnostic outpatient services related to a beneficiary's hospital admission provided to a beneficiary by the admitting hospital, or by an entity wholly owned or wholly operated by the admitting hospital (or by another entity under arrangements with the admitting hospital), within 3 days prior to and including the date of the beneficiary's admission. For more

information on the 3-Day Payment Window payment policies, see CMS Pub. 100–04, Chapter 3, section 40.3 and Chapter 4, section 10.12.

We propose that the defined population of Medicare beneficiaries whose care will be included in CCJR meet the following criteria upon admission to the anchor hospitalization. We note that these criteria are also consistent with Model 2 of BPCI, as well as most other Innovation Center models that do not target a specific subpopulation of beneficiaries. The LEJR episodes for all beneficiaries in the defined population will be included in CCJR (although certain episodes may be canceled for purposes of determining actual episode payments for reasons discussed later in this proposed rule), and we refer readers to section I.B.8 of this proposed rule for further discussion of beneficiary notification and a beneficiary's ongoing right under CCJR to obtain health services from any individual or organization qualified to participate in the Medicare program.

- The beneficiary is enrolled in Medicare Part A and Part B throughout the duration of the episode.
- The beneficiary's eligibility for Medicare is not on the basis of End Stage Renal Disease.
- The beneficiary must not be enrolled in any managed care plan (for example, Medicare Advantage, Health Care Prepayment Plans, cost-based health maintenance organizations).
- The beneficiary must not be covered under a United Mine Workers of America health plan, which provides healthcare benefits for retired mine workers.
- Medicare must be the primary payer.

Our proposal for inclusion of beneficiaries in CCJR is as broad as feasible, representing all those LEJR episodes for which we believe we have comprehensive historical Medicare payment data that allow us to appropriately include Medicare payment for all related services during the episode in order to set appropriate episode target prices. For beneficiaries whose care we propose to exclude from the model, we are unable to capture or appropriately attribute to the episode the related Medicare payments because of Medicare's payment methodology. For example, if a beneficiary is enrolled in a Medicare Advantage plan, Medicare makes capitated payments (and providers do not submit complete claims data to CMS), so we would not have a way to identify and attribute the portion of those payments related to an LEJR episode. More information on setting bundled payment target prices for episodes under CCJR is available in section III.C.4.b of this proposed rule. Including the broadest feasible array of Medicare beneficiaries' admissions in the model would provide CMS with the most robust information about the effects of this model on expenditures and quality for beneficiaries of the widest variety of ages and comorbidities, and allow the participant hospitals the greatest opportunity to benefit financially from systematic episode care redesign because most Medicare beneficiaries undergoing an LEJR procedure will be included in the model and, therefore, subject to the policies we propose.

We seek comment on our proposal on when to begin the CCJR episode, as well as to identify the care included for beneficiaries.

b. Middle of the Episode

We propose that once the episode begins for a beneficiary whose care is included, the episode continues until the end as described in the next section of this proposed rule, unless the episode is cancelled because the beneficiary no longer meets the same inclusion criteria proposed for the beginning of the episode at any point during the episode. When an episode is cancelled, the services furnished to beneficiaries prior to and following the episode cancellation will continue to be paid by Medicare as usual but we will not calculate actual episode spending that would otherwise under CCJR be reconciled against the target price for the beneficiary's care (see section III.C.6 of this proposed rule). As discussed in section III.C.10.a.(3) of this proposed rule with comment period, waivers of program rules applicable to beneficiaries in CCJR episodes would apply to the care of beneficiaries who are in CCJR episodes at the time when the waiver is used to bill for a service that is furnished to the beneficiary, even if the episode is later cancelled.

We believe it would be appropriate to cancel the episode when a beneficiary's status changes during the episode such that they no longer meet the criteria for inclusion because the episode target price reflects full payment for the episode, yet we would not have full Medicare episode payment data for the beneficiary to reconcile against the target price.

In addition, we propose that the following circumstances would also cancel the episode:

- The beneficiary is readmitted to an acute care hospital during the episode and discharged under MS–DRG 469 or 470 (in this case, the first episode would be cancelled and a new LEJR episode would begin for the beneficiary).
- The beneficiary dies during the anchor hospitalization.
- The beneficiary initiates an LEJR episode under BPCI Models 1, 2, 3 or 4.

In the case of beneficiary death during the anchor hospitalization, we believe it would be appropriate to cancel the episode as there are limited efficiencies that could be expected during the anchor hospital stay itself. In the case of beneficiary readmission during the first CCJR episode for another LEJR (typically a planned staged second procedure), we do not believe it would be appropriate to include two episodes in the model with some time periods overlapping, as that could result in attribution of the Medicare payment for 2 periods of PAC to a single procedure.

We seek comment on our proposals to cancel episodes once they have begun but prior to their end.

c. End of the Episode

LEJR procedures are typically major inpatient surgical procedures with significant associated morbidity and a prolonged recovery period that often is marked by significant PAC needs, potential complications of surgery, and more intense management of chronic conditions that may be destabilized by the surgery. In light of the course of recovery from LEJRs for Medicare beneficiaries, we propose that an episode in the CCJR model end 90 days after discharge from the acute care hospital in which the anchor hospitalization (for MS–DRG 469 or 470) took place. Hereinafter, we refer to the proposed CCJR model episode duration as the ''90-day post-discharge'' episode. To the extent that a Medicare payment for included services spans a period of care that extends beyond the episode duration, these payments would be prorated so that only the portion attributable to care during the fixed duration of the episode is attributed to the episode spending.

We note for the vast majority of beneficiaries undergoing a hip or knee joint replacement, a 90-day post-discharge episode duration encompasses the full transition from acute care and PAC to recovery and return to activities. We believe the 90-day post-discharge episode duration encourages acute care hospitals, physicians, and PAC providers to promote coordinated, quality care as the patient transitions from the inpatient to outpatient settings and the community.

In proposing the 90-day post-discharge duration for LEJR episodes in CCJR, we took into consideration the literature regarding the clinical

experiences of patients who have undergone THA or TKA procedures. In 2007–2008, the 30-day all-cause readmission rate for primary THA among Medicare beneficiaries was 8.5 percent, while the 90-day all-cause readmission rate was 11.9 percent, indicating that while the rate of readmission begins to taper after 30 days, readmissions continue to accrue throughout this 90 day window.[6] In single center studies, Schairer et al found unplanned 30-day hospital readmission rates were 3.5 percent and 3.4 percent and unplanned 90-day hospital admission rates were 4.5 percent and 6 percent for primary THA and TKA, respectively, demonstrating that the risk of readmission remains significantly elevated from 30 through 90 days post-hospital discharge.[7] [8] Further exploring the reasons for unplanned admission for TKAs within 90 days of a knee replacement procedure, Schairer et al found that 75 percent were caused by surgical causes such as arthrofibrosis and surgical site infection. Additional information on the common reasons for hospital readmission following TKA or THA can be obtained from The American College of Surgeons National Surgical Quality Improvement Program.[9] These data identified the top ten reasons for readmission within 30 days of a hip or knee arthroplasty:

- Surgical site infections (18.8 percent).
- Prosthesis issues (7.5 percent).
- Venous thromboembolism (6.3 percent).
- Bleeding (6.3 percent).
- Orthopedic related (5.1 percent).
- Pulmonary (3.2 percent).
- Cardiac (2.4 percent).
- CNS or CVA (2.4 percent).
- Ileus or Obstruction (2.3 percent).
- Sepsis (2.1 percent).

In addition, the authors concluded that ''readmissions after surgery were associated with new post-discharge complications related to the procedure and not exacerbation of prior index hospitalization complications, suggesting that readmissions after surgery are a measure of post-discharge complications.'' Finally, with regard to the potential for readmission for joint replacement revision within a 90-day post-discharge episode, in a twelve-year study on Medicare patients conducted by Katz, et al., the risk of revision after THA remained elevated at approximately 2 percent per year for the first eighteen months and then 1 percent per year for the remainder of the follow-up period.[10] This study suggests that a longer episode, as opposed to a shorter episode, is more likely to simulate the increased risk of revision LEJR patients face.

In order to address the complication rates associated with elective primary total hip or knee arthroplasty, we developed an administrative claims-based measure (for a detailed description of the measure see section III.D of this proposed rule). During the development of the Hospital-level Risk-Standardized Complication Rate (RSCR) following elective primary THA or TKA or both, complications of elective primary total hip or knee replacement were identified to occur within specific timeframes.[11] For example, analyses done during the development of the measure as well as Technical Expert Panel opinion found that—(1) mechanical complications and periprosthetic joint infection/wound infection are still attributable to the procedure for the 90 days following admission for surgery; (2) death, surgical site bleeding, and pulmonary embolism are still likely attributable to the hospital performing the procedure for up to 30 days; and (3) medical complications of acute myocardial infarction (AMI), pneumonia, and sepsis/septicemia/shock are more likely to be attributable to the procedure for up to 7 days.

Other factors further supporting a 90-day post-discharge episode duration are the elevated risk of readmission throughout this time period, as well as the fact that treatment for pneumonia is considered by American Thoracic Society guidelines to be ''health care-associated'' if it occurs up to 90 days following an acute care hospitalization of at least 2 days.[12] According to the American Academy of Orthopedic Surgeons, patients undergoing total hip replacement should be able to resume most normal light activities of daily living within 3 to 6 weeks following surgery.[13] In a small randomized controlled trial of two approaches to hip arthroplasty, average time to ambulation without any assistive device was 22–28 days.[14] According to a 2011 systematic review of studies evaluating physical functioning following THA, patients have recovered to about 80 percent of the levels of controls by 8 months after surgery.[15]

We also refer readers to a study by the Assistant Secretary for Planning and Evaluation (ASPE) in the U.S Department of Health and Human Services that assessed the mean payments for acute care, PAC, and physician services grouped in the MS–DRG 470.[16] In this study, CMS payment for services following an MS–DRG 470 hospitalization were concentrated within the first 30 days following discharge, with plateauing of payments between 60- or 90-days post-discharge.

[6] Cram P, Lu X, Kates SL, Singh JA, Li Y, Wolf BR. Total Knee Arthroplasty Volume, Utilization, and Outcomes Among Medicare Beneficiaries, 1 991–2010. JAMA. 2012;308(12):1227–1236. doi:10.1001/2012.jama.11153.

[7] Schairer WW, et al. Causes and frequency of unplanned hospital readmission after total hip arthroplasty. Clin Orthop Relat Res. 2014 Feb;472(2):464–70. doi: 1 0.1007/s11999–013–3121–5.

[8] Schairer WW, et al. What are the rates and causes of hospital readmission after total knee arthroplasty? Clin Orthop Relat Res. 2014 Jan;472(1):181–7. doi: 1 0.1007/s11999–013–3030–7.

[9] Merkow RP, Ju MH, Chung JW, et al. Underlying Reasons Associated With Hospital Readmission Following Surgery in the United States. JAMA. 2015;313(5):483–495. doi:10.1001/jama.2014.18614.

[10] Katz JN, et al. Twelve-Year Risk of Revision After Primary Total Hip Replacement in the U.S. Medicare Population. J Bone Joint Surg Am. 2012 Oct 1 7; 94(20): 1 825–1832. doi: 1 0.2106/JBJS.K.00569

[11] Hospital Quality Initiatives. Measure Methodology. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.* See Hip and Knee Arthroplasty Complications zip file under downloads. Accessed on April 10, 2015.

[12] Guidelines for the management of adults with hospital-acquired, ventilator-associated, and healthcare-associated pneumonia. American Thoracic Society, Infectious Diseases Society of America. Am J Respir Crit Care Med. 2005;171(4):388.

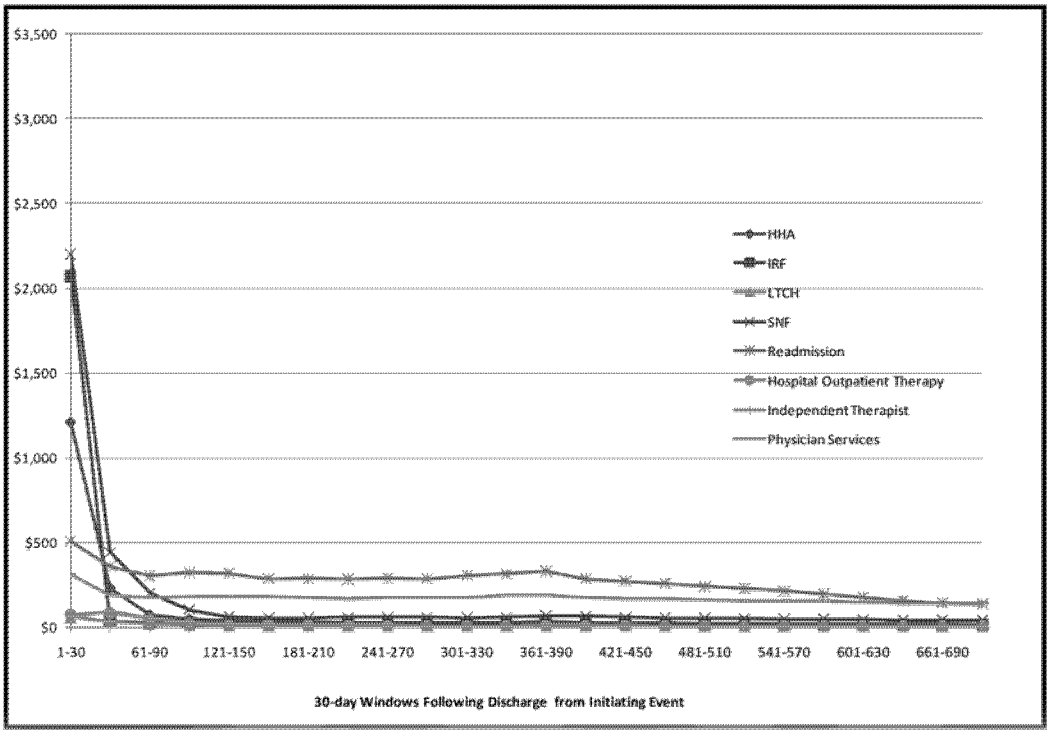
[13] *http://orthoinfo.aaos.org/topic.cfm?topic=A00377.*

[14] Taunton MJ, et al. Direct Anterior Total Hip Arthroplasty Yields More Rapid Voluntary Cessation of All Walking Aids: A Prospective, Randomized Clinical Trial The Journal of Arthroplasty. Volume 29, Issue 9, Supplement, September 2014, Pages 169–172.

[15] Vissers MM, et al. Recovery of Physical Functioning After Total Hip Arthroplasty: Systematic Review and Meta-Analysis of the Literature. Physical Therapy May 2011 vol. 91 no. 5 615–629.

[16] Post-Acute Care Episodes Expanded Analytic File. Assistant Secretary for Planning and Evaluation. U.S. Department of Health and Human Services. April 2011.

Mean Acute, PAC, and Physician Payments Per PAC User Following Discharge From an Acute Initiating Event, by Type of Claim, MS-DRG 470, "Major Joint Replacement or Reattachment of Lower Extremity w/o MCC"



Note: All initiating events occurred in 2006. Twenty-four 30-day windows were constructed following discharge from the initiating event to follow service use for 2 years.

Source: RTI analysis of 2006, 2007, and 2008 Medicare claims (M3MM181).

Finally, payment and length of stay analyses found the average length of stay in PAC during a 90-day post-discharge episode for MS–DRG 470 to be 47.3 days, indicating that a longer period post-discharge of 90 days is reasonable as a proposal to end the episode of care.[17] We note that these analyses did not include any time between hospital discharge and the start of PAC.

TABLE 5—COST AND LENGTH OF STAY STATISTICS FOR MS–DRG 470 FOR VARIOUS EPISODE DURATIONS

Statistics for DRG 470 (2006 data)	30-day episode	60-day episode	90-day episode
Mean Medicare spending per hospital discharge (acute+PAC+physician)	$18,838	$20,343	$21,125
Mean payment for anchor hospitalization	10,463	10,463	10,463
Mean payment for PAC	6,835	8,339	9,122
Mean payment for physicians (during anchor hospitalization)	1,540	1,540	1,540
Mean payment for readmission (includes all PAC users, even if no readmission occurs during the episode).	550	929	1,242
Mean length of stay (LOS) for PAC	25.5 days	39.6 days	47.3 days

Note: Data are per PAC user (88% of beneficiaries hospitalized under MS–DRG 470 are discharged to PAC). PAC users are defined as beneficiaries discharged to SNF, IRF, or LTCH within 5 days of discharge from the index acute hospitalization, or discharged to HHA or hospital outpatient therapy within 14 days of discharge from the index acute hospitalization. Mean LOS for PAC does not include any gap between hospital discharge date and start of PAC.

Other tests of bundled payment models for hip and knee replacement have used 90-day post-discharge episodes.[18] We also note that despite BPCI Model 2 allowing participants a choice between 30-, 60-, or 90-day post-discharge episodes, over 86 percent of participants have chosen the 90-day post-discharge episode duration for the LEJR episode. Further, a 90-day post-discharge episode duration aligns with the 90-day global period included in the Medicare Physician Fee Schedule payment for the surgical procedure.

We also considered proposing a 60-day post-discharge episode duration, but the full transition of care following LEJR would exceed this window for some beneficiaries, especially those who are discharged to an institutional post-acute provider initially and then

[17] Analysis of Post Acute Care Episode Definitions File. *http://innovation.cms.gov/initiatives/bundled-payments/learning-area.html.*

[18] -Ridgely MS, et al. Bundled Payment Fails To Gain A Foothold In California: The Experience Of The IHA Bundled Payment Demonstration. Health Affairs, 33, no.8 (2014):1345–1352.

transition to home health or outpatient therapy services for continued rehabilitation. According to a report from ASPE on Medicare beneficiaries receiving PAC following major joint replacement in 2006, 13 percent first receive SNF services and then receive HHA services—with a total mean episode duration of 56.8 days.[19] An additional 9.2 percent receive HHA services first and then receive outpatient therapy services—with a total mean episode duration of 78.7 days. Finally, 6.7 percent receive IRF services first and then HHA services (total mean length of stay 55.3 days), and 4.8 percent receive SNF services first and then outpatient therapy services (total mean length of stay 71.5 days). The remainder only receives one type of PAC.

Therefore, in order to be inclusive of most possible durations of recovery, and services furnished to reach recovery, we propose the 90-day post-discharge episode duration for CCJR. We believe that beneficiaries will benefit from aggressive management and care coordination throughout this episode duration, and hospitals will have opportunities under CCJR to achieve efficiencies from care redesign during the 90-day post-discharge episode period.

We seek comment on our proposal to end the episode 90 days after the date of discharge from the anchor hospitalization, as well as on the alternative we considered of ending the CCJR episode 60 days after the date of discharge.

In accordance with section 1115A of the Act, we are proposing to codify these proposals in regulation in the new proposed Part 510.

C. Proposed Methodology for Setting Episode Prices and Paying Model Participants under the CCJR Model

1. Background

As described in section II.B of this proposed rule, we propose to use the CCJR episode payment model to incentivize participant hospitals to work with other health care providers to improve quality of care for Medicare beneficiaries undergoing LEJR procedures and post-operative recovery, while enhancing the efficiency with which that care is provided. We propose to apply this incentive by paying participant hospitals or holding them responsible for repaying Medicare based on their CCJR episode quality and Medicare expenditure performance. The following sections describe our proposals for—

- How CCJR episodes would be attributed to a participant hospital;
- How the reconciliation of Medicare expenditures based on actual episode spending in relation to the target price would be structured and operationalized;
- How Medicare actual episode payments under existing payment systems would be compared against episode target prices;
- How hospital quality of care for CCJR episodes would be compared against quality thresholds Medicare establishes under this model;
- How payments to or repayment amounts from participant hospitals would be determined so that, on average, the episode target prices are paid by Medicare for CCJR episodes; and
- What protections from excessive risk due to high payment cases would be in place for participant hospitals.

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

a. Performance Period

We propose that the CCJR model would have 5 performance years. The performance years would align with calendar years, beginning January 1, 2016. Table 6 includes details on which episodes would be included in each of the 5 performance years.

TABLE 6—PERFORMANCE YEARS FOR CCJR MODEL

Performance year	Calendar year	Episodes included in performance year
1	2016	Episodes that start on or after January 1, 2016, and end on or before December 31, 2016.
2	2017	Episodes that end between January 1, 2017, and December 31, 2017, inclusive.
3	2018	Episodes that end between January 1, 2018, and December 31, 2018, inclusive.
4	2019	Episodes that end between January 1, 2019, and December 31, 2019, inclusive.
5	2020	Episodes that end between January 1, 2020, and December 31, 2020, inclusive.

All episodes tested in this model will begin on or after January 1, 2016 and end on or before December 31, 2020. We note that this definition results in performance year 1 being shorter than the later performance years in terms of the length of time over which an anchor hospitalization could occur under the model. We also note that some episodes that begin in a given calendar year may be captured in the following performance year due to the episodes ending after December 31st (for example, episode beginning in December 2016 and ending in March 2017 would be part of performance year 2). We believe 5 years would be sufficient time to test the CCJR model and gather sufficient data to evaluate whether it improves the efficiency and quality of care for an LEJR episode of care. Having fewer than 5 performance years may not provide sufficient time or data for evaluation. The 5-year performance period is consistent with the performance period used for other CMMI models (for example, the Pioneer Accountable Care Organization (ACO) Model).

b. Proposed Retrospective Payment Methodology

As described in section III.B of this proposed rule, we propose that an episode in the CCJR model begins with the admission for an anchor hospitalization and ends 90 days post-discharge from the anchor hospitalization, including all related services covered under Medicare Parts A and B during this timeframe, with limited exclusions and adjustments, as described in sections III.B, III.C.3, and III.C.7 of this proposed rule. The

[19] Examining Post Acute Care Relationships in an Integrated Hospital. Assistant Secretary for Planning and Evaluation. U.S. Department of Health and Human Services. February 2009.

episodes would be attributed to the participant hospital where the anchor hospitalization occurred.

We propose to apply the CCJR episode payment methodology retrospectively. Under this proposal, all providers and suppliers caring for Medicare beneficiaries in CCJR episodes would continue to bill and be paid as usual under the applicable Medicare payment system. After the completion of a CCJR performance year, Medicare claims for services furnished to beneficiaries in that year's non-cancelled episodes would be grouped into episodes and aggregated, and participant hospitals' CCJR episode quality and actual payment performance would be assessed and compared against episode quality thresholds and target prices, as described in sections III.C.5 and III.C.4 of this proposed rule, respectively. After the participant hospitals' actual episode performance in quality and spending are compared against the aforementioned episode quality thresholds and target prices, we would determine if Medicare would make a payment to the hospital (reconciliation payments), or if the hospital owes money to Medicare (resulting in Medicare repayment). The possibility for hospitals to receive reconciliation payments or be subject to repayment (note: participant hospitals would not be subject to repayment for performance year 1) is further discussed in section III.C.2.c. of this proposed rule.

We considered an alternative option of paying for episodes prospectively by paying one lump sum amount to the hospital for the expected costs of the 90-day episode. However, we believe such an option would be challenging to implement at this time given the payment infrastructure changes for both hospitals and Medicare that would need to be developed to pay and manage prospective CCJR episode payments. We note that a retrospective episode payment approach is currently being utilized under BPCI Model 2. We believe that a retrospective payment approach can accomplish the objective of testing episode payment in a broad group of hospitals, including financial incentives to streamline care delivery around that episode, without requiring core billing and payment changes by providers and suppliers, which would create substantial administrative burden. However, we seek comment on potential ways to implement a prospective payment approach for CCJR in future performance years of the model.

c. Proposed Two-Sided Risk Model

We propose to establish a two-sided risk model for hospitals participating in the CCJR model. We propose to provide episode reconciliation payments to hospitals that meet or exceed quality performance thresholds and achieve cost efficiencies relative to CCJR target prices established for them, as defined later in sections III.C.4 and III.C.5 of this proposed rule. Similarly, we propose to hold hospitals responsible for repaying Medicare when actual episode payments exceed their CCJR target prices in each of performance years 2 through 5, subject to certain proposed limitations discussed in section III.C.8 of this proposed rule. Target prices would be established for each participant hospital for each performance year.

We propose that hospitals will be eligible to receive reconciliation payments from Medicare based on their quality and actual episode spending performance under the CCJR model in each of CCJR performance years 1 through 5. Additionally, we propose to phase in the responsibility for hospital repayment of episode actual spending if episode actual spending exceeds their target price starting in performance year 2 and continuing through performance year 5. Under this proposal in performance year 1, participant hospitals would not be required to pay Medicare back if episode actual spending is greater than the target price.

We considered an episode payment structure in which, for all 5 performance years of the model, participant hospitals would qualify for reconciliation payments if episode actual spending was less than the episode target price, but would not be required to make repayments to Medicare if episode actual spending was greater than the episode target price. However, we believe not holding hospitals responsible for repaying excess episode spending would reduce the incentives for hospitals to improve quality and efficiency. We also considered starting the CCJR payment model with hospital responsibility for repaying excess episode spending in performance year 1 to more strongly align participant hospital incentives with care quality and efficiency. However, we believe hospitals may need to make infrastructure, care coordination and delivery, and financial preparations for the CCJR episode model, and that those changes can take several months or longer to implement. With this consideration in mind, we propose to begin hospitals' responsibility for repayment of excess episode spending beginning in performance year 2 to afford hospitals time to prepare, while still beginning some incentives earlier (that is, reconciliation payments in year 1) to improve quality and efficiency of care for Medicare beneficiaries. We solicit comment on the proposed incentive structure for CCJR.

In an effort to further ensure hospital readiness to assume responsibility for circumstances that could lead to a hospital repaying to Medicare actual episode payments that exceed the episode target price, we propose to begin to phase in this responsibility for performance year 2, with full responsibility for excess episode spending (as proposed in this rule) applied for performance year 3 through performance year 5. To carry out this ''phase in'' approach, we propose during the first year of any hospital financial responsibility for repayment (performance year 2) to set an episode target price that partly mitigates the amount that hospitals would be required to repay (see section III.C.4.b of this proposed rule), as well as more greatly limits (as compared to performance years 3 through 5) the maximum amount a hospital would be required to repay Medicare across all of its episodes (see section III.C.8 of this proposed rule).

3. Adjustments to Payments Included in Episode

Medicare payments during the model's performance year for Parts A and B claims for services included in the episode definition, as discussed in section III.B of this proposed rule, would be summed together for each non-cancelled CCJR episode that occurred to create the actual episode payment amount. We propose three adjustments to this general approach for—(1) special payment provisions under existing Medicare payment systems; (2) payment for services that straddle the end of the episode; and (3) high payment episodes. We note there would be further adjustments to account for overlaps with other Innovation Center models and CMS programs; we refer readers to section III.C.7 of this proposed rule.

We do not propose to adjust hospital-specific or regional components of target prices for any Medicare repayment or reconciliation payments made under the CCJR model; CCJR repayment and reconciliation payments would be not be included per the proposed episode definition in section III.B of this proposed rule. Including reconciliation payments and Medicare repayments in target price calculations would perpetuate the initial set of target prices

once CCJR performance years are captured in the 3- historical-years of data used to set target prices, as proposed in section III.C.4. of this proposed rule, beginning with performance year 3 when performance year 1 would be part of the 3-historical-years. Including any prior performance years' reconciliations or repayments in target price calculations would approximately have the effect (excluding impact of the proposed adjustments for high payment episodes (see section III.C.3.c. of this proposed rule) and proposed limits or adjustments to hospital financial responsibility (see section III.C.8. of this proposed rule)) of Medicare paying hospitals the target price, regardless of whether the hospital went below, above, or met the target price in the prior performance years before accounting for the reconciliation payments or repayments. We intend for target prices to be based on historical patterns of service actually provided, so we do not propose to include reconciliation payments or repayments for prior performance years in target price calculations.

a. Proposed Treatment of Special Payment Provisions Under Existing Medicare Payment Systems

Many of the existing Medicare payment systems have special payment provisions that have been created by regulation or statute to improve quality and efficiency in service delivery. IPPS hospitals are subject to incentives under the HRRP, the Hospital Value-Based Purchasing (HVBP) Program, the Hospital-Acquired Condition (HAC) Reduction Program, and the Hospital Inpatient Quality Reporting Program (HIQR) and Outpatient Quality Reporting Program (OQR). IPPS hospitals and CAHs are subject to the Medicare EHR Incentive Program. Additionally, the majority of IPPS hospitals receive additional payments for Medicare Disproportionate Share Hospital (DSH) and Uncompensated Care, and IPPS teaching hospitals can receive additional payments for Indirect Medical Education (IME). IPPS hospitals that meet a certain requirements related to low volume Medicare discharges and distance from another hospital receive a low volume add-on payment. As mentioned in section III.B.2.b of this proposed rule, acute care hospitals may receive new technology add-on payments to support specific new technologies or services that substantially improve the diagnosis or treatment of Medicare beneficiaries and would be inadequately paid otherwise under the MS–DRG system. Also, some IPPS hospitals qualify to be sole community hospitals (SCHs) or Medicare-dependent hospitals (MDHs), and they may receive enhanced payments based on cost-based hospital-specific rates for services; whether a SCH or MDH receives enhanced payments may vary year to year, in accordance with §§ 419.43(g) and 412.108(g), respectively.

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

Ambulatory Surgical Centers have their own Quality Reporting Program (ASC QRP). Physicians also have a set of special payment provisions based on quality and reporting: the Medicare EHR Incentive Program for Eligible Professionals, the Physician Quality Reporting System (PQRS), and the Physician Value-based Modifier Program.

The intent of the CCJR model is not to replace the various existing incentive programs or add-on payments, but instead to test further episode payment incentives towards improvements in quality and efficiency beyond Medicare's existing policies. Therefore, we propose that the hospital performance and potential reconciliation payment or Medicare repayment be independent of, and not affect, these other special payment provisions.

We propose to exclude the special payment provisions as discussed previously when calculating actual episode payments, setting episode target prices, comparing actual episode payments with target prices, and determining whether a reconciliation payment should be made to the hospital or funds should be repaid by the hospital.

Not excluding these special payment provisions would create incentives that are not aligned with the intent of the CCJR model. Not excluding the quality and reporting-related special payment provisions could create situations where a high-quality or reporting compliant hospital or both receiving incentive payments, or those hospitals that discharge patients to PAC providers that receive incentives for being reporting compliant, may appear to be ''high episode payment'' under CCJR. Conversely, lower quality or hospitals not complying with reporting programs or both that incur payment reduction penalties, or hospitals that discharge to PAC providers that are not reporting compliant, may appear to be ''low episode payment'' under CCJR. Such outcomes would run counter to CCJR's goal of improving quality. Also, not excluding add-on payments for serving more indigent patients, having low Medicare hospital volume, being located in a rural area, supporting greater levels of provider training, choosing to use new technologies, and having a greater proportion of CCJR beneficiaries with HIV from CCJR actual episode payment calculations may inappropriately result in hospitals having worse episode payment performance. Additionally, not excluding enhanced payments for MDHs and SCHs may result in higher or lower target prices just because these hospitals received their enhanced payments in one historical year but not the other, regardless of actual utilization. We believe the proposed approach of excluding special payment provisions would ensure a participant hospital's actual episode payment performance is not artificially improved or worsened because of payment reduction penalties or incentives or enhanced or add-on payments, the effects of which we are not proposing to test with CCJR.

In addition to the various incentive, enhanced, and add on payments, sequestration came into effect for Medicare payments for discharges on or after April 1, 2013, per the Budget Control Act of 2011 and delayed by the American Taxpayer Relief Act of 2012. Sequestration applies a 2 percent reduction to Medicare payment for most Medicare FFS services. Similar to the previously discussed incentive, enhanced, and add-on payments, we intend CCJR to be independent of the introduction and potential future elimination of sequestration. We do not intend to have participant hospitals' episodes appear to be ''low payment''

episodes relative to historical data, for part of which sequestration may not have been in effect, just because of an across-the-board Medicare payment reduction through sequestration. Therefore, we propose to account for the effects of sequestration when calculating actual episode payments, setting episode target prices, comparing actual episode payments with target prices, and determining whether a reconciliation payment should be made to the hospital or hospitals should repay Medicare.

In order to operationalize the exclusion of the various special payment provisions in calculating episode expenditures, we propose to apply the CMS Price (Payment) Standardization Detailed Methodology described on the QualityNet Web site at *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350.* This pricing standardization approach is the same as used for the HVBP program's Medicare spending per beneficiary metric.

We solicit comment on this proposed approach to treating special payment provisions in the various Medicare payment systems.

b. Proposed Treatment of Payment for Services That Extend Beyond the Episode

As we proposed a fixed 90-day post-discharge episode as discussed in section III.B of this proposed rule, we believe there would be some instances where a service included in the episode begins during the episode but concludes after the end of the episode and for which Medicare makes a single payment under an existing payment system. An example would be a beneficiary in a CCJR episode who is admitted to a SNF for 15 days, beginning on Day 86 post-discharge from the anchor CCJR hospitalization. The first 5 days of the admission would fall within the episode, while the subsequent 10 days would fall outside of the episode.

We propose that, to the extent that a Medicare payment for included episode services spans a period of care that extends beyond the episode, these payments would be prorated so that only the portion attributable to care during the episode is attributed to the episode payment when calculating actual Medicare payment for the episode. For non-IPPS inpatient hospital (for example, CAH) and inpatient PAC (for example, SNF, IRF, LTCH, IPF) services, we propose to prorate payments based on the percentage of actual length of stay (in days) that falls within the episode window. Prorated payments would also be similarly allocated to the 30-day post-episode payment calculation in section III.C.8.e. of this proposed rule. In the prior example, one-third of the days in the 15-day length of stay would fall within the episode window, so under the proposed approach, one-third of the SNF payment would be included in the episode payment calculation, and the remaining two-thirds (because the entirety of the remaining payments fall within the 30 days after the episode ended) would be included in the post-episode payment calculation.

For HHA services that extend beyond the episode, we propose that the payment proration be based on the percentage of days, starting with the first billable service date (''start of care date'') and through and including the last billable service date, that fall within the CCJR episode. Prorated payments would also be similarly allocated to the 30-day post-episode payment calculation in section III.C.8.e of this proposed rule. For example, if the patient started receiving services from an HHA on day 86 after discharge from the anchor CCJR hospitalization and the last billable home health service date was 55 days from the start of home health care date, the HHA claim payment amount would be divided by 55 and then multiplied by the days (5) that fell within the CCJR episode. The resulting, prorated HHA claim payment amount would be considered part of the CCJR episode. Services for the prorated HHA service would also span the entirety of the 30 days after the CCJR episode spends, so the result of the following calculation would be included in the 30-day post-episode payment calculation: HHA claim payment amount divided by 55 and then multiplied by 30 days (the number of days in the 30-day post-episode period that fall within the prorated HHA service dates).

There may also be instances where home health services begin prior to the CCJR episode start date, but end during the CCJR episode. In such instances, we would also prorate HHA payments based on the percentage of days that fell within the episode. Because these services end during the CCJR episode, prorated payments for these services would not be included in the 30-day post-episode payment calculation discussed in section III.C.8.e. of this proposed rule. For example, if the patient's start of care date for a home health 60-day claim was February 1, the anchor hospitalization was March 1 through March 4 (with the CCJR episode continuing for 90 days after March 4), and the patient resumed home care on March 5 with the 60-day home health claim ending on April 1 (that is, April 1 was the last billable service date), we would divide the 60-day home health claim payment amount by 60 and then multiply that amount by the days from the CCJR admission through April 1 (32 days) to prorate the HHA payment. This proposed prorating method for HHA claims is consistent with how partial episode payments (PEP) are paid for on home health claims.

For IPPS services that extend beyond the episode (for example, readmissions included in the episode definition), we propose to separately prorate the IPPS claim amount from episode target price and actual episode payment calculations as proposed in section III.C.8 of this proposed rule, called the normal MS–DRG payment amount for purposes of this proposed rule. The normal MS–DRG payment amount would be pro-rated based on the geometric mean length of stay, comparable to the calculation under the IPPS PAC transfer policy at §§ 412.4(f) and as published on an annual basis in Table 5 of the IPPS/LTCH PPS Final Rules. Consistent with the IPPS PAC transfer policy, the first day for a subset of MS–DRGs (indicated in Table 5 of the IPPS/LTCH PPS Final Rules) would be doubly weighted to count as 2 days to account for likely higher hospital costs incurred at the beginning of an admission. If the actual length of stay that occurred during the episode is equal to or greater than the MS–DRG geometric mean, the normal MS–DRG payment would be fully allocated to the episode. If the actual length of stay that occurred during the episode is less than the geometric mean, the normal MS–DRG payment amount would be allocated to the episode based on the number of inpatient days that fall within the episode. If the full amount is not allocated to the episode, any remainder amount would be allocated to the 30 day post-episode payment calculation discussed in section III.C.8.e of this proposed rule. The proposed approach for prorating the normal MS–DRG payment amount is consistent with the IPPS transfer per diem methodology.

The following is an example of prorating for IPPS services that extend beyond the episode. If beneficiary has a readmission for MS–DRG 493—lower extremity and humerus procedures except hip, foot, and femur, with complications—into an IPPS hospital on the 89th day after discharge from a CCJR anchor hospitalization, and is subsequently discharged after a length of stay of 5 days, Medicare payment for this readmission would be prorated for inclusion in the episode. Based on Table

5 of the IPPS/LTCH PPS Final Rule for FY 2015, the geometric mean for MS–DRG 493 is 4 days, and this MS–DRG is indicated for double-weighting the first day for proration. This readmission has only 2 days that falls within the episode, which is less than the MS–DRG 493 geometric mean of 4 days. Therefore, the normal MS–DRG payment amount associated with this readmission would be divided by 4 (the geometric mean) and multiplied by 3 (the first day is counted as 2 days, and the second day contributes the third day), and the resulting amount is attributed to the episode. The remainder one-fourth would be captured in the post-episode spending calculation discussed in section III.C.8 of this proposed rule. If the readmission occurred on the 85th day after discharge from the CCJR anchor hospitalization, and the length of stay was 7 days, the normal MS–DRG payment amount for the admission would be included in the episode without proration because length of stay for the readmission falling within the episode (6 days) is greater than or equal to the geometric mean (4 days) for the MS–DRG.

We considered an alternative option of including the full Medicare payment for all services that start during the episode, even if those services did not conclude until after the episode ended, in calculating episode target prices and actual payments. Previous research on bundled payments for episodes of PAC services noted that including the full payment for any claim initiated during the fixed episode period of time will capture continued service use. However, prorating only captures a portion of actual service use (and payments) within the bundle. [20] As discussed in section III.B of this proposed rule, the CCJR model proposes an episode length that extends 90 days post-discharge, and Table 5 in section III.B.3.c. of this proposed rule demonstrates that the average length of stay in PAC during a 90-day episode with a MS–DRG 470 anchor hospitalization is 47.3 days. Therefore, the length of the episode under CCJR (90 days) should be sufficient to capture the vast majority of service use within the episode, even if payments for some services that extend beyond the episode duration are prorated and only partly attributed to the episode.

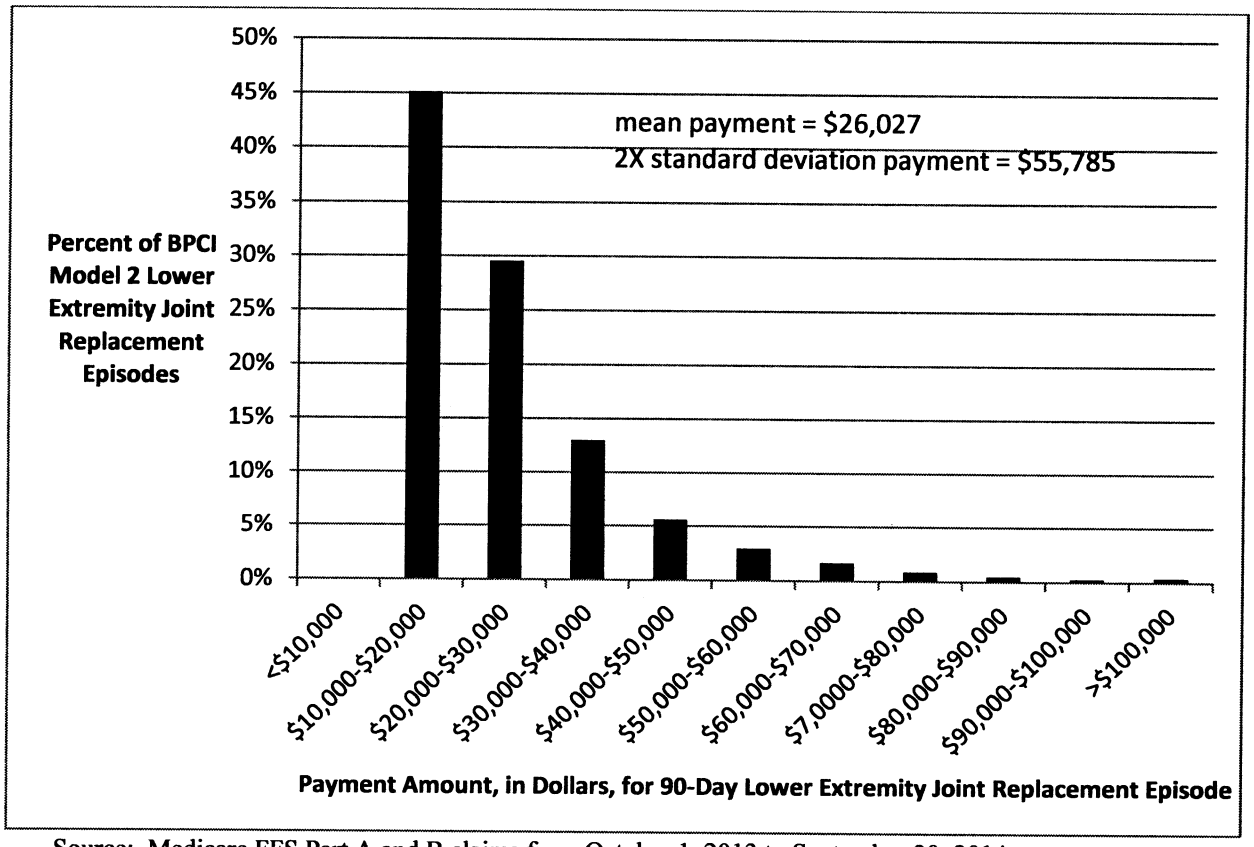
c. Proposed Pricing Adjustment for High Payment Episodes

Given the broad proposed LEJR episode definition and 90-day post-discharge episode duration proposed for CCJR, we want to ensure that hospitals have some protection from the variable repayment risk for especially high payment episodes, where the clinical scenarios for these cases each year may differ significantly and unpredictably. We do not believe the opportunity for a hospital's systematic care redesign of LEJR episodes has significant potential to impact the clinical course of these extremely disparate high payment cases.

The BPCI Model 2 uses a generally similar episode definition as proposed for CCJR and the vast majority of BPCI episodes being tested for LEJR are 90 days in duration following discharge from the anchor hospitalization. Similarly, we believe the BPCI distribution of Model 2 90-day LEJR episode payment amounts as displayed in Figure 1 provides information that is relevant to policy development regarding CCJR episodes.

[20] *http://aspe.hhs.gov/health/reports/09/pacepifinal/report.pdf.*

FIGURE 2: ESTIMATED NATIONAL DISTRIBUTION OF BPCI MODEL 2 LEJR 90-DAY EPISODE PAYMENT AMOUNTS [1 2]



Source: Medicare FFS Part A and B claims from October 1, 2013 to September 30, 2014.
1. Assumes no changes in volume or utilization pattern.
2. Payment reflects wage index removal.

As displayed, the mean episode payment amount is approximately $26,000. Five percent of all episodes are paid at two standard deviations above the mean payment or greater, an amount that is slightly more than 2 times the mean episode payment amount. While these high payment cases are relatively uncommon, we believe that incorporation of the full Medicare payment amount for such high payment episodes in setting the target price and correspondingly in Medicare's aggregate actual episode payment that is compared to the target price for the episode may lead in some cases to excessive hospital responsibility for these episode expenditures. This may be especially true when hospital responsibility for repayment of excess episode spending is introduced in performance year 2. The hospital may have limited ability to moderate spending for these high payment cases. Our proposal to exclude IPPS new technology add-on payments and separate payment for clotting factors for the anchor hospitalization from the episode definition limits excessive financial responsibility under this model of extremely high inpatient payment cases that could result from costly hospital care furnished during the anchor hospitalization. However, we believe an additional pricing adjustment in setting episode target prices and calculating actual episode payments is necessary to mitigate the hospital responsibility for the actual episode payments for high episode payment cases resulting from very high Medicare spending within the episode during the period after discharge from the anchor hospitalization, including for PAC, related hospital readmissions, and other items and services related to the LEJR episode.

Thus, in order to limit the hospital's responsibility for the aforementioned high episode payment cases, we propose to utilize a pricing adjustment for high payment episodes that would incorporate a high payment ceiling at two standard deviations above the mean episode payment amount in calculating the target price and in comparing actual episode payments during the performance year to the target prices.

Specifically, when setting target prices, we would first identify for each anchor MS–DRG in each region (discussed further in section III.C.4 of this proposed rule) the episode payment amount that is two standard deviations above the mean payment in the historical dataset used (discussed further in section III.C.4 of this proposed rule). Any such identified episode would have its payment capped at the MS–DRG anchor and region-specific value that is two standard deviations above the mean, which would be the ceiling for purposes for calculating target prices. We note that the calculation of the historical episode high payment ceiling for each region and MS–DRG anchor would be performed after other steps, including removal of effects of special payment

provisions and others described in section III.C.4.c. of this proposed rule.

When comparing actual episode payments during the performance year to the target prices, episode payments for episodes in the performance year would also be capped at two standard deviations above the mean. The high episode payment ceiling for episodes in a given performance year would be calculated based on MS–DRG anchor-specific episodes in each region. We discuss further how the high episode payment ceiling would be applied when comparing episode payments during the performance year to target prices in section III.C.6. of this proposed rule.

While this approach generally lowers the target price slightly, it provides a basis for reducing the hospital's responsibility for actual episode spending for high episode payment cases during the model performance years. When performing the reconciliation for a given performance year of the model, we would array the actual episode payment amounts for all episodes being tested within a single region, and identify the regional actual episode payment ceiling at two standard deviations above the regional mean actual episode payment amount. If the actual payment for a hospital's episode exceeds this regional ceiling, we would set the actual episode payment amount to equal the regional ceiling amount, rather than the actual amount paid by Medicare, when comparing a hospital's episode spending to the target price. Thus, a hospital would not be responsible for any actual episode payment that is greater than the regional ceiling amount for that performance year. We propose to adopt this policy for all years of the model, regardless of the reconciliation payment opportunity or repayment responsibility in a given performance year, to achieve stability and consistency in the pricing methodology. We believe this proposal provides reasonable protection for hospitals from undue financial responsibility for Medicare episode spending related to the variable and unpredictable course of care of some Medicare beneficiaries in CCJR episodes, while still fully incentivizing increased efficiencies for approximately the 95 percent of episodes for which we estimate actual episode payments to fall below this ceiling.[21] We seek comment on our proposal to apply a pricing adjustment in setting target prices and reconciling actual episode payments for high payment episodes.

4. Proposed Episode Price Setting Methodology

a. Overview

Whether a participant hospital receives reconciliation payments or is made responsible to repay Medicare for the CCJR model will depend on the hospital's quality and actual payment performance relative to episode quality thresholds and target prices. Quality performance and thresholds are further discussed in section III.C.5. of this proposed rule, and the remainder of this section will discuss the proposed approach to establishing target prices.

We propose to establish CCJR target prices for each participant hospital. For episodes beginning in performance years 1, 3, 4, and 5, a participant hospital would have eight target prices, one for each of the following:

- MS–DRG 469 anchored episodes that were initiated between January 1 and September 30 of the performance year, if the participant hospital successfully submits data on the voluntary patient reported outcome measure proposed in section III.C.5. of this proposed rule.
- MS–DRG 470 anchored episodes that were initiated between January 1 and September 30 of the performance year, if the participant hospital successfully submits data on the proposed voluntary patient reported outcome measure.
- MS–DRG 469 anchored episodes that were initiated between October 1 and December 31 of the performance year, if the participant hospital successfully submits data on the proposed voluntary patient-reported outcome measure.
- MS–DRG 470 anchored episodes that were initiated between October 1 and December 31 of the performance year, if the participant hospital successfully submits data on the proposed voluntary patient-reported outcome measure.
- MS–DRG 469 anchored episodes that were initiated between January 1 and September 30 of the performance year, if the participant hospital does not successfully submit data on the voluntary patient-reported outcome measure.
- MS–DRG 470 anchored episodes that were initiated between January 1 and September 30 of the performance year, if the participant hospital does not successfully submit data on the proposed voluntary patient-reported outcome measure.
- MS–DRG 469 anchored episodes that were initiated between October 1 and December 31 of the performance year, if the participant hospital does not successfully submit data on the proposed voluntary patient-reported outcome measure.
- MS–DRG 470 anchored episodes that were initiated between October 1 and December 31 of the performance year, if the participant hospital does not successfully submit data on the proposed voluntary patient-reported outcome measure.

For episodes beginning in performance year 2, a participant hospital would have 16 target prices. These would include the same combinations as for the other 4 performance years, but one set for determining potential reconciliation payments, and the other for determining potential Medicare repayment amounts, as part of the phasing in of two-sided risk discussed later in this section. Further discussion on our proposals for different target prices for MS–DRG 469 versus MS–DRG 470 anchored episodes, for episodes initiated between January 1 and September 30 versus October 1 and December 31, and for participant hospitals that do and do not successfully submit data on the proposed patient-reported outcome measure can be found in sections III.C.4.b and III.C.5. of this proposed rule.

We intend to calculate and communicate episode target prices to participant hospitals prior to the performance period in which they apply (that is, prior to January 1, 2017, for target prices covering episodes initiated between January 1 and September 30, 2017; prior to October 1, 2017 for target prices covering episodes initiated between October 1 and December 31, 2017). We believe prospectively communicating prices to hospitals will help them make any infrastructure, care coordination and delivery, and financial refinements they may deem appropriate to prepare for the new episode target prices.

The proposed approach to setting target prices incorporates the following features:

- Set different target prices for episodes anchored by MS–DRG 469 versus MS–DRG 470 to account for patient and clinical variations that impact hospitals' cost of providing care.
- Use 3 years of historical Medicare payment data grouped into episodes of care according to the episode definition proposed in section III.B. of this proposed rule, hereinafter termed historical CCJR episodes. The specific set of 3- historical-years used would be updated every other performance year.

[21] Medicare FFS Parts A and B claims, CCJR episodes as proposed, between October 1, 2013 and September 30, 2014.

• Apply Medicare payment system (for example, IPPS, OPPS, IRF PPS, SNF, PFS, etc.) updates to the historical episode data to ensure we incentivize hospitals based on historical utilization and practice patterns, not Medicare payment system rate changes that are beyond hospitals' control. Because different Medicare payment system updates become effective at two different times of the year, we would calculate separate target prices for episodes initiated between January 1 and September 30 versus October 1 and December 31.

• Blend together hospital-specific and regional historical CCJR episode payments, transitioning from primarily provider-specific to completely regional pricing over the course of the 5 performance years, to incentivize both historically efficient and less efficient hospitals to furnish high quality, efficient care in all years of the model. Regions would be defined as each of the nine U.S. Census divisions.

• Normalize for provider-specific wage adjustment variations in Medicare payment systems when combining provider-specific and regional historical CCJR episodes. Wage adjustments would be reapplied when determining hospital-specific target prices.

• Pool together CCJR episodes anchored by MS DRGs 469 and 470 to use a greater historical CCJR episode volume and set more stable prices.

• Apply a discount factor to serve as Medicare's portion of reduced expenditures from the CCJR episode, with any remaining portion of reduced Medicare spending below the target price potentially available as reconciliation payments to the participant hospital where the anchor hospitalization occurred.

Further discussion on each of the individual features can be found in section III.C.4.b. of this proposed rule. In section III.C.4.c. of this proposed rule, we also provide further details on the proposed sequential steps to calculate target prices and how each of the pricing features would fit together.

b. Proposed Pricing Features

(1) Different Target Prices for Episodes Anchored by MS–DRG 469 Versus MS–DRG 470

For each participant hospital we propose to establish different target prices for CCJR episodes initiated by MS–DRG 469 versus MS–DRG 470. MS–DRGs under the IPPS account for some of the clinical and resource variations that exist and that impact hospitals' cost of providing care. Specifically, MS–DRG 469 is defined to identify, and provide hospitals a higher Medicare payment to reflect the higher hospital costs for, hip and knee procedures with major complications or comorbidities. Therefore, we propose to calculate separate target prices for each participant hospital for CCJR episodes with MS–DRG 469 versus MS–DRG 470 anchor hospitalizations.

We considered adjusting the episode target prices by making adjustments or setting different prices based on patient-specific clinical indicators (for example, comorbidities). However, we do not believe there is a sufficiently reliable approach that exists suitable for CCJR episodes beyond MS–DRG-specific pricing, and there is no current standard on the best approach. At the time of developing this proposed rule Tennessee, Ohio, and Arkansas are launching multi-payer (including Medicaid and commercial payers, excluding Medicare) bundles and include hip and knee replacement as an episode [22] [23] [24]. These states' hip and knee episode definitions and payment models are consistent with, though not the same as, the proposed CCJR episode described in this proposed rule. However, each of these three states uses different risk adjustment factors. This variation across states supports our belief that there is currently no standard risk adjustment approach widely accepted throughout the nation that could be used under CCJR, a model that would apply to hospitals across multiple states. Therefore, we are not proposing to make adjustments based on patient-specific clinical indicators.

We also considered making price adjustments based on the participant hospital's average Hierarchical Condition Category (HCC) score for patients with anchor CCJR hospitalizations. The CMS–HCC risk adjustment model quantifies a beneficiary's risk by examining the beneficiary's demographics and historical claims data and predicting the beneficiary's total expenditures for Medicare Parts A and B in an upcoming year. However, the CMS–HCC risk adjustment model's intended use is to pay Medicare Advantage (MA) plans appropriately for their expected relative costs. For example, MA plans that disproportionately enroll the healthy are paid less than they would have been if they had enrolled beneficiaries with the average risk profile, while MA plans that care for the sickest patients are paid proportionately more than if they had enrolled beneficiaries with the average risk profile. The CMS–HCC risk adjustment model is prospective. It uses demographic information (that is, age, sex, Medicare/Medicaid dual eligibility, disability status) and a profile of major medical conditions in the base year to predict Medicare expenditures in the next year.[25] As previously noted, the CMS–HCC risk adjustment model is used to predict total Medicare expenditures in an upcoming year, and may not be appropriate for use in predicting expenditures over a shorter period of time, such as the CCJR episode, and may not be appropriate in instances where its use is focused on lower extremity joint replacements. Therefore, since we have not evaluated the validity of HCC scores for predicting Medicare expenditures for shorter episodes of care or for specifically lower extremity joint replacement beneficiaries, we are not proposing to risk adjust the target prices using HCC scores for the CCJR model.

We also considered making adjustments or setting different prices for different procedures, such as different prices or adjustments for hip versus knee replacements, but we do not believe there would be substantial variation in episode payments for these clinical scenarios to warrant different prices or adjustments. Moreover, Medicare IPPS payments, which account for approximately 50 percent [26] of CCJR episode expenditures, do not differentiate between hip and knee procedures, mitigating procedure-specific variation for the anchor hospitalization. Furthermore, there are no widely accepted clinical guidelines to suggest that PAC intensity would vary significantly between knee and hip replacements. We seek comment on our proposal to price episodes based on the MS–DRG for the anchor hospitalization, without further risk adjustment.

[22] Tennessee Health Care Innovation Initiative. *http://www.tn.gov/HCFA/strategic.shtml.* Accessed on April 16, 2015.

[23] Ohio Governor's Office of Health Transformation. Transforming Payment for a Healthier Ohio, June 8, 2014. *http://www.healthtransformation.ohio.gov/LinkClick.aspx?fileticket=TDZUpL4a-SI%3d&tabid=138,* Accessed on April 16, 2014.

[24] Total Joint Replacement Algorithm Summary, Arkansas Health Care Payment Improvement Initiative, November 2012. *http://www.paymentinitiative.org/referenceMaterials/Documents/TJR%20codes.pdf.* Accessed on April 17, 2015.

[25] Pope, C. et al., Evaluation of the CMS–HCC Risk Adjustment Model Final Report. Report to the Centers for Medicare & Medicaid Services under Contract Number HHSM–500–2005–00029I. RTI International. Research Triangle Park, NC. March, 2011.

[26] Medicare FFS Parts A and B claims, CCJR episodes, as proposed in this rule, between October 2013 and September 2014.

(2) Three Years of Historical Data

We propose to use 3 years of historical CCJR episodes for calculating CCJR target prices. The set of 3-historical-years used would be updated every other year. Specifically—

- Performance years 1 and 2 would use historical CCJR episodes that started between January 1, 2012 and December 31, 2014;
- Performance years 3 and 4 would use historical episodes that started between January 1, 2014 and December 31, 2016; and
- Performance year 5 would use episodes that started between January 1, 2016 and December 31, 2018. We considered using fewer than 3 years of historical CCJR episode data, but we are concerned with having sufficient historical episode volume to reliably calculate target prices. We also considered not updating the historical episode data for the duration of the model. However, we believe that hospitals' target prices should be regularly updated on a predictable basis to use the most recent available claims data, consistent with the regular updates to Medicare's payment systems, to account for actual changes in utilization. We are not proposing to update the data annually, given the uncertainty in pricing this could introduce for participant hospitals. We also note that the effects of updating hospital-specific data on the target price could be limited as the regional contribution to the target price grows, moving to two-thirds in performance year 3 when the first historical episode data update would occur.

(3) Proposed Trending of Historical Data to the Most Recent Year of the Three

We acknowledge that some payment variation may exist in the 3 years of historical CCJR episodes due to updates to Medicare payment systems (for example, IPPS, OPPS, IRF PPS, SNF PPS, etc.) and national changes in utilization patterns. Episodes in the third of the 3 historical years may have higher average payments than those from the earlier 2 years because of Medicare payment rate increases over the course of the 3 historical years. We do not intend to have CCJR incentives be affected by Medicare payment system rate changes that are beyond hospitals' control. In addition to the changes in Medicare payment systems, average episode payments may change year over year due to national trends reflecting changes in industry-wide practice patterns. For example, readmissions for all patients, including those in CCJR episodes, may decrease nationally due to improved industry-wide surgical protocols that reduce the chance of infections. We do not intend to provide reconciliation payments to (or require repayments from) hospitals for achieving lower (or higher) Medicare expenditures solely because they followed national changes in practice patterns. Instead, we aim to incentivize hospitals based on their hospital-specific inpatient and PAC delivery practices for LEJR episodes.

To mitigate the effects of Medicare payment system updates and changes in national utilization practice patterns within the 3 years of historical CCJR episodes, we propose to follow an approach similar to what is done in BPCI Model 2 and apply a national trend factor to each of the years of historical episode payments. Specifically, we propose to inflate the 2 oldest years of historical episode payments to the most recent year of the 3 historical years described in section III.C.4.b.(2) of this proposed rule. We propose to trend forward each of the 2 oldest years using the changes in the national average CCJR episode payments. We also propose to apply separate national trend factors for episodes anchored by MS–DRG 469 versus MS–DRG 470 to capture any MS–DRG-specific payment system updates or national utilization pattern changes. For example, when using CY 2012–2014 historical episode data to establish target prices for performance years 1 and 2, under our proposal we would calculate a national average MS–DRG 470 anchored episode payment for each of the 3 historical years. The ratio of the national average MS–DRG 470 anchored episode payment for CY 2014 to that of CY 2012 would be used to trend 2012 MS–DRG 470 anchored episode payments to CY 2014. Similarly, the ratio of the national average MS–DRG 470 anchored episode payment for CY 2014 to that of CY 2013 would be used to trend 2013 episode payments to CY 2014. The aforementioned process would be repeated for MS–DRG 469 anchored episodes. Trending CY 2012 and CY 2013 data to CY 2014 would capture updates in Medicare payment systems as well as national utilization pattern changes that may have occurred.

We considered adjusting for regional trends in utilization, as opposed to national trends. However, we believe that any Medicare payment system updates and significant changes in utilization practice patterns would not be region-specific but rather be reflected nationally.

We seek comment on our proposal to nationally trend historical data to the most recent year of the 3 being used to set the target prices.

(4) Update Historical Episode Payments for Ongoing Payment System Updates

We propose to prospectively update historical CCJR episode payments to account for ongoing Medicare payment system (for example, IPPS, OPPS, IRF PPS, SNF, PFS, etc.) updates to the historical episode data and ensure we incentivize hospitals based on historical utilization and practice patterns, not Medicare payment system rate changes that are beyond hospitals' control. Medicare payment systems do not update their rates at the same time during the year. For example, IPPS, the IRF prospective payment system, and the SNF payment system apply annual updates to their rates effective October 1, while the hospital outpatient prospective payment system (OPPS) and Physician Fee Schedule (PFS) apply annual updates effective January 1. To ensure we appropriately account for the different Medicare payment system updates that go into effect on January 1 and October 1, we propose to update historical episode payments for Medicare payment system updates and calculate target prices separately for episodes initiated between January 1 and September 30 versus October 1 and December 31 of each performance year. The target price in effect as of the day the episode is initiated would be the target price for the whole episode. Note that in performance year 5, the second set of target prices would be for episodes that start and end between and including October 1 and December 31 because the fifth performance period of the CCJR model would end on December 31, 2020. Additionally, a target price for a given performance year may apply to episodes included in another performance year. For example, an episode initiated in November 2016, and ending in February 2017 would have a target price based on the second set of 2016 target prices (for episodes initiated between October 1 and December 31, 2016), and it would be captured in the CY 2017 performance year (performance year 2) because it ended between January 1 and December 31, 2017. We refer readers to section III.C.3.c. of this proposed rule for further discussion on the definition of performance years.

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

- Inpatient acute.

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

A different set of update factors would be calculated for January 1 through September 30 versus October 1 through December 31 episodes each performance year. The six update factors for each of the aforementioned components would be hospital-specific and would be weighted by the percent of the Medicare payment for which each of the six components accounts in the hospital's historical episodes. The weighted update factors would be applied to historical hospital-specific average payments to incorporate ongoing Medicare payment system updates. A weighted update factor would be calculated by multiplying the component-specific update factor by the percent of the hospital's historical episode payments the component represents, and summing together the results. For example, let us assume 50 percent of a hospital's historical episode payments were for inpatient acute care services, 15 percent for physician services, 35 percent for SNF services, and 0.0 percent for the remaining services. Let us also assume for this example that the update factors for inpatient acute care services, physician services, and SNF services are 1.02, 1.03, and 1.01, respectively. The weighted update factor in this example would be the following: (0.5 * 1.02) + (0.15 * 1.03) + (0.35 * 1.01) = 1.018. The hospital in this example would have its historical average episode payments multiplied by 1.018 to incorporate ongoing payment system updates. The specific order of steps, and how this step fits in with others, is discussed further in section III.C.4.c. of this proposed rule.

Each of a hospital's six update factors would be based on how inputs have changed in the various Medicare payment systems for the specific hospital. Additional details on these update factors will be discussed later in this section.

Region-specific update factors for each of the aforementioned components and weighted update factors would also be calculated in the same manner as the hospital-specific update factors. Instead of using historical episodes attributed to a specific hospital, region-specific update factors would be based on all historical episodes initiated at any CCJR eligible hospital within the region. For purposes of this rule, CCJR eligible hospitals are defined as hospitals that were paid under IPPS and not a participant in BPCI Model 1 or in the risk-bearing period of Models 2 or 4 for LEJR episodes, regardless of whether or not the MSAs in which the hospitals are located were selected for inclusion in the CCJR model. CCJR episodes initiated at a CCJR eligible hospital will for purposes of this rule be referred to as CCJR episodes attributed to that CCJR eligible hospital.

We considered an alternative option of trending the historical episode payments forward to the upcoming performance year using ratios of national average episode payment amounts, similar to how we propose to trend the 2 oldest historical years forward to the latest historical year for historical CCJR episode payments in section III.C.4.b.(3) of this proposed rule. Using ratios of national average episode payment amounts would have the advantage of also capturing changes in national utilization patterns in addition to payment system updates between the historical years and the performance year. However, such an approach would need to be done retrospectively, after average episode payments can be calculated for the performance year, because it would rely on the payments actually incurred in the performance period, data for which would be not be available before the performance period. While the proposed approach of using component-specific update factors may be more complicated than the aforementioned alternative, we believe the additional complication is outweighed by the value to hospitals of knowing target prices before the start of an episode for which the target price would apply. We seek comment on this proposed approach of updating historical episode payments for ongoing Medicare payment system changes.

We do not propose to separately and prospectively apply an adjustment to account for changes in national utilization patterns between the historical and performance years. If a prospective adjustment factor for national utilization pattern changes were applied, it may only be meaningful in performance years 2 and 4, when the historical data used to calculate target prices would not be updated, but another year of historical data would be available. In any of the other 3 performance years, the latest available historical year of data would already be incorporated into the target prices. Given that we propose to refresh the historical data used to calculate target prices every 2 years, we do not believe an additional adjustment factor to account for national practice pattern changes is necessary to appropriately incentivize participant hospitals to improve quality of care and reduce episode payments.

(a) Proposed Inpatient Acute Services Update Factor

The proposed inpatient acute services update factor would apply to payments for services included in the episode paid under the IPPS. This would include payments for the CCJR anchor hospitalization, but not payments for related readmissions at CAHs during the episode window. Payments for related readmissions at CAHs would be captured under the update factor for other services in section III.C.4.b.(f) of this proposed rule.

The update factor applied to the inpatient acute services component of each participant hospital and region's historical average episode payments would be based on how inputs for the Medicare IPPS have changed between the latest year used in the historical 3 years of episodes and the upcoming performance period under CCJR. We propose to use changes in the following IPPS inputs to calculate the inpatient acute services update factor: IPPS base rate and average of MS–DRG weights, as defined in the IPPS/LTCH Final Rules for the relevant years. The average MS–DRG weight would be specific to each participant hospital and region to account for hospital and region-specific inpatient acute service utilization patterns. Hospital-specific and region-specific average MS–DRG weights would be calculated by averaging the MS–DRG weight for all the IPPS MS–DRGs included in the historical episodes attributed to each participant hospital and attributed to CCJR eligible hospitals in the region, respectively; including MS–DRGs for anchor admissions as well as those for subsequent readmissions that fall within the episode definition. Expressed as a ratio, the inpatient acute services adjustment factor would equal the following:

- The numerator is based on values applicable for the upcoming performance period (PP) for which a target price is being calculated.
- The denominator is based on values applicable at the end of the latest historical year used in the target price (TP) calculations.

Therefore, the proposed inpatient acute services update factor formula is shown as—

$$\frac{\text{Base Rate}_{PP} * \text{average MSDRG weight}_{PP}}{\text{Base Rate}_{TP} * \text{average MSDRG weight}_{TP}}$$

(b) Proposed Physician Services Update Factor

The proposed physician services update factor would apply to payments for services included in the episode paid under the Medicare PFS for physician services. We propose to use changes in the following PFS inputs to calculate the physician services update factor of each participant hospital and region's historical average episode payments: RVUs; work, practice expense, and malpractice liability geographic practice cost indices (GPCIs); and national conversion factor, as defined in the PFS Final Rule for the relevant years. Hospital-specific and region-specific RVU-weighted GPCIs would be calculated to account for hospital and region-specific physician service utilization patterns. Hospital-specific and region-specific RVU-weighted GPCIs would be calculated by taking the proportion of RVUs for work, practice expense, and malpractice liability for physician services included in the historical episodes and attributed to each participant hospital and attributed to CCJR eligible hospitals in the region, respectively, and multiplying each proportion by the relevant GPCI.

Expressed as a ratio, the physician services update factor would equal the following:

- The numerator is based on GPCI values applicable for the upcoming performance period (PP) for which a target price is being calculated.
- The denominator is based on GPCI applicable at the end of the latest year used in the target price (TP) calculations.

Therefore, the proposed physician services update factor formula is shown as—

$$\frac{\text{RVU} - \text{weighted GPCI}_{PP} * \text{Conversion factor}_{PP}}{\text{RVU} - \text{weighted GPCI}_{TP} * \text{Conversion factor}_{TP}}$$

(c) Proposed IRF Services Update Factor

The proposed IRF services update factor apply to payments for services included in the episode paid under the Medicare inpatient rehabilitation facility prospective payment system (IRF PPS). We propose to use changes in the IRF Standard Payment Conversion Factor, an input for the IRF PPS and defined in the IRF PPS Final Rule for the relevant years, to update Medicare payments for IRF services provided in the episode. The IRF Standard Payment Conversion Factor is the same for all IRFs and IRF services, so there is no need to account for any hospital-specific or region-specific IRF utilization patterns; each participant hospital and region would use the same IRF services update factor.

Expressed as a ratio, the IRF PPS update factor would equal the following:

- The numerator is based on values applicable for the upcoming performance period (PP) for which a target price is being calculated.
- The denominator is based on values applicable at the end of the latest historical year used in the target price (TP) calculations:

Therefore, the proposed IRF services update factor formula is shown as

$$\frac{\text{IRF Standard Payment Conversion factor}_{PP}}{\text{IRF Standard Payment Conversion factor}_{TP}}$$

(d) Proposed SNF Services Update Factor

The proposed SNF services update factor would apply to payments for services included in the episode and paid under the SNF PPS, including payments for SNF swing bed services. The update factor applied to the SNF services component of each participant hospital and region's historical average episode payments would be based on how average Resource Utilization Group (RUG–IV) Case-Mix Adjusted Federal Rates for the Medicare SNF PPS (defined in the SNF PPS Final Rule) have changed between the latest year used in the historical 3 years of episodes and the upcoming performance period under CCJR. The average RUG–IV Case-Mix Adjusted Federal Rates would be specific to each participant hospital and region to account for hospital and region-specific SNF service utilization patterns. Hospital-specific and region-specific average RUG–IV Case-Mix Adjusted Federal Rates would be calculated by averaging the RUG–IV Case-Mix Adjusted Federal Rates for all SNF services included in the historical episodes attributed to each participant hospital and attributed to CCJR eligible hospitals in the region, respectively. We note that the RUG–IV Case-Mix Adjusted Federal Rate may vary for the same RUG, depending on whether the SNF was categorized as urban or rural.

Expressed as a ratio, the SNF services update factor would equal the following:

- The numerator is based on values applicable for the upcoming performance period (PP) for which a target price is being calculated.
- The denominator is based on values applicable at the end of the latest year used in the target price (TP) calculations:

Therefore, the proposed SNF services update factor formula is shown as

$$\frac{\text{Average RUG IV Case Mix Adjusted Federal Rate}_{PP}}{\text{Average RUG IV Case Mix Adjusted Federal Rate}_{TP}}$$

(e) Proposed HHA Services Update Factor

The proposed HHA services update factor would apply to payments for services included in the episode and paid under the HH PPS, but exclude payments for Low Utilization Payment Adjustment (LUPA) claims (claims with four or fewer home health visits) because they are paid differently and would instead be captured in the update factor for other services in section III.C.4.b.(f) of this proposed rule. The update factor applied to the home health services component of each participant hospital and region's historical average episode payments would be based on how inputs for the Medicare HH PPS have changed between the latest year used in the historical 3 years of episodes and the upcoming performance period under CCJR. We propose to use changes in the HH PPS base rate and average of home health resource group (HHRG) case-mix weight, inputs for the HHA PPS and defined in the HHA PPS Final Rule for the relevant years, to calculate the home health services update factor. The average HHRG case-mix weights would be specific to each participant hospital and region to account for hospital and region-specific home health service utilization patterns. Hospital-specific and region-specific HHA services update factors would be calculated by averaging the HHRG case-mix weights for all home health payments (excluding LUPA claims) included in the historical episodes attributed to each participant hospital and attributed to CCJR eligible hospitals in the region, respectively.

Expressed as a ratio, the HHA adjustment factor would equal the following:

- The numerator is based on values applicable for the upcoming performance period (PP) for which a target price is being calculated.
- The denominator is based on values applicable at the end of the latest historical year used in the target price (TP) calculations.

Therefore, the proposed HHA services update factor formula is shown as—

$$\frac{\text{60 Day Episode Rate}_{\text{PP}} * \text{average HHRG weight}_{\text{PP}}}{\text{60 Day Episode Rate}_{\text{TP}} * \text{average HHRG weight}_{\text{TP}}}$$

(f) Proposed Other Services Update Factor

The other services update factor would apply to payments for services included in the episode and not paid under the IPPS, PFS, IRF PPS, or HHA PPS (except for LUPA claims). This component would include episode payments for home health LUPA claims and CCJR related readmissions at CAHs. For purposes of calculating the other services update factor, we propose to use the Medicare Economic Index (MEI), a measure developed by CMS for measuring the inflation for goods and services used in the provision of physician services.[27] We would calculate the other services update factor as the percent change in the MEI between the latest year used in the TP calculation and its projected value for the upcoming performance period. Because MEI is not hospital or region-specific, each participant hospital and region would use the same other services update factor.

(5) Blend Hospital-specific and Regional Historical Data

We propose to calculate CCJR episode target prices using a blend of hospital-specific and regional historical average CCJR episode payments, including CCJR episode payments for all CCJR eligible hospitals in the same U.S. Census division as discussed further in section III.C.4.b.(6) of this proposed rule. Specifically, we propose to blend two-thirds of the hospital-specific episode payments and one-third of the regional episode payment to set a participant hospital's target price for the first 2-performance years of the CCJR model (CY 2016 and CY 2017). For performance year 3 of the model (CY 2018), we propose to adjust the proportion of the hospital-specific and regional episode payments used to calculate the episode target price from two-thirds hospital-specific and one-third regional to one-third hospital-specific and two-thirds regional. Finally, we propose to use only regional historical CCJR episode payments for performance years 4 and 5 of the model (CY 2019 and CY 2020) to set a participant hospital's target price, rather than a blend between the hospital-specific and regional episode payments. The specific order of steps, and how this step fits in with others, is discussed further in section III.C.4.c. of this proposed rule. We welcome comment on the appropriate blend between hospital-specific and regional episode payments and the change in that blend over time.

We considered establishing episode target prices using only historical CCJR hospital-specific episode payments for all 5 performance years of the model (that is, episode payments for episodes attributed to the participant hospital, as previously described in section III.C.2. of this proposed rule). Using hospital-specific historical episodes may be appropriate in other models such as BPCI Model 2 where participation is voluntary and setting a region-wide target price could lead to a pattern of selective participation in which inefficient providers decline to participate, undermining the model's ability to improve the efficiency and quality of care delivered by those providers, while already-efficient providers receive windfall gains even if they do not further improve efficiency. Because CCJR model participants will be required to participate in the model, solely using hospital-specific historical episode data is not necessary to avoid this potential concern. Furthermore, using only hospital-specific historical CCJR episode payments may provide little incentive for hospitals that already cost-efficiently deliver high quality care to maintain or further improve such care. These hospitals could receive a relatively low target price because of their historical performance but have fewer opportunities for achieving additional efficiency under CCJR. They would not receive reconciliation payments for maintaining high quality and efficiency, while other hospitals that were less efficient would receive reconciliation payments for improving, even if the less historically efficient hospitals did not reach the same level of high quality and efficiency as the more historically efficient hospitals. Using only hospital-specific historical CCJR episode payments may also not be sufficient to curb inefficient care or overprovision of services for hospitals with historically high CCJR episode payments. In such instances, using hospital-specific historical episode payments for the CCJR model could result in Medicare continuing to pay an excessive amount for episodes of care provided by inefficient hospitals, and inefficient hospitals would stand to

[27] Medicare Market Basket Data. *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketData.html.*

benefit from making only small improvements. Thus, we do not propose to set target prices based solely on hospital-specific data for any performance years of the model.

We considered establishing the episode target price using only historical CCJR regional episode payments for all 5 performance years of the model. Though regional target pricing would reward the most efficient hospitals for continuing to provide high quality and cost efficient care, we are concerned about providing achievable incentives under the model for hospitals with high historical CCJR average episode payments. We believe a lower regional price for such hospitals would leave them with little financial incentive in performance year 1, especially without any responsibility to repay payments in excess of the target price as described in section III.C.3. of this proposed rule. Thus, we do not propose to set target prices solely on regional data for the entire duration of the model.

Therefore, we propose initially to blend historical hospital-specific and regional-historical episode payments and then transition to using regional-only historical episode payments in establishing target prices to afford early and continuing incentives for both historically efficient and less efficient hospitals to furnish high quality, efficient care in all years of the model. Our proposal more heavily weights a hospital's historical episode data in the first 2 years of the model (two-thirds hospital-specific, one-third regional), providing a reasonable incentive for both currently efficient and less efficient hospitals to deliver high quality and efficient care in the early stages of model implementation. Beginning in performance year 3, once hospitals have engaged in care redesign and adapted to the model parameters, we propose to shift to a more heavily weighted regional contribution (one-third hospital-specific, two-thirds regional in performance year 3) and ultimately to a regional target price for performance years 4 and 5. We believe that by performance year 4, setting target prices based solely on regional historical data would be feasible because hospitals would have had 3 years under this model to more efficiently deliver high quality care, thereby reducing some of the variation across hospitals. We believe transitioning to regional only pricing in the latter years of the model would provide important information about the reduction in unnecessary variation in LEJR episode utilization patterns within a region that can be achieved.

We believe transitioning to regional-only pricing in the latter years of the model may provide valuable information regarding potential pricing strategies for successful episode payment models that we may consider for expansion in the future. As discussed previously, substantial regional and hospital-specific variation in Medicare LEJR episode spending currently exists for beneficiaries with similar demographic and health status, so we are proposing that the early CCJR model years will more heavily weight historical hospital-specific experience in pricing episode for a participant hospital. Once the hospital has substantial experience with care redesign, we expect that unnecessary hospital-specific variation in episode spending will be minimized so that regional-only pricing would be appropriate as we have proposed. We note that, like episode payment under the CCJR model, Medicare's current payment systems make payments for bundles of items and services, although of various breadths and sizes depending on the specific payment system. For example, the IPPS pays a single payment, based on national prices with geography-specific labor cost adjustments, for all hospital services furnished during an inpatient hospital stay, such as nursing services, medications, medical equipment, operating room suites, etc. Under the IPPS, the national pricing approach incentivizes efficiencies and has, therefore, led to a substantial reduction in unnecessary hospital-specific variation in resource utilization for an inpatient hospital stay. On the other hand, the episode payment approach being tested under BPCI Model 2 relies solely on provider-specific pricing over the lifetime of the model, assuming the number of episode cases is sufficient to establish a reliable episode price, an approach that has potential limitations were expansion to be considered. Thus, we believe our proposal for CCJR will provide new, important information regarding pricing for even larger and broader bundles of services once unnecessary provider-specific variation has been minimized that would supplement our experience with patterns and pricing under existing payment systems and other episode payment models. We expect that testing of CCJR will contribute further information about efficient Medicare pricing strategies that result in appropriate payment for providers' resources required to furnish high quality, efficient care to beneficiaries who receive LEJR procedures. This is essential information for any consideration of episode payment model expansion, including nationally, in the future, where operationally feasible and appropriate pricing strategies, including provider-specific, regional, and national pricing approaches would need to be considered.

We propose an exception to the blended hospital-specific and regional pricing approach for hospitals with low historical CCJR episode volume. We propose to define hospitals with low CCJR episode volume as those with fewer than 20 CCJR episodes in total across the 3-historical-years used to calculate target prices. We believe calculating the hospital-specific component of the blended target price for these historically low CCJR episode volume hospitals may be subject to a high degree of statistical variation. Therefore, for each performance year, we propose to use 100 percent regional target pricing for participant hospitals who have fewer than twenty historical CCJR episodes in the 3-historical-years used to calculate target prices, as described in section III.C.4.b.(2) of this proposed rule. We note that the 3-historical-years used to calculate target prices would change over the course of the model, as described in section III.C.4.b.(2) of this proposed rule, and when that happens, the twenty episode threshold would be applied to the new set of historical years. If all IPPS hospitals nationally participated (for estimation purposes, only) in CCJR, we estimate about 5 percent of hospitals would be affected by this proposed low historical CCJR episode volume provision.[28] A minimum threshold of twenty episodes is almost equal to the minimum number of admissions required in the Medicare HRRP. HRRP payment adjustment factors are, in part, determined by procedure/condition-specific readmission rates for a hospital. HRRP requires at least 25 procedure/condition-specific admissions to calculate the procedure/condition-specific readmission rate and to be included in the hospital's overall HRRP payment adjustment factor. Though the proposed minimum threshold of twenty episodes is slightly less than the 25 admissions required for HRRP, we believe that because we would not be calculating infrequent events such as readmissions, we can achieve a stable price with slightly fewer episodes.

We also propose an exception to the blended hospital-specific and regional

[28] Medicare FFS Parts A and B claims, CCJR episodes, as proposed in this rule, between October 2013 and September 2014.

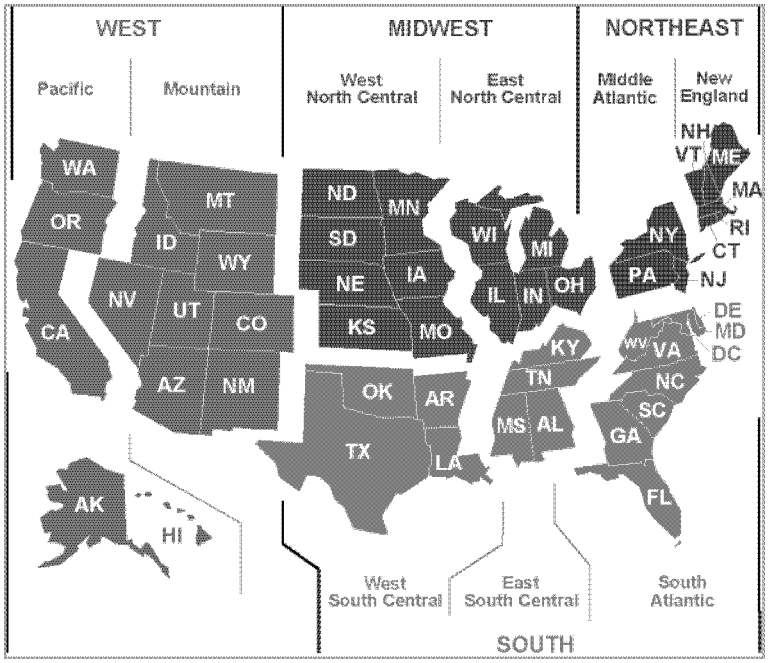
pricing approach for participant hospitals that received new CMS Certification Numbers (CCNs) during the 24 months prior to the beginning of, or during, the performance year for which target prices are being calculated. These participant hospitals with new CCNs may have formed due to a merger between or split from previously existing hospitals, or may be new hospitals altogether. As a general principle, we aim to incorporate into the target prices all the historical episodes that would represent our best estimate of CCJR historical payments for these participant hospitals with new CCNs. For participant hospitals with new CCNs that formed from a merger between or split from previously existing hospitals, we propose to calculate hospital-specific historical payments using the episodes attributed to the previously existing hospitals. These hospital-specific historical payments would then be blended with the regional historical payments according to the approach previously described in this section. For participant hospitals with new CCNs that are new hospitals altogether, we propose to use the approach previously described in this section for hospitals with fewer than 20 CCJR episodes across the 3 historical years used to calculate target prices. In other cases, due to an organizational change a hospital may experience a change to an already existing CCN during the 24 months prior to the beginning of, or during, the performance year for which target prices are being calculated. For example, one hospital with a CCN may merge with a second hospital assigned a different CCN, and both hospitals would then be identified under the single CCN of the second hospital. While there may be more than 20 CCJR episodes under the second hospital's CCN in total across the 3 historical years used to calculate target prices, in this scenario our use of only those cases under the second hospital's CCN in calculating hospital-specific historical payments would fail to meet our general principle of incorporating into target prices all the historical episodes that would represent our best estimate of CCJR historical payments for these now merged hospitals. In this scenario, we propose to calculate hospital-specific payments for the remaining single CCN (originally assigned to the second hospital only) using the historical episodes attributed to both previously existing hospitals. These hospital-specific historical payments would then be blended with the regional historical payments according to the approach previously described in this section in order to determine the episode price for the merged hospitals bearing a single CCN.

We seek comment on this proposed approach for blending hospital-specific and regional historical payments.

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

In all 5 performance years we propose to define ''region'' as one of the nine U.S. Census divisions [29] in Figure3.

FIGURE 3: U.S. CENSUS DIVISIONS[30]



We considered using states, HRRs, and the entire U.S. as alternative options to U.S. Census divisions in defining the region used in blending provider-specific and regional historical episode data for calculating target prices. However, HRR definitions are specifically based on referrals for cardiovascular surgical procedures and neurosurgery, and may not reflect referral patterns for orthopedic procedures. Using the entire U.S. would not account for substantial current regional variation in utilization, which is significant for episodes that often involve PAC use, such as lower extremity joint replacement procedures [31]. Finally, we considered

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

[30] *http://www.eia.gov/consumption/commercial/censusmaps.cfm.*

[31] Hussey PS, Huckfeldt P, Hirshman S, Mehrotra A. Hospital and regional variation in Medicare

using states as regions but were concerned that doing so would not allow for sufficient LEJR episode volume to set stable regional components of target prices, especially for participant hospitals in small states. We believe U.S. Census divisions provide the most appropriate balance between very large areas with highly disparate utilization patterns and very small areas that would be subject to price distortions due to low volume or hospital-specific utilization patterns.

We seek comment on our proposal to define a region as the U.S. Census division for purposes of the regional component of blended target prices under CCJR.

(7) Normalize for Provider-Specific Wage Adjustment Variations

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

In order to preserve how wage levels affect provider payment amounts, while minimizing the distortions introduced when calculating the regional-component of blended target prices, we propose to normalize for wage index differences in historical episode payments when calculating and blending the regional and hospital-specific components of blended target prices. Calculating blended target prices from historical CCJR episodes would help ensure we incentivize hospitals based on historical utilization and practice patterns, not Medicare payment system rate changes that are beyond hospitals' control.

We propose to normalize for provider-specific wage index variations using the IPPS wage index applicable to the anchor hospitalization (that is, the IPPS wage index used in the calculation of the IPPS payment for the anchor hospitalization). The anchor hospitalization accounts for approximately 50 percent of the total episode expenditures, and the IPPS wage index is applied to IPPS payments in a similar manner as wage indices for other Medicare payment systems are applied to their respective payments.[32] Therefore, we propose that the IPPS wage index applicable to the anchor hospitalization for each historical episode be used to normalize for wage index variations in historical episode payments across hospitals when calculating blended target prices. We propose to specifically perform this normalization using the wage normalization factor (0.7 * IPPS wage index + 0.3) to adjust the labor-related portion of payments affected by wage indices. The 0.7 approximates the labor share in IPPS, IRF PPS, SNF, and HHA Medicare payments. We would normalize for provider-specific wage index variations by dividing a hospital's historical episode payments by the wage normalization factor.

We propose to reintroduce the hospital-specific wage variations by multiplying episode payments by the wage normalization factor when calculating the target prices for each participant hospital, as described in section III.C.4.c. of this proposed rule. When reintroducing the hospital-specific wage variations, the IPPS wage index would be the one that applies to the hospital during the period for which target prices are being calculated (for example, FY 2016 wage indices for the target price calculations for episodes that begin between January 1 and September 30, 2016). The specific order of steps, and how this step fits in with others, is discussed further in section III.C.4.c. of this proposed rule. We seek comment on our proposal to normalize for wage index differences using participant hospitals' wage indices in order to calculate blended target prices.

(8) Proposed Combination of CCJR Episodes Anchored by MS–DRGs 469 and 470

We propose to pool together CCJR episodes anchored by MS–DRGs 469 and 470 for target price calculations to use a greater historical CCJR episode volume and set more stable target prices. We note that we would still calculate separate target prices for episodes anchored by MS–DRGs 469 versus 470, described later in this section.

To pool together MS–DRG 469 and 470 anchored episodes, we propose to use an anchor factor and hospital weights. The anchor factor would equal the ratio of national average historical MS–DRG 469 anchored episode payments to national average historical MS–DRG 470 anchored episode payments. The national average would be based on episodes attributed to any CCJR eligible hospital. The resulting anchor factor would be the same for all participant hospitals. For each participant hospital, a hospital weight would be calculated using the following formula, where episode counts are participant hospital-specific and based on the episodes in the 3 historical years used in target price calculations:

$$\frac{\textit{Count of MS DRG } 469 \textit{ and MS DRG } 470 \textit{ anchored episodes}}{\textit{MS DRG } 469 \textit{ anchored episode count} * \textit{anchor factor} + \textit{MS DRG } 470 \textit{ anchored episode count}}$$

A hospital-specific pooled historical average episode payment would be calculated by multiplying the hospital's hospital weight by its combined historical average episode payment (sum of MS–DRG 469 and 470 anchored historical episode payments divided by the number of MS–DRG 469 and 470 historical episodes).

The calculation of the hospital weights and the hospital-specific pooled historical average episode payments would be comparable to how case mix indices are used to generate case mix-

payment for inpatient episodes of care [published online April 13, 2015]. JAMA Intern Med. doi:10.1001/jamainternmed.2015.0674.

[32] Medicare FFS Parts A and B claims, CCJR episodes, as proposed in this rule, between October 2013 and September 2014.

adjusted Medicare payments. The hospital weight essentially would count each MS–DRG 469 triggered episode as more than one episode (assuming MS–DRG 469 anchored episodes have higher average payments than MS–DRG 470 anchored episodes) so that the pooled historical average episode payment, and subsequently the target price, is not skewed by the hospital's relative breakdown of MS–DRG 469 versus 470 anchored historical episodes.

The hospital-specific pooled historical average payments would be modified by blending and discount factors, as described in section III.C.4.c. of this proposed rule. Afterwards, the hospital-specific pooled calculations would be ''unpooled'' by setting the MS–DRG 470 anchored episode target price to the resulting calculations, and by multiplying the resulting calculations by the hospital weight to produce the MS–DRG 469 anchored target prices.

We would calculate region-specific weights and region-specific pooled historical average payments following the same steps proposed for hospital-specific weights and hospital-specific pooled average payments. Instead of grouping episodes by the attributed hospital as is proposed for hospital-specific calculations, region-specific calculations would group together episodes that were attributed to any CCJR eligible hospital located within the region. The hospital-specific and region-specific pooled historical average payments would be blended together as discussed in section III.C.4.b.(3) of this proposed rule. The specific order of steps, and how this step fits in with others, is discussed further in section III.C.4.c. of this proposed rule.

We considered an alternative option of independently setting target prices for MS–DRG 470 and 469 anchored episodes without pooling them. However, hospital volume for MS–DRG 469 was substantially less than for MS–DRG 470. In 2013 across all IPPS hospitals, there were more than 10 times as many MS–DRG 470 anchored episodes as compared to MS–DRG 469 anchored episodes. [33] In the same analysis, the median number of episodes for a hospital with at least 1 episode for the MS–DRG anchored episode was more than 80 for MS–DRG 470 anchored episodes, though fewer than 10 for MS–DRG 469 anchored episodes. Calculating target prices for MS–DRG 469 anchored episodes separately for each participant hospital may result in too few historical episodes to calculate reliable target prices. We also considered pooling together MS–DRG 469 and 470 anchored episodes without any anchor factor or hospital weights. However, internal analyses suggest that average episode payments for these two MS–DRG anchored episodes significantly differed; CCJR episodes initiated by MS–DRG 469 had payments almost twice as large as those initiated by MS–DRG 470.[34] This difference is reasonable given that Medicare IPPS payments differ for MS–DRG 469 and 470 admissions, and inpatient payments comprise approximately 50 percent of CCJR episode payments. Thus, pooling together MS–DRG 469 and 470 anchored episodes without any anchor factor or hospital weights would introduce distortions due only to case-mix differences.

(9) Discount Factor

When setting an episode target price for a participant hospital, we propose to apply a discount to a hospital's hospital-specific and regional blended historical payments for a performance period to establish the episode target price that would apply to the participant hospital's CCJR episodes during that performance period and for which the hospital would be fully, or partly, accountable for episode spending in relationship to the target price, as discussed in section III.C.3. of this proposed rule. We expect participant hospitals to have significant opportunity to improve the quality and efficiency of care furnished during episodes in comparison with historical practice, because this model would facilitate the alignment of financial incentives among providers caring for beneficiaries throughout the episode. This discount would serve as Medicare's portion of reduced expenditures from the CCJR episode, with any episode expenditure below the target price potentially available as reconciliation payments to the participant hospital where the anchor hospitalization occurred. We propose to apply a 2 percent discount for performance years 1 through 5 when setting the target price. We believe that applying a 2 percent discount in setting the episode target price allows Medicare to partake in some of the savings from the CCJR model, while leaving considerable opportunity for participant hospitals to achieve further episode savings below the target price that they would be paid as reconciliation payments, assuming they meet the quality requirements as discussed in section III.C.5 of this proposed rule.

The proposed 2 percent discount is similar to the range of the discounts used for episodes in the Medicare Acute Care Episode (ACE) demonstration.[35] In the Medicare ACE, a demonstration program that included orthopedic procedures such as those included in CCJR, participant hospitals negotiated with Medicare discounts of 2.5 to 4.4 percent of all Part A orthopedic services and 0.0 to 4.4 percent of all Part B orthopedic services during the inpatient stay (excluding PAC). Hospitals received the discounted payment and reported that they were still able to achieve savings.[36] We believe there is similar, if not potentially more, opportunity for savings in the CCJR payment model because it includes acute inpatient, as well as PAC, an area of episode spending that accounts for approximately 25 percent of CCJR episode payments and exhibits more than 2 times the episode payment variation [37] than that of acute inpatient hospitalization.[38] We believe that with the proposed 2 percent discount, participant hospitals have an opportunity to create savings for themselves as well as Medicare, while also maintaining or improving quality of care for beneficiaries.

The proposed 2 percent discount also matches the discount used in the BPCI Model 2 90-day episodes, and is less than the discount used in BPCI Model 2 30-day and 60-day episodes (3 percent). Hundreds of current BPCI participants have elected to take on responsibility for repayment in BPCI Model 2 with a 2 to 3 percent discount. Because many BPCI participants volunteered to participate in a bundled payment model with a discount, we believe that a discount percent that is within, and especially a discount of 2 percent that is at the lower end of, the BPCI discount range would allow CCJR

[33] Source: CCW Part A and Part B claims for CCJR episodes beginning in CY 2013.

[34] Medicare FFS Parts A and B claims, CCJR episodes, as proposed in this rule, between October 2013 and September 2014.

[35] IMPAQ International. Evaluation of the Medicare Acute Care Episode (ACE) Demonstration: Final Evaluation Report. Columbia, MD: IMPAQ International; May 2013. *http://downloads.cms.gov/files/cmmi/ACE-EvaluationReport-Final-5-2-14.pdf.* Accessed April 1 6, 2015.

[36] IMPAQ International. Evaluation of the Medicare Acute Care Episode (ACE) Demonstration: Final Evaluation Report. Columbia, MD: IMPAQ International; May 2013. *http://downloads.cms.gov/files/cmmi/ACE-EvaluationReport-Final-5-2-14.pdf.* Accessed April 1 6, 2015.

[37] Variation for purposes of this calculation refers to standard deviation of inpatient and institutional post-acute episode payments as a percentage of average inpatient and post-acute episode payments, respectively.

[38] Medicare FFS Parts A and B claims, CCJR episodes, as proposed in this rule, between October 2013 and September 2014.

participant hospitals to create savings for both themselves and Medicare.

As mentioned previously in section III.C.3. of this proposed rule, we propose to phase in the financial responsibility of hospitals for repayment of actual episode spending that exceeds the target price starting in performance year 2. In order to help hospitals transition to taking on this responsibility, we propose to apply a reduced discount of one percent in performance year 2 for purposes of determining the hospital's responsibility for excess episode spending, but maintain the 2 percent discount for purposes of determining the hospital's opportunity to receive reconciliation payment for actual episode spending below the target price. For example, under this proposal in performance year 2, a hospital that achieves CCJR actual episode payments below a target price based on a 2 percent discount would retain savings below the target price, assuming the quality thresholds for reconciliation payment eligibility are met (discussed in section III.C.5. of this proposed rule) and the proposed performance year stop-gain limit (discussed in section III.C.8. of this proposed rule) does not apply. Medicare would hold responsible for repayment hospitals whose CCJR actual episode payments exceed a target price based on a one percent discount, assuming the proposed performance year 2 stop-loss limit (discussed in section III.C.8. of this proposed rule) does not apply. Hospitals that achieve CCJR actual episode payments between a 2 percent-discounted target price and 1 percent-discounted target price would neither receive reconciliation payments nor be held responsible for repaying Medicare. The decision on which percent-discounted target price applies will be made by evaluating actual episode payments in aggregate after the completion of performance year 2, and the same percent-discounted target price would apply to all episodes that are initiated in performance year 2. We propose to apply this reduced one percent discount for purposes of hospital repayment responsibility only in performance year 2 and apply the 2 percent discount for excess episode spending repayment responsibility for performance years 3 through 5. Under this proposal, the discount for determination of reconciliation payment for episode actual spending below the target price would not deviate from 2 percent through performance years 1 through 5.

In section III.C.5. of this proposed rule, we propose voluntary submission of data for a patient-reported outcome measure. We propose to incent participant hospitals to submit data on this measure by reducing the discount percentage by 0.3 percentage points for successfully submitting data, as defined in section III.D. of this proposed rule. By successfully submitting data on this metric for episodes ending in performance years 1, 2, 3, 4, and or 5, we would adjust the discount percentage in the corresponding year(s) as follows:

- For episodes beginning in performance year 2, set the discount percentage in a range from 2 percent to 1.7 percent for purposes of determining the hospital's opportunity to receive reconciliation payment for actual episode spending below the target price, and set the discount percentage in a range from 1 percent to 0.7 percent for purposes of determining the amount the hospital would be responsible for repaying Medicare for actual episode spending above the target price.
- For episodes beginning in performance years 3 through 5, set the discount percentage in a range from 2 percent to 1.7 percent for purposes of reconciliation payment and Medicare repayment calculations.

The determination of whether the hospital successfully submitted data on the patient-reported outcome measure cannot be made until after the performance year ends and data is reported. Therefore, participant hospitals would be provided target prices for both scenarios whether the successfully submit data or not and such determination will happen at the time of payment reconciliation (discussed further in section III.C.6. of this proposed rule).

We seek comment on our proposed discount percentage of 2 percent for CCJR episodes, our proposal to reduce the discount to 1 percent on a limited basis in performance year 2, and our proposal to reduce the discount by 0.3 percentage points for successfully reporting patient-reported outcomes data in the corresponding year.

c. Proposed Approach to Combine Pricing Features

In section III.C.4.(b) of this proposed rule we discuss the various features we propose to incorporate into our approach to set target prices. We refer readers to that section for more information on rationale and alternatives considered for each feature. In this section we discuss how the different pricing features, as well as the episode definition (section III.B. of this proposed rule) and adjustments to payments included in the episodes (section III.C.3. of this proposed rule), would fit together and be sequenced to calculate CCJR episode target prices for participant hospitals. As previously discussed in sections III.C.4.a and III.C.4.b of this proposed rule, we propose to calculate sixteen target prices for performance year 2, and eight target prices for each of the other 4 performance years. The following steps would be used to calculate MS–DRG 469 and 470 anchored episode target prices for both January 1 through September 30 and October 1 through December 31 each performance year. The output of each step would be used as the input for the subsequent step, unless otherwise noted.

- Calculate historical CCJR episode payments for episodes that were initiated during the 3- historical-years (section III.C.4.b.(2) of this proposed rule) for all CCJR eligible hospitals for all Medicare Part A and B services included in the episode. We note that specific PBPM payments may be excluded from historical episode payment calculations as discussed in section III.C.7.d. of this proposed rule.
- Remove effects of special payment provisions (section III.C.3.a. of this proposed rule).
- Prorate Medicare payments for included episode services that span a period of care that extends beyond the episode (section III.C.3.b of this proposed rule.).
- Normalize for hospital-specific wage adjustment variation by dividing the episodes outputted in step (3) by the hospital's corresponding wage normalization factor described in section III.C.4.b.(7) of this proposed rule.
- Trend forward 2 oldest historical years of data to the most recent year of historical data. As discussed in section III.C.4.b.(3) of this proposed rule, separate national trend factors would be applied to episodes anchored by MS–DRG 469 versus MS–DRG 470.
- Cap high episode payment episodes with a region and MS–DRG anchor-specific high payment ceiling as discussed in section III.C.3.c. of this proposed rule, using the episode output from the previous step.
- Calculate anchor factor and participant hospital-specific weights (section III.C.4.b.(8) of this proposed rule) using the episode output from the previous step to pool together MS–DRG 469 and 470 anchored episodes, resulting in participant hospital-specific pooled historical average episode payments. Similarly, calculate region-specific weights to calculate region-specific pooled historical average episode payments. We have posted region-specific pooled historical average

episode payments on the CCJR proposed rule Web site at *http://innovation.cms.gov/initiatives/ccjr/.*

- Calculate participant hospital-specific and region-specific weighted update factors as described in section III.C.4.b.(4) of this proposed rule. Multiply each participant hospital-specific and region-specific pooled historical average episode payment by its corresponding participant hospital-specific and region-specific weighted update factors to calculate participant hospital-specific and region-specific updated, pooled, historical average episode payments.
- Blend together each participant hospital-specific updated, pooled, historical average episode payment with the corresponding region-specific updated, pooled, historical average episode payment according to the proportions described in section III.C.4.b.(5) of this proposed rule. Participant hospitals that do not have the minimum episode volume across the historical 3 years would use 0.0 percent and 100 percent as the proportions for hospital and region, respectively.
- Reintroduce hospital-specific wage variations by multiplying the participant hospital-specific blended, updated, and pooled historical average episode payments by the corresponding hospital-specific wage normalization factor, using the hospital's IPPS wage index that applies to the hospital during the period for which target prices are being calculated (section III.C.4.b.(7) of this proposed rule).
- Multiply the appropriate discount factor, as discussed in section III.C.4.b.(9) of this proposed rule to each participant hospital's wage-adjusted, blended, updated, and pooled historical average episode payment. For performance years 1, 3, 4, and 5, two discount factors would be used, one if the hospital successfully submits data on the patient-reported outcomes measure proposed in section III.C.5 of this proposed rule, and one if the hospital does not successfully submit the data. For performance year 2, 4 discount factors would be used to account for the 4 combinations of the following: a) whether or not the hospital successfully submits data on the patient-reported outcomes measure; and b) for the different discount factors proposed for purposes of calculating reconciliation payments vs. calculating repayment amounts. The result of this calculation would be the participant hospital-specific target prices for MS–DRG 470 anchored episodes.
- Multiply participant hospitals' target prices for MS–DRG 470 anchored episodes by the anchor factor (section III.C.4.b.(8) of this proposed rule) to calculate hospitals' target prices for MS–DRG 469 anchored episodes.

The aforementioned steps would be used to calculate target prices for episodes that begin between January 1 and September 30, as well as for episodes that begin between October 1 and December 31, for each performance year. The target price calculations for the two different time periods each performance year would differ by the IPPS wage index used in step (11) and the update factors used in step (8). By following these eight steps, we would calculate eight target prices for each participant hospital for performance years 1, 3, 4, and 5, and 16 target prices for performance year 2. We refer readers to section III.C.4.b. of this proposed rule for further details on each of the specific steps.

We seek comment on the proposed approach to sequence and fit together the different pricing features, the episode definition (section III.B. of this proposed rule), and adjustments to payments included in the episodes (section III.C.3. of this proposed rule) to calculate CCJR episode target prices for participant hospitals.

5. Proposed Use of Quality Performance in the Payment Methodology

a. Background

Over the past several years Medicare payment policy has moved away from FFS payments unlinked to quality and towards payments that are linked to quality of care. Through the Affordable Care Act, we have implemented specific IPPS programs like the HVBP (subsection (o) of section 1886 of the Act), the Hospital Acquired Conditions Reduction Program (HACRP) (subsection (q) of section 1886) and the HRRP (subsection (p) of section 1886), where quality of care is linked with payment. We have also implemented the MSSP, an accountable care organization program that links shared savings payment to quality performance. Since the implementation of the HRRP in October 2012, readmission rates for various medical conditions like THA and TKA (THA/TKA) have improved. Trend analyses show a decrease in readmission rates and specifically with THA/TKA risk-standardized readmissions rates (RSRR) from 5.4 percent (July 2010-June 2011) to 4.8 percent (July 2012-June 2013).[39] Additionally, hospital THA/TKA RSCR decreased from 3.4 percent (April 2010 through March 2011) to 3.1 percent (April 2012 through March 2013). Despite the downward trend of THA/TKA RSRRs and RSCRs, the wide dispersion in these readmission rates suggests there is still room for hospitals to improve their performance on these measures as illustrated by a THA/TKA RSRR distribution of 2.8 to 9.4 percent (July 2010-June 2013) and a THA/TKA RSCR distribution of 1.5 to 6.4 percent (April 2010-March 2013). We believe that the CCJR Model provides another mechanism for hospitals to improve quality of care, while also achieving cost efficiency. Incentivizing high-value care through episode-based payments for LEJR procedures is a primary objective of CCJR. Therefore, incorporating quality performance into the episode payment structure is an essential component of the CCJR model. We also believe that the financial opportunity proposed in section III.C.3. of this proposed rule provides the appropriate incentives necessary to reward a participant hospital's achievement of episode savings when the savings are greater than the discounted target price. For the reasons stated previously, we believe it is important for the CCJR model to link the financial reward opportunity with achievement in quality of care for Medicare beneficiaries undergoing LEJR.

As discussed in section III.C of this proposed rule, which outlines the payment structure for the CCJR model, each participant hospital will have target prices calculated for MS–DRG 469 and 470 anchored episodes; each anchored episode includes an anchor hospitalization for an LEJR procedure and a 90–day period after the date of discharge from the anchor hospitalization. These episode target prices represent expected spending all related Part A and Part B spending for such episodes, with a discount. Hospitals who achieve actual episode spending below a target price for a given performance period would be eligible for a reconciliation payment from CMS, subject to the proposed stop-gain limit policy as discussed in section III.C.8. of this proposed rule.

In the next section of this proposed rule, we propose quality performance standards that must also be met in order for a hospital to be eligible to receive a reconciliation payment under CCJR. Specifically, we describe our proposal to include a performance measure result threshold on select outcomes-based quality measures as a requirement for participants to receive a reconciliation payment if actual episode spending is

[39] Hospital Quality Initiatives. CMS Hospital Quality Chartbook 2014. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Medicare-Hospital-Quality-Chartbook-2014.pdf* . Accessed April 21, 2015.

less than the target price under CCJR in a performance year, in addition to a payment adjustment for successful reporting of a voluntary measure in development. Beginning in performance year one and continuing throughout the duration of the model, we propose to make reconciliation payments only to those CCJR hospital participants that meet or exceed a minimum measure result threshold. We also discuss an alternative approach to determining CCJR reconciliation payment eligibility and adjusting payment based on a quality score developed from performance on three outcomes-based quality measures and success in reporting the voluntary measurement in development.

b. Proposed Implementation of Quality Measures for Reconciliation Payment Eligibility

In section III.D. of this proposed rule we propose three measures to assess quality of care of the hospitals participating in the CCJR Model. We also propose voluntary data submission for a patient-reported outcome measure. In this section we propose using three measures to determine eligibility for a reconciliation payment, as well as propose rewarding hospitals that voluntarily submit data for the patient-reported outcome measure. We also discuss an alternative approach to determining reconciliation payment eligibility and adjusting payment based on a composite quality score calculated from the three required outcome measures and success on reporting voluntary data on the patient-reported outcome measure.

(1) General Selection of Proposed Quality Measures

The CCJR model is designed to provide financial incentives to improve coordination of care for beneficiaries that we expect to lead to avoidance of post-surgical complications and hospital readmissions, as well as to improve patient experience through care redesign and coordination. Furthermore, we acknowledge that achievement of savings while ensuring high-quality care for Medicare FFS beneficiaries in LEJR episodes will require close collaboration among hospitals, physicians, PAC providers, and other providers. In order to encourage care collaboration among multiple providers of patients undergoing THA and TKA, we propose three measures, as described in detail in section III.D.2. of this proposed rule, to determine hospital quality of care and to determine eligibility for a reconciliation payment under the CCJR model. The measures we are proposing are as follows:

- Hospital-level 30-day, all-cause RSRR following elective primary THA and/or TKA (NQF #1551), an administrative claims-based measure.
- Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550), an administrative claims-based measure.
- HCAHPS Survey measure.

Beginning in performance year 1 and continuing throughout the duration of the model, we propose to make reconciliation payments only to those CCJR participant hospitals that meet or exceed a minimum performance threshold on the measures previously listed. We propose that hospitals must meet or exceed the measure reporting thresholds and other requirements described in section III.C and III.D. of this proposed rule on all three measures in order to be eligible for a reconciliation payment.

These three outcome measures were chosen due to their: (1) Alignment with the goals of the CCJR model; (2) hospitals' familiarity with the measures due to their use in other CMS hospital quality programs, including programs that tie payment to performance such as HVBP and HRRP; and (3) assessment of CMS priorities to improve the rate of LEJR complications and readmissions, while improving patient experience. We believe the three quality measures we propose for reconciliation payment eligibility reflect these goals and accurately measure hospitals' level of achievement on such goals.

(2) Proposal To Adjust the Payment Methodology for Voluntary Submission of Data for Patient-Reported Outcome Measure

During our consideration of quality metrics for the CCJR model, we examined the feasibility of linking voluntary data submission of patient-reported outcomes, beyond the current three required measures proposed in section III.D.2. of this proposed rule for use in the model, with the possibility of incentivizing participant hospitals under the episode payment model to participate in this voluntary submission of data. We specifically examined potential patient-reported outcome measures since this type of outcome measure aligns with the CCJR model goal of improving LEJR episode quality of care, including a heightened emphasis on patient-centered care where patients provide meaningful input to their care. Furthermore, the availability of patient reported outcome data would provide additional information on a participant hospital's quality performance, especially with respect to a patient's functional status, beyond the current three required measures proposed in section III.D.2. of this proposed rule for use in the model. We note that we have a measure in development, the Hospital-Level Performance Measure(s) of Patient-Reported Outcomes Following Elective Primary THA or TKA measure or both (hence forth referred to as ''THA/TKA patient-reported outcome-based measure''), that would support the National Quality Strategy domain of patient and family engagement, and could capture meaningful information that would not otherwise be available on patient outcomes that are related to the quality of LEJR episodes under CCJR. We believe that incorporating this measure into CCJR by adjusting the payment methodology for successful voluntary data submission on the THA/TKA patient-reported outcome-based measure (henceforth referred to as ''THA/TKA voluntary data'') would provide participant hospitals with valuable information on functional outcomes that would assist them in assessing an important patient-centered outcome, engaging other providers and suppliers in care redesign for LEJR episodes, as well as provide them with the potential for greater financial benefit from improved LEJR episode efficiencies. We do not believe it would be appropriate at this time to hold any participant hospitals financially accountable for their actual THA/TKA voluntary data, as we have proposed for the three required measures described in section III.C.5.b.(2) of this proposed rule.

Instead, we propose to adjust the episode payment methodology for participant hospitals that successfully submit THA/TKA voluntary data by reducing the discount percentage used to set the target price from 2.0 percent to 1.7 percent of expected episode spending based on historical CCJR episode data, hereinafter referred to as the voluntary reporting payment adjustment. The proposed payment policies with respect to reconciliation payment eligibility and the discount percentage based on hospital voluntary data submission are summarized in Table 7 for performance years 3 through 5 where hospitals have full repayment responsibility. The specific percentages that would apply for purposes of the repayment amount and reconciliation payment are outlined for performance years 1 and 2 in the discussion that follows.

TABLE 7—RECONCILIATION PAYMENT ELIGIBILITY AND DISCOUNT PERCENTAGE INCLUDED IN THE TARGET PRICE FOR EACH PARTICIPANT HOSPITAL BASED ON QUALITY PERFORMANCE IN PERFORMANCE YEARS 3–5

Discount percentage included in target price/reconciliation payment eligibility	Meets thresholds for all 3 required quality measures	Does not meet thresholds for one or more of 3 required quality measures
Successfully submits THA/TKA voluntary data	1.7%/eligible	1.7%/ineligible.
Does not successfully submit THA/KA voluntary data	2.0%/eligible	2.0%/ineligible.

We refer readers to section III.D.3. of this proposed rule for further discussion of the THA/TKA patient-reported outcome-based measure and our proposed definition of successful reporting. In addition, we refer readers to section III.C.4.b.(9) of this proposed rule for discussion of the proposed discount of 2.0 percent (without the voluntary reporting payment adjustment) to establish the target price. We believe that a voluntary reporting payment adjustment of 0.3 percent of expected episode spending would, on average, cover the participant hospitals' additional administrative costs of voluntarily reporting patient risk variables and patient-reported reported function for outcome calculation. We estimate the value of this discount reduction, on average, to be about $75 per LEJR episode at a participant hospital, which we believe would be sufficient to pay hospitals for the resources required to survey beneficiaries pre- and post-operatively about functional status and report this information required for measure development to CMS. We also believe that voluntary reporting on this patient-reported outcome measure is integral to implementation of the CCJR model, as it will allow us to further develop and evaluate the measure for potential use in this model in the future as a measure of quality that is important and not captured in any other available measures.

The voluntary reporting payment adjustment would be available for all years of the model, unless we find the measure to be unfeasible or have adequately developed the measure such that continued voluntary data collection is no longer needed for measure development during the course of the model. In those situations, we would notify participant hospitals that the voluntary reporting payment adjustment was no longer available as we would cease collecting the data.

When we provide the episode target price to each participant hospital at 2 times during the performance year, we would provide different target prices reflecting the 2.0 percent and 1.7 percent discounts. At the time of reconciliation for the performance year, we would determine which participant hospitals successfully reported the THA/TKA voluntary data for that performance year. The effects of this voluntary reporting payment adjustment would vary for each year of the model, depending on the proposed reconciliation payment and repayment policies for that performance year. For hospitals that achieved successful reporting of the THA/TKA voluntary data in performance year 3, 4, or 5,we would use the target price reflecting the 1.7 percent discount (compared with the 2.0 percent discount for nonreporting or unsuccessfully reporting hospitals) to calculate the hospital's reconciliation payment or repayment amount. Based on this comparison, consistent with the proposal described in section III.C.6. of this proposed rule, we would make a reconciliation payment if actual episode spending is less than the target price (and the thresholds for reconciliation payment eligibility are met for the three required quality measures) or make participant hospitals responsible for repaying Medicare if actual episode spending exceeds the target price. For performance year 2, when repayment responsibility is being phased-in, for participant hospitals with successful THA/TKA voluntary data reporting, we would use a target price reflecting the 1.7 percent discount (compared with the 2.0 percent discount for nonreporting or unsuccessfully reporting hospitals) to determine if actual episode spending was below the target price, whereupon the participant hospital would receive a reconciliation payment if the quality thresholds on the three required measures are met. In order to help hospitals transition to taking on repayment responsibility, we propose to apply a reduced discount of 0.7 percent for successful THA/TKA voluntary data reporting hospitals (compared with 1.0 percent for nonreporting or unsuccessfully reporting hospitals) in performance year 2 for purposes of determining the hospital's repayment responsibility for excess episode spending. For performance year 1, when there is no repayment responsibility, for participant hospitals with successful THA/TKA voluntary data reporting, we would use a target price reflecting the 1.7 percent discount (compared with the 2.0 percent discount for nonreporting or unsuccessfully reporting hospitals) to determine if actual episode spending was below the target price, whereupon the participant hospital would receive a reconciliation payment if the quality thresholds on the three required measures are met. We believe this proposed voluntary reporting payment adjustment provides the potential for increased financial benefit for participant hospitals due to a higher target price (that reflects a lower discount percentage) that successfully report the measure. Participant hospitals that successfully report the voluntary data would be subject to a lower repayment amount (except for performance year 1 when hospitals have no repayment responsibility) or a higher reconciliation payment (assuming the thresholds are met on the three required measures for reconciliation payment eligibility), than hospitals that do not successfully report the voluntary data.

In general, participant hospitals that meet the performance thresholds for the three required quality measures and reduce actual episode spending below the target price, as well as successfully report the THA/TKA voluntary data, would be eligible to retain an additional 0.3 percent of the reduced episode expenditures relative to participant hospitals that successfully report the three required quality measures but do not report voluntary data, funds which would offset additional administrative costs that the participant hospitals would incur in reporting on the measure. Additionally, for performance years 2–5 where participant hospitals have payment responsibility, participant hospitals with increased actual episode spending above the target price would not be required to repay 0.3 percent of the increased episode expenditures (relative to participant hospitals that do not report voluntary data), funds that would offset additional administrative costs that the participant hospitals would incur in reporting on the measure. These costs would include the hospital staff time required for training on the measure, as well as then gathering and reporting on multiple patient risk variables from LEJR episode

beneficiaries' medical records and locating beneficiaries and administering via phone survey questions on functional status, which would also then be reported to CMS. Thus, we expect that the proposal would encourage reporting by a number of participant hospitals, and it has the potential to benefit those hospitals that successfully report on the measure. Therefore, this proposal could financially benefit reporting hospitals that would also collect valuable information on patient functional outcomes that could inform their LEJR care redesign. While this measure remains in development from our perspective to ensure translation of data across care settings and the respective hospital communities during the 90-day post-discharge episode of care, participant hospitals would gain anecdotal, locally relevant information regarding the patient-reported outcomes of their own patients that could inform participant hospitals' continuous quality improvement efforts.

We considered two alternative options to adjust the CCJR payment methodology by modifying the required quality measure thresholds for reconciliation payment eligibility for those participant hospitals that successfully submit the THA/TKA voluntary data. First, we considered adjusting the threshold that hospitals must meet on the three required quality measures for reconciliation payment eligibility if reduced episode spending is achieved from the unadjusted 30th percentile threshold to the adjusted 20th percentile threshold for performance years 1, 2, and 3, and from the unadjusted 40th percentile to the adjusted 30th percentile for performance years 4 and 5. Second, we considered only requiring hospitals to meet the 30th percentile threshold on two of three outcome measures for performance years 1, 2, and 3, and the 40th percentile threshold on two of three outcome measures for performance years 4 and 5. These options would provide the opportunity for some participant hospitals, specifically those that missed the unadjusted percentile for one or more of the three required quality measures by a specified margin, to receive reconciliation payments if actual episode spending was less than the target price. However, these options could benefit only a subset of participant hospitals that successfully reported the THA/TKA voluntary data. For the majority of participant hospitals that we expect would meet the unadjusted thresholds for all three required measures, these options do not provide any incentive to voluntarily report the data because the hospitals would not benefit from voluntarily reporting the additional measure. We decided not to propose either of these options to adjust the CCJR payment methodology for participant hospitals that voluntarily report data on the new measure because the limited benefit could result in few hospitals choosing to report on the measure, thereby limiting our progress in developing the measure. We note that these two considered options and our proposal are not mutually exclusive.

We seek comment on the proposed voluntary reporting payment adjustment of reducing the discount percentage from 2.0 percent to 1.7 percent for CCJR participant hospitals that voluntarily and successfully report on the THA/TKA voluntary data. Given our interest in robust hospital participation in reporting on the THA/TKA voluntary data under CCJR, we are specifically interested in information on the additional resources and their associated costs that hospitals would incur to report THA/TKA voluntary data, as well as the relationship of these costs to the potential financial benefit participant hospitals could receive from the proposed reduced discount of 1.7 percent. Based on such information, we would consider whether a change from the proposed discount factor reduction due to successful voluntary data submission would be appropriate. We also seek comment on whether the alternative payment methodology adjustments considered, or combination of adjustments, would more appropriately incentivize CCJR participant hospitals to submit THA/TKA voluntary data. We believe that development of the THA/TKA patient-reported outcome measure would benefit from reporting by a broad array of participant hospitals, including those that currently deliver high quality, efficient LEJR episode care and those that have substantial room for improvement on quality and or cost-efficiency.

Furthermore, in light of our interest in encouraging CCJR participant hospital THA/TKA voluntary data reporting, we also considered alternative approaches to collect this information or provide hospitals with funds to help cover their associated administrative costs other than adjustments to the CCJR model payment methodology. One alternative would be for hospitals to collect and report on patient pre-operative information collected 0 to 90 days before surgery, while CMS would engage a contractor to collect and report the post-operative information collected 9 to 12 months after surgery. This approach would reduce some of the administrative burden of collection and reporting on hospitals, although participant hospitals would need to provide CMS with certain beneficiary information, including contact information that would be needed for a CMS contractor to contact the beneficiary at a later date. We seek comment on this alternative, including whether hospitals would incur significant additional administrative costs to report on the data prior to surgery and how CMS could best provide funds to offset some of those costs, through an adjustment to the CCJR payment methodology or other means. We also seek comment on the information participant hospitals would need to provide to CMS so a CMS contractor could collect and report the post-operative data, and the most efficient ways for hospitals to provide this information to us. Finally, we considered an approach that would provide hospitals with separate payment outside of an adjustment to the CCJR payment methodology to specifically assist in covering their administrative costs of reporting THA/TKA voluntary data, in order to achieve robust hospital participation in reporting. We seek comment on the hospital administrative costs that would be incurred for reporting, as well as on approaches we could take to ensure that hospitals achieved successful reporting under such an approach if separate payment was made. Finally, we are interested in comments regarding the comparative strength of these various alternatives in encouraging hospitals to participate in reporting THA/TKA voluntary data.

For a detailed description of this measure see section III.D.3 of this proposed rule

(3) Measure Risk-Adjustment and Calculations

All three proposed outcome measures are risk-adjusted and we refer readers to section III.D.2 of this proposed rule for a full discussion of these measures and risk-adjustment methodologies. We believe that risk-adjustment for patient case-mix is important when assessing hospital performance based on patient outcomes and experience and understanding how a given hospital's performance compares to the performance of other hospitals with similar case-mix.

(4) Applicable Time Period

We propose to use a 3-year rolling performance or applicable period for the

Hospital-level 30-day, all-cause RSRR following elective primary THA and/or TKA (NQF #1551) and the Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550) measures. We also specifically propose to align with the HIQR program's 3-year rolling performance period for the RSSR and RSCR measures since we believe that a 3-year performance period yields the most consistently reliable and valid measure results (FY 2015 IPPS/LTCH 70 FR 50208 through 50209). For the HCAHPS Survey measure, we propose to follow the same performance period as in the HIQR program (FY 2015 IPPS/LTCH Final rule 79 FR 50259). HCAHPS scores are created from 4 consecutive quarters of survey data; publicly reported HCAHPS results are also based on 4 quarters of data. For the voluntary data collection for the proposed THA/TKA patient-reported outcome-based performance measure, the optimal reporting time period has not been determined. Therefore, we propose defining the applicable time period as 12 month intervals that may begin between July 1, 2016 and December 31, 2016, and continue in subsequent performance years for a total of four or fewer performance periods. Participant hospitals will submit required data to CMS in a mechanism similar to the data submission process for the HIQR program within sixty days of the end of each 12 month period. As described in section III.C.5.b.(3) of this proposed rule, the proposed voluntary reporting payment adjustment of reducing the discount percentage from 2.0 percent to 1.7 percent for CCJR participant hospitals that successfully report on the THA/TKA voluntary data would begin in year 2 and also apply to subsequent years of the model.

(5) Criteria for Applicable Hospitals and Performance Scoring

(a) Identification of Participant Hospitals for the CCJR Model

As discussed in section III.A.2 of this proposed rule, all CCJR participant hospitals would be IPPS hospitals.

(b) Methodology to Determine Performance on the Quality Measures

To determine performance on the quality measures, we propose to calculate measure results for all three measures as outlined in the Quality Measures section III.D.2 of this proposed rule. Performance on the three measures for the CCJR model participant hospitals would be compared to the national distribution of measure results for each of these measures obtained through the HIQR program. The HIQR program is an IPPS program in which public reporting is a focus of the program for the nation's acute care hospitals, and we propose using the absolute value of the CCJR model participant hospital's result to determine if that participant hospital is eligible for a reconciliation payment. In essence we intend to take the HIQR program measure results (also posted publicly) for the proposed measures, identify the threshold as outlined in section III.C.5.b.(3) of this proposed rule, and apply the thresholds also outlined in section III.C.5.b.(7) of this proposed rule. We believe it is reasonable to use the HIQR program distribution of measure results to identify a measure result threshold because—(1) the hospitals in the HIQR program represent most acute care hospitals in the nation; (2) the CCJR model participant hospitals are a subset of the hospitals in the HIQR program; and (3) the expectation that the CCJR model participant hospitals meet a measure result threshold based on a national distribution of measure results will encourage the CCJR model participant hospitals to strive to attain measure results consistent with or better than hospitals across the nation. For a detailed description of how we will determine the measure result thresholds for consideration of a reconciliation payment adjustment see section III.C.5.b.(3) and III.C.7.of this proposed rule. We would not want to encourage CCJR model participant hospitals to strive for measure results or quality of care performance that may be lower than the national measure results. Given that the CCJR participant hospitals are a subset of the HIQR program participant hospitals, they are familiar with these three measures and may have put into place processes that will help to improve quality of care in the LEJR patient population. Finally, once the measure results are calculated, we propose to use these results to determine eligibility for reconciliation payment, which is discussed in detail in the next section.

To be considered to have successfully reported the voluntary data collection and submission for the THA/TKA voluntary data, we propose that successfully reporting will mean participant hospitals must meet all of the following:

- Submit the data elements listed in section III.D.3.a.(2) of this proposed rule.
- Data elements listed in section III.D.3.a.(2) of this proposed rule must be submitted on at least 70 percent of their eligible elective primary THA/TKA patients (patients eligible for pre-operative THA/TKA voluntary data submission are those described in section III.D.3.a.(3)of this proposed rule); patients eligible for post-operative THA/TKA voluntary data submission are those described in section III.D.3.a(3) of this proposed rule and also having a THA/TKA procedure date during the anchor hospitalization at least 366 days prior to the end of the data collection period. Therefore, hospitals are not expected to collect and submit post-operative THA/TKA voluntary data on patients who are fewer than 366 days from the date of surgery.
- THA/TKA voluntary data submission must occur within 60 days of the end of the most recent 12 month period.

Hospitals meeting these three standards, and have successfully submitted THA/TKA voluntary data, will be eligible for the proposed voluntary reporting payment adjustment of reducing the discount percentage from 2.0 percent to 1.7 percent for CCJR participant hospitals that voluntarily and successfully report on the THA/TKA voluntary data. Encouraging collection and submission of the THA/TKA voluntary data through the CCJR model will increase availability of patient-reported outcomes to both participant hospitals that collect and submit data on their own patients in the model (and their patients as well); further development of an outcomes measure that provides meaningful information on patient-reported outcomes for THA/TKA procedures that are commonly furnished to Medicare beneficiaries; provide another quality measure that may be incorporated into the CCJR model policy linking quality to payment in future performance years, pending successful development of the measure; and inform the quality strategy of future payment models. Collecting data on at least 70 percent of hospital's eligible THA/TKA patients would provide sufficiently representative data to allow for development and testing of the THA/TKA patient-reported outcome-based performance measure.

We invite public comment on the proposal to calculate measure results for all three measures as outlined in the Quality Measures section III.D.2 of this proposed rule. We also seek public comment on our proposal for hospitals to meet three requirements, previously outlined, in order to be considered as successfully submitting THA/TKA voluntary data.

(c) Proposed Methodology To Link Quality and Payment

(i) Background

In proposing a methodology for linking payment for LEJR episodes to quality under this model, we considered several alternatives. Specifically, we considered making reconciliation payments to hospitals tied to achievement and improvement in quality performance or, alternatively, establishing minimum quality performance thresholds for selected quality measures from the beginning of the model or a later year, which would reward achievement but not necessarily improvement. While we propose in section III.C.5.b.(6)(c) of this proposed rule to establish minimum thresholds for participant hospital performance on three selected quality measures for reconciliation payment eligibility each performance year from the beginning of the model, we also discuss in detail an alternative we considered, which would make quality incentive payments related to hospital achievement and improvement on the basis of a composite quality score developed for each performance year. The composite quality score would affect reconciliation payment eligibility and change the effective discount included in the target price experienced by a participant hospital at reconciliation.

Similar to the proposal described in section III.C.5.b.(6)(c) of this proposed rule, the alternatives considered would require a determination of participant hospital performance on all three required quality measures, described in section III.D. of this proposed rule, based on the national distribution of hospital measure result performance, but instead of identifying the participant hospital's performance percentile for comparison with a threshold requirement, we would do so for purposes of assigning points toward a hospital composite quality score. Both the hospital-level 30-day, all cause Risk-Standardized Readmission Rate (RSRR) following elective primary THA and/or TKA (NQF #1551) measure and the hospital-level Risk-Standardized Complication Rate (RSCR) following elective primary THA and/or TKA (NQF #1550) measure directly yield rates for which a participant hospital performance percentile could be determined and compared to the national distribution in a straightforward manner. As discussed in section III.D.2.c.of this proposed rule, we propose to use the HCAHPS Linear Mean Roll Up (HLMR) score calculated using the HCAHPS Survey (NQF #1661) measure. Once the HLMR scores are calculated, the participant hospital performance percentile could also be determined and compared to the national distribution in a straightforward manner. In addition, the alternatives considered would account for the successful submission of voluntary THA/TKA data on the patient-reported outcome measure, as discussed in section III.C.5.b.(2) of this proposed rule, in the calculation of the composite quality score.

(ii) Alternatives Considered To Link Quality and Payment

We considered assigning each participant hospital a composite quality score, developed as the sum of the individual quality measure scores described later in this section, which were set to reflect the intended weights for each of the quality measures and the successful submission of THA/TKA voluntary data in the composite quality score. The participant hospital's composite quality score would affect reconciliation payment eligibility and could also provide the opportunity for quality incentive payments under the CCJR model. Each quality measure would be assigned a weight in the composite quality score and possible scores for the measures would be set to reflect those weights. A composite quality score for each performance year would be calculated for each participant hospital based on its own performance that would affect reconciliation payment eligibility and the hospital's opportunity to receive quality incentive payments under the model. The composite quality score would also change the effective discount included in the target price experienced by the hospital at reconciliation for that performance year. We would weigh participant hospital performance on each of the three measures and successful submission of voluntary THA/TKA data according to the measure weights displayed in Table 8.

TABLE 8—QUALITY MEASURE WEIGHTS IN COMPOSITE QUALITY SCORE

Quality measure	Weight in composite quality score %
Hospital-level 30-day, all-cause RSRR following elective primary THA and/or TKA (NQF #1551)	20
Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550)	40
HCAHPS survey (NQF #1661)	30
Voluntary THA/TKA data submission on patient-reported outcome measure	10

We would assign the lowest weight of 10 percent to the successful submission of THA/TKA data on the patient-reported outcome measure because these data represent a hospital's meaningful participation in advancing the quality measurement of LEJR patient-reported outcomes but not actual outcome performance for LEJR episodes under the CCJR model. We believe the three required measures that represent LEJR outcomes deserve higher weights in the composite quality score. We would assign a modest weight of 20 percent to the readmissions measure because, while we believe that readmissions are an important quality measure for LEJR episodes, the episode payment methodology under the model already provides a strong financial incentive to reduce readmissions that otherwise would contribute significantly to greater actual episode payments. Furthermore, hospitals generally have already made significant strides over the past several years in reducing readmissions due to the inclusion of this measure in other CMS hospital programs that make payment adjustments based on performance on this measure. We believe that a higher weight than 20 percent would overvalue the contribution of readmissions performance as an indicator of LEJR episode quality in calculating the composite quality score. Furthermore, other CMS hospital programs may also make a payment adjustment based on hospital performance on the readmissions measure so we would not want this measure to also strongly influence reconciliation payment eligibility and the opportunity for quality incentive payments under the CCJR model. We would assign a higher

weight of 30 percent to the HCAHPS survey measure because we believe that incorporating this quality measure, which reflects performance regarding patients' perspectives on care, including communication, care transitions, and discharge information, is a highly meaningful outcome measure of LEJR episode quality under the CCJR model. However, we do not propose to assign the HCAHPS survey measure the highest weight of the four measures, as the measure is not specific to LEJR episode care, but rather to all clinical conditions treated by participant hospitals. Finally, we would assign the highest weight, 40 percent, to the complications measure. We believe this measure should be weighted the most because it is specific to meaningful outcomes for primary THA and TKA that are the major procedures included in LEJR episodes under the CCJR model. The measure includes important complications of LEJR episodes, such as myocardial infarction, pneumonia, surgical site bleeding, pulmonary embolism, death, mechanical joint complications, and joint infections occurring within various periods of time during the LEJR episode. LEJR episodes under the CCJR model are broadly defined so that reducing complications should be a major focus of care redesign that improves quality and efficiency under this model, yet because complications may not be as costly as readmissions, the payment incentives under the model do not as strongly target reducing complications as reducing readmissions. We seek comment on this weighting of the individual quality scores in developing a composite quality score for each participant hospital.

Under such an approach, we would first score individually each participant hospital on the Hospital-level 30-day, all-cause RSRR using the elective primary THA and/or TKA (NQF #1551) measure; Hospital-level RSCR following using the elective primary THA and/or TKA (NQF #1550) measure; and HCAPHS survey (NQF #1661) measure based on the participant hospital's performance percentile as compared to the national distribution of hospitals' measure performance, assigning scores according to the point values displayed in Table 9 These individual measure scores have been set to reflect the measure weights included in Table 9 so they can ultimately be summed without adjustment in calculating the composite quality score.

TABLE 9—INDIVIDUAL SCORING FOR THREE REQUIRED QUALITY MEASURES

Performance percentile	Complications measure quality score (points)	HCAHPS survey quality score (points)	Readmissions measure quality score (points)
≥90th	8.00	6.00	4.00
≥80th and <90th	7.40	5.55	3.70
≥70th and <80th	6.80	5.10	3.40
≥60th and <70th	6.20	4.65	3.10
≥50th and <60th	5.60	4.20	2.80
≥40th and <50th	5.00	3.75	2.50
≥30th and <40th	4.40	3.30	2.20
<30th	0.00	0.00	0.00

Given the current national distribution of hospital performance on these measures, we believe that small point increments related to higher measure performance deciles would be the most appropriate way to assign more points to reflect meaningfully higher quality performance on the measures. The absolute differences for each decile among the three measures reflect the intended weight of the measure in the composite quality score. We would assign any low volume participant hospital without a reportable value for the measure to the 50th performance percentile of the measure, so as not to disadvantage a participant hospital based on its low volume alone because that hospital may in actuality provide high quality care. These three measures are well-established measures in use under CMS hospital programs, so we do not believe that scores below the 30th percentile reflect quality performance such that they should be assigned any individual quality measure score points for LEJR episodes under CCJR. However, we also considered reducing scores incrementally across the bottom three deciles in order to provide greater incentives for quality improvement for hospitals that may not believe they can attain the 30th performance percentile on one or more of the three measures and to avoid creating a ''cliff'' at the 30th performance percentile. We seek comment on this scoring approach to the three required quality measures.

Additionally, we would assign a measure quality score of one point for participant hospitals that successfully submit THA/TKA voluntary data and 0 points for participant hospitals that do not successfully submit these data. Because we would not use the actual THA/TKA voluntary data on the patient-reported outcome measure in assessing LEJR episode quality performance under the model, we propose this straightforward binary approach to scoring the submission of THA/TKA voluntary data for the patient-reported outcome measure development.

We note that the MSSP utilizes a similar scoring and weighting methodology, which is described in detail in the CY2011 Shared Savings Program Final Rule (see § 425.502). The HVBP and HACRP programs also utilize a similar scoring methodology, which applies weights to various measures and assigns an overall score to a hospital (79 FR 50049 and 50102).

We would sum the score on the three quality measures and the score on successful submission of THA/TKA voluntary data to calculate a composite quality score for each participant hospital. Then we would incorporate this score in the model payment methodology by first, requiring a minimum composite quality score for reconciliation payment eligibility if the participant hospital's actual episode spending is less than the target price and second, by making quality incentive payments that change the effective discount percentage included in the target price experienced by the hospital in the reconciliation process. The payment policies we would apply are displayed in Tables 10, 11, and 12 for the performance years of the model. Under the CCJR model as proposed, there is no participant hospital repayment responsibility in performance year 1 and this responsibility begins to be phased-in in

performance year 2, with full implementation in performance year 3.

TABLE 10—PERFORMANCE YEAR 1: RELATIONSHIP OF COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT PERCENTAGE EXPERIENCED AT RECONCILIATION

Composite quality score	Eligible for reconciliation payment	Eligible for quality incentive payment	Effective discount percentage for reconciliation payment	Effective discount percentage for repayment amount
≤5.00	No	No	3.0	Not applicable.
>5.00 and ≤9.25	Yes	No	3.0	Not applicable.
>9.25 and ≤15.20	Yes	Yes	2.0	Not applicable.
>15.20	Yes	Yes	1.5	Not applicable.

TABLE 11—PERFORMANCE YEAR 2: RELATIONSHIP OF COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT PERCENTAGE EXPERIENCED AT RECONCILIATION

Composite quality score	Eligible for reconciliation payment	Eligible for quality incentive payment	Effective discount percentage for reconciliation payment	Effective discount percentage for repayment amount
≤5.00	No	No	3.0	2.0
>5.00 and ≤9.25	Yes	No	3.0	2.0
>9.25 and ≤15.20	Yes	Yes	2.0	1.0
>15.20	Yes	Yes	1.5	0.5

TABLE 12—PERFORMANCE YEARS 3–5: RELATIONSHIP OF COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT PERCENTAGE EXPERIENCED AT RECONCILIATION

Composite quality score	Eligible for reconciliation payment	Eligible for quality incentive payment	Effective discount percentage for reconciliation payment	Effective discount percentage for repayment amount
≤5.00	No	No	3.0	3.0
>5.00 and ≤9.25	Yes	No	3.0	3.0
>9.25 and ≤15.20	Yes	Yes	2.0	2.0
>15.20	Yes	Yes	1.5	1.5

Under this approach, the CCJR model discount included in the target price without consideration of the composite quality score would be 3.0 percent, not the 2.0 percent described under our payment proposal in section III.C.4.b.(9) of this proposed rule. We believe that a discount percentage of 3.0 percent without explicit consideration of episode quality is reasonable as it is within the range of discount percentages included in the ACE demonstration and it is the Model 2 BPCI discount factor for 30 and 60 day episodes, where a number of BPCI participants are testing LEJR episodes subject to the 3.0 percent discount factor. Hospitals that provide high quality episode care would have the opportunity to receive quality incentive payments that would reduce the effective discount percentage as displayed in Tables 10, 11, and 12. Depending on the participant hospital's actual composite quality score, quality incentive payments could be valued at 1.0 percent to 1.5 percent of the hospital's benchmark episode price (that is, of the expected episode spending prior to application of the discount factor to calculate a target price).

Under this methodology, we would require hospitals to achieve a minimum composite quality score of greater than 5.00 to be eligible for a reconciliation payment if actual episode spending was less than the target price. Participant hospitals with below acceptable quality performance reflected in a composite quality score less than or equal to 5.00 would not be eligible for a reconciliation payment if actual episode spending was less than the target price. A level of quality performance that is below acceptable would not affect participant hospitals' repayment responsibility if actual episode spending exceeds the target price. We believe that excessive reductions in utilization that lead to low actual episode spending and that could result from the financial incentives of an episode payment model would be limited by a requirement that this minimum level of LEJR episode quality be achieved for reconciliation payments to be made. This policy would encourage hospitals to focus on appropriate reductions or changes in utilization to achieve high quality care in a more efficient manner. Therefore, these hospitals would be ineligible to receive a reconciliation payment if actual episode spending was less than the target price.

For hospitals with composite quality scores of less than or equal to 5.00, we also considered a potential alternative approach. Under this approach, we would still permit this group of hospitals to receive reconciliation payments but would impose a quality penalty that would reduce their effective discount percentage to 4.0 percent for purposes of calculating the reconciliation payment or recoupment amount in performance years 3 through 5, 4.0 percent for calculating the reconciliation payment and 3.0 percent for calculating the repayment amount in performance year 2, and 4.0 percent for calculating the reconciliation payment in performance year 1 where participant

hospitals have no repayment responsibility. A potential advantage of this approach is that it would provide stronger incentives for quality improvement for participant hospitals with low performance on quality, even if they did not expect to be able to reduce actual episode spending below the target price. In addition, this approach would provide financial incentives to improve the efficiency of care even for hospitals that did not expect to meet the minimum quality score for reconciliation payment eligibility, while still providing strong incentives to provide high-quality care. The disadvantage of this approach is that it could provide reconciliation payments even to hospitals that did not achieve acceptable quality performance.

Participant hospitals with an acceptable composite quality score of >5.00 and ≤9.25 would be eligible for a reconciliation payment if actual episode spending was less than the target price because their quality performance was at the acceptable level established for the CCJR model. They would not be eligible for a quality incentive payment at reconciliation because their episode quality performance, while acceptable, was not good or excellent. Therefore, these hospitals would be eligible to receive a reconciliation payment if actual episode spending was less than the target price.

Participant hospitals with a good composite quality score of >9.25 and ≤15.20 would be eligible for a quality incentive payment at reconciliation if actual episode spending was less than the target price because their quality performance exceeded the acceptable level required for reconciliation payment eligibility under the CCJR model. In addition, they would be eligible for a quality incentive payment at reconciliation for good quality performance that equals 1.0 percent of the participant hospital's benchmark price, thereby changing the effective discount percentage included in the target price experienced by the hospital at reconciliation. Thus, participant hospitals achieving this level of quality for LEJR episodes under CCJR would either have less repayment responsibility (that is, the quality incentive payment would offset a portion of their repayment responsibility) or receive a higher payment (that is, the quality incentive payment would add to the reconciliation payment) at reconciliation than they would have otherwise based on a comparison of actual episode spending to the target price that reflects a 3.0 percent discount. Therefore, these hospitals would be eligible to receive a reconciliation payment if actual episode spending was less than the target price and would also receive a quality incentive payment.

Finally, hospitals with an excellent composite score quality score of >15.20 would be eligible to receive a reconciliation payment if actual episode spending was less than the target price because their quality performance exceeded the acceptable level required for reconciliation payment eligibility under the CCJR model. In addition, they would be eligible for a higher quality incentive payment at reconciliation for excellent quality performance that equals 1.5 percent of the participant hospital's benchmark price, thereby changing the effective discount percentage included in the target price experienced by the hospital at reconciliation. Thus, participant hospitals achieving this level of quality for LEJR episodes under CCJR would either have less repayment responsibility (that is, the quality incentive payment would offset a portion of their repayment responsibility) or receive a higher payment (that is, the quality incentive payment would add to the reconciliation payment) at reconciliation than they would have otherwise based on a comparison of actual episode spending to the target price that reflects a 3.0 percent discount. Therefore, these hospitals would be eligible to receive a reconciliation payment if actual episode spending was less than the target price and would also receive a quality incentive payment.

Under this methodology, the proposed stop-loss and stop-gain limits discussed in section III.C.8 of this proposed rule would not change. We believe this approach to quality incentive payments based on the composite quality score could have the effect of increasing the alignment of the financial and quality performance incentives under the CCJR model to the potential benefit of participant hospitals and their collaborators as well as CMS, although it would substantially increase the complexity of the methodology to link quality and payment. We seek comment on this alternative approach to basing reconciliation payment eligibility and quality incentive payments on the participant hospital's composite quality score under the CCJR model, as well as the composite quality scoring ranges applicable to the respective payment policies.

While we describe in detail this alternative considered to link quality to payment under CCJR, we are not proposing this methodology for several reasons. First, the MSSP and HVBP program utilize many more measures than we are proposing for the CCJR model. For example, the MSSP incorporates thirty three measures across four quality domains (79 FR 67916 and 67917). The range of measures in the MSSP and the HVBP program lends itself to a scoring approach, which can account for many measures and allows providers to achieve a high score despite performing well on some measures but achieving lower performance on others. There is a detailed description of the MSSP scoring methodology in the 2011 Shared Savings Program Final rule (76 FR 67895 through 67900). We believe that given the more limited set of measures chosen for the CCJR model, a scoring approach such as the alternative described in this section could diminish the importance of each measure. Use of a scoring approach would not allow hospital performance on two different outcomes to be easily reviewed and understood with respect to the impact of individual measure performance on Medicare's actual payment for the episode under the model. Second, we believe the measures proposed for this model represent goals of clinical care that should be achievable by all hospitals participating in the model that heighten their focus on these measures, especially the readmissions and complications measures, for LEJR episodes based on the financial incentives in the model. Finally, we believe that a methodology that assesses performance based on absolute values of a specific set of measures that are already in use, as we are proposing for the CCJR model, is the most appropriate methodology to provide achievable and predictable quality targets for participant hospitals on measures that monitor the most meaningful quality of care outcomes in a model where some acute care hospitals that might not choose to participate in a voluntary model are also included. Our proposed method as discussed in the next section reflects our expectation that hospitals achieve a certain level of performance on measures to ensure that hospitals provide high-quality care under the model.

Finally, we also considered an approach whereby participant hospitals would not be penalized with regard to their eligibility for reconciliation payments in CCJR for failure to meet the specified thresholds for the quality measures in performance year 1 of the model; in other words, we would delay the proposal described in the next

section to performance year 2 rather than beginning in performance year 1. We considered calculating participant hospital performance on the required measures for the model, and, if actual episode spending was less than the target price, the participant hospital would receive a full reconciliation payment of savings achieved beyond the target price, regardless of performance on the quality measures. However, we do not believe this would be appropriate for the CCJR model, given that two of the measures are administrative claims-based and thus impose no additional reporting burden on hospitals; rather, these two measures are established measures in existing CMS quality programs, and a central goal of the model is improving care for Medicare beneficiaries in LEJR episodes. We note that the HCAHPS survey measure is also an established measure in HIQR and would not impose additional reporting burden on hospitals.

(iii) Proposal To Link Quality and Payment Through Thresholds for Reconciliation Payment Eligibility

For the reasons outlined in the previous section, we do not propose to use similar methodologies to other CMS programs that would tie CCJR episode reconciliation payment eligibility and reconciliation payment and Medicare repayment amounts to a composite quality score on specified quality measures, but as discussed later in this section, we instead propose to simply assess performance or achievement on a quality measure by setting a measure result threshold for each measure beginning in performance year 1 of the model.

The CCJR measure result threshold would be based on the measure results from the HIQR program, a nationally-established program, and would use its national distribution of measure results. These are the same measure results posted on Hospital Compare or in the Hospital Compare downloadable database (*https://data.medicare.gov/data/hospital-compare*) for the HIQR program. We refer readers to the earlier discussion of the HIQR Program, which utilizes measures to assess most acute care hospitals in the nation. Determining the CCJR model target thresholds are discussed in the next section.

As previously described, the CCJR model proposes the following three required measures to assess LEJR episode quality of care:

- Hospital-level 30-day, all-cause RSRR following elective primary THA and/or TKA (NQF #1551).
- Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550).
- HCAHPS survey (NQF #0166).

We also propose to make a voluntary reporting payment adjustment for CCJR participant hospitals who successfully and voluntarily submit data for the THA/TKA patient-reported outcome-based performance measure (henceforth referred to as ''THA/TKA voluntary data'') as described in sections III.C.5.b.(3) and III.D.3.a.(2) of this proposed rule. We propose that participant CCJR hospitals must meet or surpass a specified threshold for each required measure beginning for performance year 1 of the model in order to be eligible for a reconcilation payment if actual episode payments are less than the target price. The calculation of the HCAHPS survey measure is described in section III.D.2.c.of this proposed rule. We propose to use the individual measure results calculated as specified in section III.D. of this proposed rule for the three required measures to determine hospital eligibility for reconciliation payment for each performance year of the CCJR model. Also, as discussed in section III.C.4 of this proposed rule, which outlines the payment structure for the CCJR model, target prices for MS–DRG 470 anchored episodes and for MS–DRG 469 anchored episodes will be calculated for hospitals participating in the model for an episode of care extending 90-days after discharge from the anchor hospitalization. Participant hospitals that achieve actual episode payment below the specified target price for a given performance period would be eligible for a reconciliation payment, provided that the participant hospital also met episode quality thresholds on the three required measures for the performance period.

We propose to use the following quality criterion to determine if a participant hospital qualifies for a reconciliation payment based on the episode quality thresholds on the three required measures:

The hospital's measure result is at or above the 30th percentile of the national hospital measure results calculated for all HIQR-program participant hospitals for each of the three required measures for each performance period (for a detailed description of how we determined the performance period and reconciliation payment eligibility, see section III.C.5. of this proposed rule).

Using HIQR program's 3 year rolling period as outlined in section III.D.2.a.(6) and III.D.2.b.(6) of this proposed rule, if a participant hospital performed at or above the 30th percentile of all HIQR program hospitals for each of the three required measures and if actual episode payment was less than the target price for the specified performance year, we would make a reconciliation payment to the hospital. Failure to achieve the threshold on one or more measures would result in the participant hospital not receiving a reconciliation payment regardless of whether the actual episode payment was less than the target price for that performance period. We propose that for hospitals with insufficient volume to determine performance on an individual measure, these hospitals will be considered to be performing at the threshold level and their results will be publicly posted with all other participant hospitals' measure results (for a detailed summary of public reporting, see section III.D.5. of this proposed rule). We do not believe it would be appropriate to potentially penalize high quality, efficient hospitals due to their low volume, given that meeting the required quality measure thresholds is required for reconciliation payment eligibility.

We also propose for performance years 4 and 5 to increase the measure result threshold to the 40th percentile. We believe that increasing the measure result threshold to the 40th percentile would encourage participants to strive for continued quality improvement throughout the 5 performance years of the model. We seek comment on our proposal to make a reconciliation payment to a participant hospital that achieves actual episode spending below the target price for a performance year and performs at or above the 30th percentile of HIQR program participant hospitals for all three required quality measures in performance years 1 through 3 or the 40th percentile in performance years 4 and 5, as well as our proposal to consider low volume hospitals to be performing at the threshold level.

We propose to require hospitals to meet the threshold for all three measures for the following reasons. The measures chosen for this model are fully developed, NQF-endorsed, and implemented measures in CMS IPPS programs. These measures are also publicly reported on the Hospital Compare Web site. Hospitals are familiar with the complications and readmissions quality measures and with the HCAHPS Survey, as they are currently included in HIQR, HVBP, and HRRP (79 FR 50031, 50062, 50208, 50209 and 50259), and we believe that there is minimal additional administrative burden for hospitals. All three measures are widely utilized nationally; thus, a nationally-based

threshold is an appropriate benchmark. In addition, the goal of the CCJR model is LEJR episode care redesign that includes effective care coordination and management of care transitions. Strategies to prevent and efficiently manage post-procedure complications and hospital readmissions following an LEJR procedure are consistent with the goals of the model; a hospital cannot succeed in this model without engaging in care redesign efforts that would address aspects of care included in these measures. Failure to perform successfully on these key quality measures (defined by meeting the minimum thresholds) would indicate that hospitals are not achieving quality consistent with the goals of the model to specifically incentivize greater improvement on these measures than hospitals not participating in the CCJR model, and should not be eligible to receive a reconciliation payment from Medicare even if reduced episode spending is achieved. Finally, the approach we propose is consistent with CMS' goal of moving hospitals and other providers to value-based payment that ties payment to quality. In the 5 performance years of this model, performance on quality measures would only be applied to determining eligibility for a reconciliation payment; quality measures would not be used to determine participant hospitals' financial responsibility, except for the proposed voluntary reporting payment adjustment described in described in section III.C.5.b.(3) of this proposed rule. In essence, participant hospitals' responsibility to repay Medicare the difference between their target price and their actual episode payment, should actual episode payments exceed the target price, would not be impacted by performance on quality measures.

Finally, we propose to increase the measure result thresholds for the final 2 performance years of the model, to ensure that CCJR participant hospitals continue to maintain a high level of quality performance or improve performance on these measures as they gain experience with implementation of this payment model. More specifically, we propose that in order for a participant hospital to receive a reconciliation payment for actual episode spending that is less than the target price for performance years 4 and 5, the participant hospital's measure result must be at or above the 40th percentile of the national hospital measure results calculated for all HIQR-program participant hospitals for each of the three required measures for each performance period. As previously noted, we propose to use the most recently available HCAHPS 4-quarter roll-up to calculate the HLMR. We believe that holding the participant hospitals to a set measure result threshold for the first 3 years, and increasing this threshold for performance years 4 and 5, emphasize the need to maintain and improve quality of care while cost efficiencies are pursued. We seek comment on our proposed approach to incorporating quality performance into eligibility for reconciliation payments under the CCJR model for participant hospitals.

Table 13 displays the proposed thresholds that participant hospitals must meet on the various measures over the 5 model performance years.

TABLE 13—PROPOSED THRESHOLDS FOR REQUIRED QUALITY MEASURES TO DETERMINE PARTICIPANT HOSPITAL RECONCILIATION PAYMENT ELIGILBITY OVER 5 YEARS

Measure	PY1 threshold	PY2 threshold	PY3 threshold	PY4 threshold	PY5 threshold
Hospital-level 30-day, all-cause RSRR following elective primary THA and/or TKA (NQF #1551).	30th percentile	30th percentile	30th percentile	40th percentile	40th percentile.
Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550).	30th percentile	30th percentile	30th percentile	40th percentile	40th percentile.
HCAHPS survey (NQF #0166)	30th percentile	30th percentile	30th percentile	40th percentile	40th percentile.

We seek comment on our proposed methodology to utilize quality measure performance in the payment methodology for CCJR, as well as the proposed thresholds for participant hospital reconciliation payment eligibility over the performance years of the model.

As discussed in section III.C.5.c.(3) of this proposed rule, we also believe that hospitals that choose to submit THA/TKA voluntary data should have the potential to benefit financially through an adjustment to the payment methodology of the model. We propose a voluntary reporting payment adjustment for hospitals that successfully submit the THA/TKA voluntary data by reducing the discount percentage incorporated into the target price from 2.0 percent to 1.7 percent. This voluntary reporting payment adjustment would start in performance year 1 and would be available through performance year 5 of the model for each year that the hospital successfully reports THA/TKA voluntary data. As proposed, reporting THA/TKA voluntary data would not affect eligibility for a reconciliation payment if actual episode payments are less than the target price. Participant hospitals would still need to meet the 30th or 40th percentile threshold, as applicable to the given performance year, on all three required quality measures (Table 13).

We considered, but are not proposing, two other alternatives to adjust the payment methodology for participant hospitals that successfully report the THA/TKA voluntary data as described in section III.C.5.c.(3) of this proposed rule. These alternatives would change the threshold percentile for the three required quality measures or, alternatively, reduce the number of required measures in which the threshold must be met provided that successful THA/TKA voluntary data were reported for a performance year. First, we considered reducing the threshold for reconciliation payment eligibility that participant hospitals must meet on the three required quality measures from the 30th percentile threshold to the 20th percentile threshold for performance years 1, 2, and 3, and from the 40th percentile to the 30th percentile for performance year. Second, we considered only requiring hospitals to meet the 30th percentile threshold on two of three outcome measures for performance years 1, 2, and 3, and the 40th percentile threshold on two of three outcome measures in performance years 4 and 5. Under both of these alternatives, the eligibility for reconciliation payments could change based on the THA/TKA voluntary data. We seek comment on these alternative payment methodology

adjustments that could impact reconciliation payment eligibility, unlike the proposed voluntary reporting payment adjustment. We note that the other alternative approaches to encouraging THA/TKA voluntary data reporting for CCJR beneficiaries as discussed in section III.C.5.c.(3) of this proposed rule that would not require adjustments to the CCJR payment methodology would also not affect reconciliation payment eligibility.

6. Proposed Process for Reconciliation

This section outlines our proposals on how we intend to reconcile aggregate related Medicare payments for a hospital's beneficiaries in CCJR episodes during a performance year against the applicable target price in order to determine if reconciliation payment (or Medicare repayment, beginning in performance year 2) is applicable under this model. We refer readers to section III.B of this proposed rule for our proposed definition of related services for lower extremity joint replacement episodes under CCJR, to section III.C.2.a. of this proposed rule for our proposed definition of performance years, and to section III.C.4 of this proposed rule for our proposed approach to establish target prices.

a. Net Payment Reconciliation Amount

After the completion of a performance year, we propose to retrospectively calculate a participant hospital's actual episode performance based on the episode definition. We note that episode payments for purposes of the CCJR model would exclude the effects of special payment provisions under existing Medicare payment systems (section III.C.3.a. of this proposed rule), be subject to proration for services that extend beyond the episode (section III.C.3.b. of this proposed rule), and exclude PBPM payments for programs and models specified in section III.C.7.d. of this proposed rule. Some episodes may be excluded entirely from the CCJR model due to overlap with BPCI episodes, as discussed in section III.C.7.b. of this proposed rule. Finally, actual episode payments calculated for purposes of CCJR would be capped at anchor MS–DRG and region-specific high episode payment ceilings (section III.C.3.c. of this proposed rule). We would apply the high episode payment ceiling policy to episodes in the performance year similarly to how we propose to apply it to historical episodes (section III.C.4.c. of this proposed rule). Episode payments for episodes attributed to CCJR eligible hospitals would be divided by the wage normalization factor, using the IPPS wage index applicable to the anchor admission, and for each MS–DRG anchor and region, the high episode payment ceiling would be calculated as two standard deviations above the mean. Any actual episode payment amount above the high payment ceiling would be capped at said ceiling. After applying the cap, wage variations would be reapplied to episodes by multiplying them by the same wage normalization factor, using the IPPS wage index applicable to the anchor admission.

Each participant hospital's actual episode payment performance would be compared to its target prices. We note that, as discussed in section III.C.4. of this proposed rule, a participant hospital would have multiple target prices for episodes ending in a given performance year, based on the MS–DRG anchor (MS–DRG 469 versus MS–DRG 470), the performance year when the episode was initiated, when the episode was initiated within a given performance year (January 1 through September 30 of the performance year, October 1 through December 31 of the performance year, October 1 through December 31 of the prior performance year), and whether the participant hospital successfully submitted THA/TKA voluntary data. The applicable target price for each episode would be determined using the aforementioned criteria, and the difference between each CCJR episode's actual payment and the relevant target price (calculated as target price subtracted by CCJR actual episode payment) would be aggregated for all episodes for a participant hospital within the performance year, representing the raw Net Payment Reconciliation Amount (NPRA). This amount would be adjusted per the steps discussed later in this section, creating the NPRA.

The NPRA would include adjustments to account for post-episode payment increases (section III.C.8.e. of this proposed rule). The NPRA would also include adjustments for stop-loss and stop-gain limits (section III.C.8.b. of this proposed rule), after adjustments are made for the aforementioned post-episode payment increases. Any NPRA amount greater than the proposed stop-gain limit would be capped at the stop-gain limit, and any NPRA amount less than the proposed stop-loss limit would be capped at the stop-loss limit.

We do not propose to include any CCJR reconciliation payments or repayments to Medicare under this model for a given performance year in the NPRA for a subsequent performance year. We want to incentivize providers to provide high quality and efficient care in all years of the model. If reconciliation payments for a performance year are counted as Medicare expenditures in a subsequent performance year, a hospital would experience higher Medicare expenditures in the subsequent performance year as a consequence of providing high quality and efficient care in the prior performance year, negating some of the incentive to perform well in the prior year. Therefore, we propose to not have the NPRA for a given performance year be impacted by CCJR Medicare repayments or reconciliation payments made in a prior performance year. However, as discussed in section III.C.6.b, during the following performance year's reconciliation process, we propose to account for additional claims run-out and overlap from the prior performance year, and net that amount with the subsequent performance year's NPRA to determine the reconciliation or repayment amount for the current reconciliation.

b. Payment Reconciliation

We propose to reconcile payments retrospectively through the following reconciliation process. We would reconcile a participant hospital's CCJR actual episode payments against the target price 2 months after the end of the performance year. More specifically, we would capture claims submitted by March 1st following the end of the performance year and carry out the NPRA calculation as described previously to make a reconciliation payment or hold hospitals responsible for repayment, as applicable, in quarter 2 of that calendar year.

To address issues of overlap with other CMS programs and models that are discussed in section III.C.7. of this proposed rule, we also propose that during the following performance year's reconciliation process, we would calculate the prior performance year's episode spending a second time to account for final claims run-out, as well as overlap with other models as discussed in section III.C.7 of this proposed rule. This would occur approximately 14 months after the end of the prior performance year. As discussed later in this section, the amount from this calculation, if different from zero, would be applied to the NPRA for the subsequent performance year in order to determine the amount of the payment Medicare would make to the hospital or the hospital's repayment amount. We note that the subsequent reconciliation calculation would be applied to the previous calculation of NPRA for a performance year to ensure the stop loss and stop gain limits discussed in section

III.C.8. of this proposed rule are not exceeded for a given performance year.

For the performance year 1 reconciliation process, we would calculate a participant's NPRA, as described above, and if positive, the hospital would receive the amount as a reconciliation payment from Medicare. If negative, the hospital would not be responsible for repayment to Medicare, consistent with our proposal to phase in financial responsibility beginning in performance year 2. Starting with the CCJR reconciliation process for performance year 2, in order to determine the reconciliation or repayment amount, the amount from the subsequent reconciliation calculation would be applied to the NPRA. If the amount is positive, and if the hospital meets the quality thresholds for that performance year (discussed further in section III.C.5. of this proposed rule), the hospital would receive the amount as a reconciliation payment from Medicare. If the amount is negative, Medicare would hold the participant hospital responsible for repaying the absolute value of the repayment amount following the rules and processes for all other Medicare debts. Note that given our proposal to not hold participant hospitals financially responsible for repayment for the first performance year, during the reconciliation process for performance year 2 only, the subsequent calculation amount (for performance year 1) would be compared against the performance year 1 NPRA to ensure that the sum of the NPRA calculated for performance year 1 and the subsequent reconciliation calculation for year 1 is not less than zero. For performance years 2 through 5, though, Medicare would hold the participant hospital responsible for repaying the absolute value of the repayment amount following the rules and processes for all other Medicare debts.

This reconciliation process would account for overlaps between the CCJR model and other CMS models and programs as discussed in section III.C.7 of this proposed rule, and would also involve updating performance year episode claims data. For example, for performance year 1 for the CCJR model in 2016, we would capture claims submitted by March 1st, 2017, and reconcile payments for participant hospitals approximately 6 months after the end of the performance year in quarter 2 of calendar year 2017. We would carry out the subsequent calculation in the following year in quarter 2 of calendar 2018, simultaneously with the reconciliation process for the second performance year, 2017. Table 14 provides the proposed reconciliation timeframes for the model. Lastly, we propose that the reconciliation payments to or repayments from the participant hospital would be made by the Medicare Administrative Contractor (MAC) that makes payment to the hospital under the IPPS. This approach is consistent with BPCI Model 2 operations.

We believe our proposed approach balances our goals of providing reconciliation payments in a reasonable timeframe, while being able to account for overlap and all Medicare claims attributable to episodes. We believe that pulling claims 2 months after the end of the performance year provides sufficient claims run-out to conduct the reconciliation in a timely manner, given that our performance year includes episodes ending, not beginning, by December 31st. We note that in accordance with the regulations at § 424.44 and the Medicare Claims Processing Manual (Pub. L. 100–04), Chapter 1, Section 70, Medicare claims can be submitted no later than 1 calendar year from the date of service. We recognize that by pulling claims 2 months after the end of the performance year to conduct reconciliation, we would not have complete claims run-out. However, we believe that the 2 months of claims run out would be an accurate reflection of episode spending and consistent with the claims run-out timeframes used for reconciliation in other payment models, such as BPCI Models 2 and 3. The alternative would be to wait to reconcile until we have full claims run out 12 months after the end of the performance year, but we are concerned that this approach would significantly delay earned reconciliation payments under this model. Because we propose to conduct a second calculation to account for overlap with other CMS models and programs, we can incorporate updated claims data with 14 months run out at that time. However, we do not expect that the updated data should substantially, in and of itself, affect the reconciliation results assuming hospitals and other providers furnishing services to Medicare beneficiaries in CCJR episodes follow usual patterns of claims submission and do not alter their billing practices due to this model.

TABLE 14—PROPOSED TIMEFRAME FOR RECONCILIATION IN CCJR

Model performance year	Model performance period	Reconciliation claims submitted by	Reconciliation payment or repayment	Second calculation to address overlaps and claims run-out	Second calculation adjustment to reconciliation amount
Year 1*	Episodes ending March 31, 2016 to December 31, 2016.	March 1, 2017	Q2 2017	March 1, 2018	Q2 2018
Year 2	Episodes ending January 1, 2017 through December 31, 2017.	March 1, 2018	Q2 2018	March 1, 2019	Q2 2019
Year 3	Episodes ending January 1, 2018 through December 31, 2018.	March 1, 2019	Q2 2019	March 2, 2020	Q2 2020
Year 4	Episodes ending January 1, 2019 through December 31, 2019.	March 2, 2020	Q2 2020	March 1, 2021	Q2 2021
Year 5	Episodes ending January 1, 2020 through December 31, 2020.	March 1, 2021	Q2 2021	March 1, 2022	Q2 2022

* Note that the reconciliation for Year 1 would not include repayment responsibility from CCJR hospitals.

7. Proposed Adjustments for Overlaps With Other Innovation Center Models and CMS Programs

a. Overview

We acknowledge that there may be circumstances where a Medicare beneficiary in a CCJR episode may also be assigned to an ACO participating in the MSSP or otherwise accounted for in a payment model being tested by the Innovation Center. Current or forthcoming programs and models with potential overlap with CCJR are displayed in Table 15. For purposes of this proposed rule, ''total cost of care'' models refer to models in which episodes or performance periods include participant financial responsibility for all Part A and Part B spending, as well as some Part D spending in select cases. We use the term ''shared savings'' in this proposed rule to refer to models in which the payment structure includes a calculation of total savings and CMS and the model participants each retain a particular percentage of that savings. We note that there exists the possibility for overlap between CCJR episodes and shared savings models such as the Pioneer ACO Model, other total cost of care models such as the Oncology Care Model (OCM), other Innovation Center payment models such as BPCI, and other models or programs that incorporate per-beneficiary-per-month fees or other payment structures.

TABLE 15—CURRENT PROGRAMS AND MODELS WITH POTENTIAL OVERLAP WITH PROPOSED CCJR MODEL

Program/model	Brief description	Shared savings?	Per-beneficiary-per-month (PBPM) payments?
Pioneer	ACO shared savings program	Yes	No.
Medicare Shared Savings Program (MSSP)	ACO shared savings program	Yes	No.
Next Generation ACO	ACO shared savings program	Yes	No.
Comprehensive Primary Care initiative (CPCi)	Pays primary care providers for improved and comprehensive care management.	Yes	Yes.
Multi-payer Advanced Primary Care Practice (MAPCP)	Multi-payer model for advanced primary care practices, or ''medical homes''.	Yes	Yes.
Bundled Payments for Care Improvement (BPCI)	Bundled payment program for acute or post-acute services or both.	No	No.
Oncology Care Model (OCM)	Multi-payer model for oncology physician group practices.	No	Yes.
Comprehensive ESRD Care Initiative (CEC)	ACO for ESRD Medicare beneficiaries	Yes	No.
Million Hearts	Model targeting prevention of heart attack and stroke	No	Yes.
Medicare Care Choices Model	Hospice concurrent care model	No	Yes.

Four different issues may arise in such overlap situations that must be addressed under CCJR. First, beneficiaries in CCJR episodes could also be part of BPCI Model 2 or 3 LEJR episodes, and the clinical services provided as part of each episode may overlap entirely or in part. Second, CCJR reconciliation payments and Medicare repayments that are made under Part A and B and attributable to a specific beneficiary's episode may be at risk of not being accounted for by other models and programs when determining the cost of care under Medicare for that beneficiary. Third, some Innovation Center models make PBPM payments to entities for care coordination and other activities, either from the Part A or B Trust or both, or from the Innovation Center's own appropriation (see section 1115A(f) of the Act). These payments may occur during a CCJR episode. Finally, there could be instances when the expected Medicare savings for a CCJR beneficiary's episode is not achieved by Medicare because part of that savings is paid back to the hospital or another entity under a shared savings program or other model in which the beneficiary is also included. We seek comment on our proposals to account for overlap with other models, including those listed in Table 15 as well as other CMS models or programs.

b. CCJR Beneficiary Overlap With BPCI Episodes

BPCI is an episode payment model testing LEJR episodes, as well as 47 other episodes, in acute or PAC or both (Models 1, 2, 3 or 4). As discussed in section III.A. of this proposed rule, we propose to exclude from selection for participation in the CCJR payment model those geographic areas where 50 percent or more of LEJR episodes are initiated at acute care hospitals testing the LEJR episode in BPCI in Models 1, 2 or 4 as of July 1, 2015. In that same section, we propose that acute care hospitals in selected geographic areas participating in BPCI under Model 1 (acute care only) and those participating as episode initiators for the LEJR episode in Model 2 (acute and PAC from 30 to 90 days post-discharge) or Model 4 (prospective episode payment for the LEJR anchor hospital stay and related readmissions for 30 days post-discharge) be excluded from CCJR.

While we believe these proposals will mitigate the overlap of CCJR beneficiaries with BPCI episodes, there may still be instances of model overlap that we need to account for under CCJR. These include circumstances when a beneficiary is admitted to a participating CCJR hospital for an LEJR procedure where the beneficiary would also be in a BPCI Model 2 episode under a physician group practice that would initiate the episode under BPCI. In another example, a beneficiary discharged from an anchor hospitalization under CCJR could enter a BPCI Model 2 LEJR episode at another hospital for a phased second joint replacement procedure or enter a BPCI Model 3 LEJR episode upon initiation of PAC services at a BPCI post-acute provider episode initiator for the LEJR episode. Similarly, a beneficiary in a BPCI Model 2 or Model 3 LEJR episode could be admitted to a CCJR participant hospital for a phased second joint replacement. In all such scenarios in which there is overlap of CCJR beneficiaries with any BPCI LEJR episodes, we propose that the BPCI LEJR episode under Models 1, 2, 3, or 4 take precedence and we would cancel (or never initiate) the CCJR episode. Because the cancellation (or lack of initiation) would only occur for overlap with BPCI LEJR episodes, we expect that the participant hospital and treating physician would generally be aware of the beneficiary's care pathway that

would cancel or not initiate the CCJR episode. Therefore, we would exclude the CCJR episode from the CCJR participant hospital's reconciliation calculations where we compare actual episode payments to the target price under the CCJR model. If we were to allow both CCJR and BPCI LEJR episodes to overlap, we would have no meaningful way to apply the payment policies in two models with overlapping care redesign interventions and episodes. Participants in BPCI have an expectation that eligible episodes will be part of the BPCI model test, whereas based on our proposal CCJR participants would be aware that episodes may be canceled when there is overlap with BPCI episodes as previously discussed in this section. We aim to preserve the integrity of ongoing model tests without introducing major modifications (that is, CCJR episode precedence) that could make evaluation of existing models more challenging.

We considered that there may also be instances of overlap between CCJR and BPCI Model 3 LEJR episodes where our proposal to give precedence to all BPCI episodes could lead to undesirable patient steering because the BPCI Model 3 episode does not begin until care is initiated at an episode-initiating PAC provider. It could be possible for a participating CCJR hospital to purposefully guide a beneficiary to a BPCI Model 3 LEJR episode initiating PAC provider to exclude that beneficiary's episode from CCJR. We considered giving precedence to the CCJR episode in overlap with Model 3 beneficiaries because the CCJR episode begins with admission for the anchor hospitalization and thus includes more of the episode services. However, we believe the steering opportunities would be limited due to the preservation of beneficiary choice of provider in this model (as discussed in section III.E. of this proposed rule). As outlined in section III.E. of this proposed rule, CCJR hospitals must provide patients with a complete list of all available PAC options. Moreover, BPCI Model 3 post-acute providers are actively involved in the decision to admit patients to their facilities. As episode initiators in BPCI, such providers are subject to monitoring and evaluation under that model and would be vigilant about not engaging in steering themselves or spurred by other providers. Nevertheless, we will monitor CCJR hospitals to ensure steering or other efforts to limit beneficiary access or move beneficiaries out of the model are not occurring (see section III.F. of this proposed rule).

We seek comment on the proposed approach to address overlap between CCJR and BPCI episodes.

c. Accounting for CCJR Reconciliation Payments and Repayments in Other Models and Programs

Under CCJR, we would annually, as applicable, make reconciliation payments to or receive repayments from participating CCJR hospitals based on their quality performance and Medicare expenditures, as described in section III.C.6. of this proposed rule. While we propose that these reconciliation payments or repayments would be handled by MACs, the calculation of these amounts would be done separately before being sent through the usual Medicare claims processing systems. Nevertheless, it is important that other models and programs in which providers are accountable for the total cost of care be able to account for the full Medicare payment, including CCJR-related reconciliation payments and repayments as described in section III.C.6. of this proposed rule, for beneficiaries who are also in CCJR episodes. Accordingly, it is necessary to have beneficiary-specific information on CCJR-related reconciliation payments and repayments available when those models and programs make their financial calculations. Thus, in addition to determining reconciliation payments and repayments for the participant hospitals in the CCJR model, we propose to also calculate beneficiary-specific reconciliation payment or repayment amounts for CCJR episodes to allow for those other programs and models, as their reconciliation calculation timeframes permit, to determine the total cost of care for overlapping beneficiaries. We would perform the reconciliation calculations for CCJR hospitals and make information about the CCJR reconciliation or repayment amounts available to other programs and models, such as MSSP and Pioneer ACO, that begin reconciliation calculations after CCJR. For example, this strategy is currently in place to account for overlaps between beneficiaries aligned to Pioneer and MSSP ACOs and BPCI model beneficiaries. Beneficiary-specific reconciliation payment or repayment amounts are loaded into a shared repository for use during each program or model's respective reconciliations. However, we note that we would not make separate payments to, or collect repayments from, participating CCJR hospitals for each individual episode, but, instead, propose to make a single aggregate reconciliation payment or repayment determination for all episodes for a single performance year, as discussed in section III.C.6. of this proposed rule.

As described in section III.C.6 of this proposed rule on the Proposed Process for Reconciliation, we propose to conduct reconciliation based on claims data available 2 months after the end of the performance year and a second calculation based on claims data available 14 months after the end of a performance year to account for claims run-out and potential overlap with other models. The rationale for this reconciliation process is to be able make payments to, and recoup payments from, CCJR participant hospitals in a timely manner and to be able to account for overlaps in other models and programs. In addition, the timing of the reconciliation was determined giving consideration to when the other total cost of care models conduct their reconciliations so that when they perform their financial calculations, they will have the information necessary to account for beneficiary-specific payments/repayments made under the CCJR model. We intend to report beneficiary-specific payments and repayment amounts made for the CCJR model in the CMS Master Database Management System that generally holds payments/repayment amounts made for CMS models and programs. Other total cost of care models and programs can use the information on CCJR payment/repayment amounts reported in the Master Database Management System in their financial calculations such as in their baseline or benchmark calculations or reconciliations, to the extent that is consistent with their policies.

We seek comment on our proposed approach to ensuring that the full CCJR episode payment for a beneficiary is accounted for when performing financial calculations for other total cost of care and episode-based payment models and programs.

d. Accounting for PBPM Payments in the Episode Definition

There are currently five CMS models that pay PBPM payments to providers for new or enhanced services as displayed in Table 15. These PBPM payments vary as to their funding source (Medicare Trust Funds or Innovation Center appropriation), as well as to their payment methodology.

In general, these PBPM payments are for new or enhanced provider or supplier services that share the goal of improving quality of care overall and reducing Medicare expenditures for services that could be avoided through improved care coordination. Some of

these PBPM payments may be made for services furnished to a beneficiary that is in another Innovation Center model at the that same time that the beneficiary is in a CCJR LEJR episode, but the clinical relationship of services paid by the PBPM payments to the CCJR episode will vary. For purposes of CCJR, we consider clinically related those services paid by PBPMs that are for the purpose of care coordination and care management of any beneficiary diagnosis or hospital readmission not excluded from the CCJR episode definition, as discussed in section III.B.2 of this proposed rule.

We would determine whether the services paid by PBPM payments are excluded from the CCJR episode on a model by model basis based on their funding source and clinical relationship to CCJR episodes. If we determine a model's PBPM payments are for new or enhanced services that are clinically related to the CCJR episode and the PBPM payment is funded through the Medicare Part A or B Trust Fund, we would include the services paid by the PBPM payment to the extent they otherwise meet the proposed episode definition for the CCJR model. That is, we would include the clinically related services paid by a PBPM payment if the services would not otherwise be excluded based on the principal diagnosis code on the claim, as discussed in section III.B.2 of this proposed rule. The PBPM payments for clinically related services would not be excluded from the historical CCJR episodes used to calculate target prices when the PBPM payments are present on Part A or Part B claims, and they would not be excluded from calculation of episode actual expenditures during the performance period. PBPM model payments that we determine are clinically unrelated would be excluded, regardless of the funding mechanism or diagnosis codes on claims for those payments. We note that in the case of PBPM model payments, principal diagnosis codes on a Part B claim (which are used to identify exclusions from CCJR episodes, as discussed in section III.B.), would not denote the only mechanism for exclusion of a service from the CCJR episode. All such PBPM model payments we determine are clinically unrelated would be excluded as discussed in this proposal. Finally, all services paid by PBPM payments funded through the Innovation Center's appropriation under section 1115A of the Act would be excluded from CCJR episodes, without a specific determination of their clinical relationship to CCJR episodes. We believe including such PBPM payments funded under the Innovation Center's appropriation and not included on claims would be operationally burdensome and could significantly delay any reconciliation payments and repayments for the CCJR model. In addition, because these services are not paid for from the Medicare Part A or B Trust Fund, we are not confident that they would be covered by Medicare under existing law. Therefore, we believe the services paid by these PBPM payments are most appropriately excluded from CCJR episodes. Our proposal for the treatment of services paid through model PBPM payments in CCJR episodes would pertain to all existing models with PBPM payments, as well as future models and programs that incorporate PBPM payments. We believe that this proposal is fully consistent with our goal of including all related Part A and Part B services in the CCJR episodes, as discussed in section III.B.2. of this proposed rule.

Under this proposal, only one of the four existing models displayed in Table 15 include services paid by PBPM payments that would not be excluded from CCJR episodes. The MAPCP model makes PBPM payments that are funded through the Trust Fund for new or enhanced services that coordinate care, improve access, and educate patients with chronic illnesses. We expect these new or enhanced services to improve quality and reduce spending for services that may have otherwise occurred, such as hospital readmissions, and consider them to be clinically related to CCJR episodes because the PBPM payments would support care coordination for medical diagnoses that are not excluded from CCJR episodes. Thus, we propose that services paid by PBPM payments under the MAPCP model not be excluded from CCJR episodes to the extent they otherwise meet the proposed episode definition. While the OCM model will pay for new or enhanced services through PBPM payments funded by the Medicare Part B Trust Fund, we do not believe these services are clinically related to CCJR episodes. The OCM model incorporates episode-based payment initiated by chemotherapy treatment, a service generally reported with ICD–9–CM codes that are specifically excluded from the proposed CCJR episode definition in section III.B.2. of this proposed rule. We believe the care coordination and management services paid by OCM PBPM payments would be focused on chemotherapy services and their complications, so the services would be clinically unrelated to CCJR episodes. Therefore, we propose that services paid by PBPM payments under the OCM model be excluded from CCJR episodes. Similarly, we propose to exclude services paid by PBPM payments under the Medicare Care Choices model, because the model's focus on palliative care for beneficiaries with a terminal illness means the PBPM payments would pay for services that are clinically unrelated to CCJR episodes. The services paid by PBPM payments under this model would commonly pertain to diagnoses that are excluded from the proposed CCJR episode definition. Finally, new or enhanced services paid by PBPM payments under the Comprehensive Primary Care initiative (CPCi) are paid out of the Innovation Center's appropriation and thus would be excluded from CCJR episodes according to this proposal.

We acknowledge there may be new models not included Table 15 that could incorporate a PBPM payment for new or enhanced services. We would plan to make our determination about whether services paid by a new model PBPM payment that is funded under the Medicare Trust Funds are clinically related to CCJR episodes through the same subregulatory approach that we are proposing to use to update the episode definition (excluded MS–DRGs and ICD–9–CM diagnosis codes). We would assess each model's PBPM payment to determine if it would be primarily used for care coordination or care management services for excluded clinical conditions under the LEJR episode definition for CCJR based on the standards we propose to use to update the episode definition that are discussed in section III.B.2 of this proposed rule.

If we determine that the PBPM payment would primarily be used to pay for services to manage an excluded clinical condition, we would exclude the PBPM payment from the CCJR episode on the basis that it pays for unrelated services. If we determine that the PBPM payment could primarily be used for services to manage an included clinical condition, we would include the PBPM payment in the CCJR episode if the diagnosis code on the claim for the PBPM payment was not excluded from the episode, following our usual process for determining excluded claims for Part B services in accordance with the episode definition discussed in section III.C.2 of this proposed rule. We would post our proposed determination about whether the PBPM payment would be included in the episode to the CMS Web site to allow for public input on our planned application of these standards, and then adopt changes to

the overlap list with posting to the CMS Web site of the final updated list after our consideration of the public input.

We seek comment on our proposals to account for Innovation Center model PBPM payments under CCJR.

e. Accounting for Overlap With Shared Savings Programs and Total Cost of Care Models

In addition to the Medicare Shared Savings Program (MSSP) under section 1899 of the Act, there are several ACO and other Innovation Center models that make or will make, once implemented, providers accountable for total cost of care over 6 to 12 months, including the Pioneer ACO Model, Next Generation ACO, Comprehensive ESRD Care (CEC) Model, CPCi, OCM, and the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration. Some of these are shared savings models (or programs, in the case of MSSP), while others are not shared savings but hold participating providers accountable for the total cost of care during a defined episode of care, such as OCM. Note that as discussed in section III.C.7.a. of this proposed rule, for purposes of this proposed rule, ''total cost of care'' models refer to models in which episodes or performance periods include participant financial responsibility for all Part A and Part B spending, as well as some Part D spending in select cases. Each of these payment models holds providers accountable for the total cost of care over the course of an extended period of time or episode of care by applying various payment methodologies. We believe it is important to simultaneously allow beneficiaries to participate in broader population-based and other total cost of care models, as well as episode payment models that target a specific episode of care with a shorter duration, such as CCJR. Allowing beneficiaries to receive care under both types of models may maximize the potential benefits to the Medicare Trust Funds and participating providers and suppliers, as well as beneficiaries. Beneficiaries stand to benefit from care redesign that leads to improved quality for LEJR episodes of care even while also receiving care under these broader models, while entities that participate in other models and programs that assess total cost of care stand to benefit, at least in part, from the cost savings that accrue under CCJR. For example, a beneficiary receiving an LEJR procedure may benefit from a hospital's care coordination efforts with regard to care during the inpatient hospital stay. The same beneficiary may be attributed to a primary care physician affiliated with an ACO who is actively engaged in coordinating care for all of the beneficiary's clinical conditions throughout the entire performance year, beyond the 90-day post-discharge LEJR episode.

We propose that a beneficiary could be in a CCJR episode, as defined in section III.B. of this proposed rule, by receiving an LEJR procedure at a CCJR hospital, and also attributed to a provider participating in a model or program in Table 15. For example, a beneficiary may be attributed to a provider participating in the Pioneer ACO model for an entire performance year, as well as have a CCJR episode during the ACO's performance year. Each model incorporates a reconciliation process, where total included spending during the performance period or episode are calculated, as well as any potential savings achieved by the model or program. Given that we are proposing to allow for such beneficiary overlap, we believe it is important to account for savings under CCJR and the other models and programs with potential overlap in order that CMS can apply the respective individual savings-related payment policies of the model or program, without attributing the same savings to more than one model or program.

We believe that when overlap occurs, it is most appropriate to attribute Medicare savings accrued during the CCJR time period (hospital stay plus 90 days post-discharge) to CCJR to the extent possible. The CCJR episode has a shorter duration and is initiated by a major surgical procedure, requiring an inpatient hospitalization. In contrast, the total cost of care models listed in Table 15 incorporate 6 to 12 month performance periods for participants and, in general, have a broader focus on beneficiary health. Our intention is to ensure that CCJR episodes are attributed the full expected savings to Medicare to the extent possible. As such, we propose the following policies to ensure that other models are able to account for the reconciliation payments paid to CCJR hospitals to the extent possible prior to performing their own reconciliation calculations and that, in all appropriate circumstances, the CCJR model or the other model would make an adjustment for savings achieved under the CCJR model and partially paid back through shared savings/performance payments under other initiatives to ensure that the full CCJR model savings to Medicare is realized.

We propose that the total cost of care calculations under non-ACO total cost of care models would be adjusted to the extent feasible to account for beneficiaries that are aligned to participants in the model and whose care is included in CCJR in order to ensure that the savings to Medicare achieved under CCJR (the discount percentage) are not paid back under these other models through shared savings or other performance-based payment. Thus, the non-ACO total cost of care models would adjust their calculations to ensure the CCJR discount percentage is not paid out as savings or other performance-based payment to the other model participants. As previously discussed, we believe that the efficiencies achieved during the CCJR episode should be credited to the entity that is closest to that care for the episode of care in terms of time, location, and care management responsibility, rather than the broader entity participating in a total cost of care model that spans a longer duration. We propose that the non-ACO total cost of care models to which this policy would apply would include CPCi, OCM, and MAPCP. We seek comment on our proposal to account for overlap with those non-ACO total cost of care models and any other current or forthcoming models.

We propose a different policy for accounting for overlap with MSSP and other ACO models. We note that given the operational complexities and requirements of the MSSP reconciliation process, it is not feasible for MSSP to make an adjustment to account for the discount to Medicare under a CCJR episode under existing program rules and processes. Additionally, for programmatic consistency among ACO models and programs, given that our ACO models generally are tested for the purpose of informing future potential changes to MSSP, we believe that the ACO model overlap adjustment policy should be aligned with the MSSP policy. Thus, we propose that under CCJR, we would make an adjustment to the reconciliation amount if available to account for any of the applicable discount for an episode resulting in Medicare savings that is paid back through shared savings under MSSP or any other ACO model, but only when a CCJR participant hospital also participates in the ACO and the beneficiary in the CCJR episode is also aligned to that ACO. This adjustment would be necessary to ensure that the applicable discount under CCJR is not reduced because a portion of that discount is paid out in shared savings to the ACO and thus, indirectly, back to the hospital.

However, we propose not to make an adjustment under CCJR when a

beneficiary receives an LEJR procedure at a participant hospital and is aligned to an ACO in which the hospital is not participating. While this proposal would leave overlap unaccounted for in such situations, we do not believe it would be appropriate to hold responsible for repayment the hospital that managed the beneficiary during the episode through a CCJR adjustment, given that the participant hospital may have engaged in care redesign and reduced spending during the CCJR episode. The participant hospital may be unaware that the beneficiary is also aligned to an ACO. However, we recognize that as proposed this policy would allow an unrelated ACO full credit for the Medicare savings achieved during the episode. The evaluation of the CCJR model, as discussed in section IV of this proposed rule, would examine overlap in such situations and the potential effect on Medicare savings.

We note that our proposed policy as outlined in this proposed rule would entail CCJR reclaiming from the participant hospital any discount percentage paid out as shared savings for MSSP 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 CPCi would adjust for the discount percentage in their calculations. While it is operationally feasible for smaller total cost of care models in testing, such as CPCi, to make an adjustment to account for any CCJR discount percentage paid out as sharing savings or other performance-based payments, the operational complexities and requirements of the large permanent Medicare ACO program, MSSP, make it infeasible for that program to make an adjustment in such cases, and we believe that other ACO models in testing that share operating principles with the MSSP should follow the same policies as the CCJR MSSP adjustment for certain overlapping ACO beneficiaries. As the landscape of CMS models and programs changes, we may revisit this policy through future rulemaking.

We seek comment on our proposals for adjustments to account for overlap between CCJR and shared savings programs and total cost of care models.

8. Proposals To Limit or Adjust Hospital Financial Responsibility

a. Overview

As discussed in section III.A of this proposed rule, we propose designating as the financially responsible providers in CCJR all acute care hospitals paid under the IPPS that are located in the selected geographic areas for this test of 90-day post-discharge LEJR episodes, with the exception of some hospitals that we propose to exclude because of participation in BPCI (Models 1, 2, or 4) for LEJR episodes. We are interested in ensuring a broad test of episode payment for this clinical condition among different types of hospitals, including those who may not otherwise choose to participate in an episode payment model. Many of the participant hospitals would likely be key service providers in their communities for a variety of medical and surgical conditions extending well beyond orthopedic procedures. We want to gain experience with this model before extending it to hospitals in uncommon circumstances. In addition, we acknowledge that hospitals designated for participation in CCJR currently vary with respect to their readiness to function under an episode payment model with regard to their organizational and systems capacity and structure, as well as their beneficiary population served. Some hospitals may more quickly be able to demonstrate high quality performance and savings than others, even though we propose that the episode target prices be based predominantly on the hospital's own historical episode utilization in the early years of CCJR.

We also note that providers may be incentivized to excessively reduce or shift utilization outside of the CCJR episode, even with the quality requirements discussed in section III.C.5 of this proposed rule. In order to mitigate any excessive repayment responsibility for hospitals or reduction or shifting of care outside the episode, especially beginning in performance year 2 of the model when we propose to begin to phase in responsibility for repaying Medicare for excess episode spending, we propose several specific policies that are also referenced in section III.C.6.b. of this proposed rule.

b. Proposed Limit on to Raw NPRA Contribution to Repayment Amounts and Reconciliation Payments

(1) Proposed Limit on Raw NPRA Contribution to Repayment Amounts

When hospital repayment responsibility begins in the second performance year of CCJR, under this proposed rule, hospitals would be required to repay Medicare for episode expenditures that are greater than the applicable target price. As discussed in the section III.C.3.c of this proposed rule regarding our proposed pricing adjustment for high payment episodes, hospitals participating in CCJR would not bear financial responsibility for actual episode payments greater than a ceiling set at two standard deviations above the mean regional episode payment. Nevertheless, hospitals would begin to bear repayment responsibility beginning in performance year 2 for those episodes where actual episode expenditures are greater than the target price up to the level of the regional episode ceiling. In aggregate across all episodes, the money owed to Medicare by a hospital for actual episode spending above the applicable target price could be substantial if a hospital's episodes generally had high payments. As an extreme example, if a hospital had all of its episodes paid at two standard deviations above the mean regional episode payment, the hospital would need to repay Medicare a large amount of money, especially if the number of episodes was large.

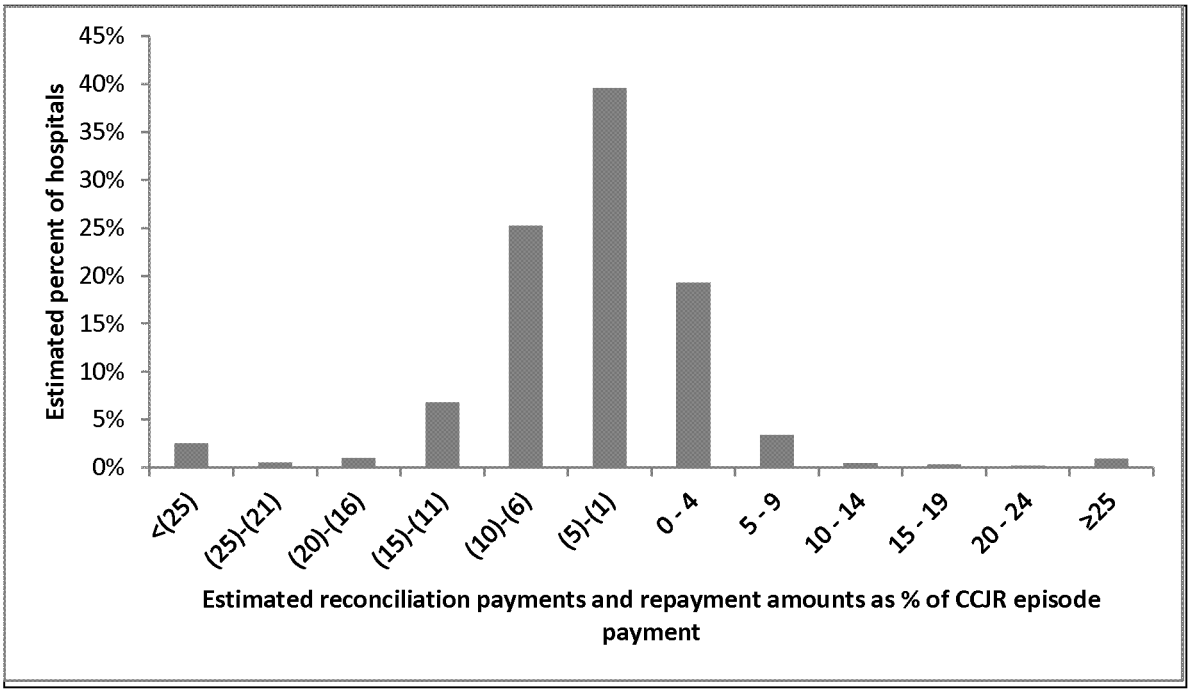
To limit a hospital's overall repayment responsibility for the raw NPRA contribution to the repayment amount under this model, we propose a 10 percent limit on the raw NPRA contribution to the repayment amount in performance year 2 and a 20 percent limit on the raw NPRA contribution to the repayment amount in performance year 3 and subsequent years. Hereinafter we refer to these proposed repayment limits as stop-loss limits. In performance year 2 as we phase in repayment responsibility, the hospital would owe Medicare under the proposed CCJR payment model no more than 10 percent of the hospital's target price for the anchor MS–DRG multiplied by the number of the hospital's CCJR episodes anchored by that MS–DRG during the performance year, for each anchor MS–DRG in the model. Ten percent provides an even transition with respect to maximum repayment amounts from performance year 1, where the hospital bears no repayment responsibility, to the proposed stop-loss limit in performance years 3 through 5 of 20 percent. In performance years 3 through 5 when repayment responsibility is fully phased in, no more than 20 percent of the hospital's target price for the MS–DRG multiplied by the number of the hospital's CCJR episodes with that MS–DRG in that performance year would be owed by the hospital to Medicare under the proposed CCJR payment model. The proposed stop-loss percentage of 20 percent would be symmetrical in performance years 3 through 5 with the proposed limit on the raw NPRA contribution to reconciliation payments discussed in the following section.

We believe that a stop-loss limit of 20 percent is appropriate when the hospital bears full repayment responsibility,

based on our assessment of the changes in practice pattern and reductions in quality of care that could lead to significant repayment responsibility under the CCJR model, as compared to historical LEJR episode utilization. We estimate that the IPPS payment for the anchor hospital stay makes up approximately 50 percent of the episode target price, and we expect that the anchor hospital stay offers little opportunity for efficiencies to be achieved by reducing Medicare expenditures. In contrast, we expect significant episode efficiencies could be achieved in the 90 days following discharge from the anchor hospital stay through reductions in related hospital readmissions and increased utilization of appropriate lower intensity PAC providers, specifically increased utilization of home health services and outpatient therapy and reduced utilization of SNFs and IRFs. Hospital readmissions and facility-based PAC increase the typical Medicare episode payment by 30 to 45 percent over episodes that do not include these services. The proposed 20 percent stop-loss limit related to the total episode payment corresponds to approximately 40 percent of episode payment for the post-discharge period only, where the major opportunities for efficiency through care redesign occur. Thus, taking into consideration the historical patterns used to set target prices, we believe it is reasonable to hold participant hospitals responsible for repayment of actual episode spending that is up to 20 percent greater than the target price. If a participant hospital's repayment amount due to the raw NPRA would otherwise have exceeded the stop-loss limit of 20 percent (comparable to 40 percent of Medicare payment for the post-discharge period), the hospital's episodes would include much poorer episode efficiency as compared to the hospital's historical episodes, with large proportions of episodes including related readmissions and facility-based PAC, costly services that we do not expect to be necessary for most beneficiaries whose care is well-coordinated and appropriate throughout a high quality LEJR episode.

The following hypothetical example illustrates how the proposed stop-loss percentage would be applied in a given performance year for the episodes of a participant hospital. In performance year 3, a participant hospital had ten episodes triggered by MS–DRG 469, with a target price for these episodes of $50,000. The hospital's episode actual spending for these ten episodes was $650,000. The hospital's raw NPRA that would otherwise be $150,000 ((10 × $50,000) − $650,000) would be capped at the 20 percent stop-loss limit of $100,000 (.2 × 10 × $50,000) so the hospital would owe CMS $100,000, rather than $150,000. In performance year 3, the same participant hospital also has 100 episodes triggered by MS–DRG 470, with a target price for these episodes of $25,000. The hospital's episode actual spending for these 100 episodes was $2,800,000. The hospital's raw NPRA would be $300,000 ((100 × $25,000) − $2,800,000), an amount that would be due to CMS in full as it would not be subject to the 20 percent stop-loss limit of $500,000 (.2 × 100 × $25,000).

FIGURE 4: ESTIMATED DISTRIBUTION OF RECONCILIATION PAYMENTS AND REPAYMENT AMOUNTS UNDER PERFORMANCE YEAR 2 POLICIES, BEFORE CONSIDERATION OF CHANGES IN UTILIZATION, WITHOUT APPLICATION OF STOP-LOSS OR STOP-GAIN LIMITS, BEFORE CONSIDERATION OF QUALITY THRESHOLDS



Source: Medicare Parts A and B claims, CCJR episodes as proposed, between October 1, 2013 and September 30, 2014. Assumes no change in utilization patterns, 2% discount factor, 33%/66% regional and hospital-specific blended target price, and 20 episode threshold for using low historical volume pricing approach. Assumes all participant hospitals with actual episode spending below target prices meet minimum quality thresholds.

As illustrated in Figure 4 where we display results from our national model for the proposed CCJR performance year 2 policies when the phase-in of repayment responsibility begins and under the assumption that utilization remains constant, we estimate that the 10 percent stop-loss limit would impact the amount of repayment due to the raw NPRA for about 11 percent of hospitals. For performance year 3, the 20 percent stop-loss limit would affect significantly fewer hospitals, only about 3 percent. We note that the stop-loss limit for years 3 through 5 where repayment responsibility is fully implemented is consistent with the BPCI Model 2 policy. While Figure 3 assumes no change in utilization patterns, under the model test we expect that the proposed stop-loss limits could actually affect a smaller percentage of hospitals in each performance year because we expect LEJR episode care redesign incentivized by the model's financial opportunities to generally reduce unnecessary utilization, thereby reducing actual episode spending and, correspondingly, any associated repayment amounts due to the raw NPRA. We note that we would include any post-episode spending amount due to Medicare according to the policy proposed in section III.C.8.d of this proposed rule in assessing the total repayment amount due to the raw NPRA against the stop-loss limit for the performance year to determine a hospital's total payment due to Medicare, if applicable.

We seek comment on our proposal to adopt a 10 percent stop-loss limit in performance year 2 and 20 percent stop-loss limit in performance year 3 and beyond in CCJR as hospital repayment responsibility for excess episode spending above the target price is phased in and then maintained in the model.

(2) Proposed Limit on Raw NPRA Contribution to Reconciliation Payments

We believe a limit on reconciliation payments for CCJR would be appropriate for several reasons. Due to the proposed nature of the CCJR model during performance year 1, when hospitals have no repayment responsibility for excess episode spending above the target price, CMS bears full financial responsibility for Medicare actual episode payments for an episode that exceed the target price, and we believe our responsibility should have judicious limits. Therefore, we believe it would be reasonable to cap a hospital's reconciliation payment due to the raw NPRA as a percentage of episode payment on the basis of responsible stewardship of CMS resources. In addition, we note that beginning in performance year 1, participant hospitals would be eligible for reconciliation payments due to the NPRA if actual episode expenditures are

less than the target price, assuming the proposed quality thresholds are met. This proposal for reconciliation payments due to the NPRA provides a financial incentive to participant hospitals from the beginning of the model to manage and coordinate care throughout the episode with a focus on ensuring that beneficiaries receive the lowest intensity, medically appropriate care throughout the episode that results in high quality outcomes. Therefore, we also believe it would be reasonable to cap a hospital's reconciliation payment due to the raw NPRA based on concerns about potential excessive reductions in utilization under the CCJR model that could lead to beneficiary harm.

In determining what would constitute an appropriate reconciliation payment limit due to the raw NPRA, we believe it should provide significant opportunity for hospitals to receive reconciliation payments for greater episode efficiency that includes achievement of quality care and actual episode payment reductions below the target price, while avoiding creating significant incentives for sharply reduced utilization that could be harmful to beneficiaries. Thus, for all 5 performance years of the model, we propose a limit on the raw NPRA contribution to the reconciliation payment of no more than 20 percent of the hospital's target prices for each MS–DRG multiplied by the number of the hospital's episodes for that MS–DRG. Hereinafter we refer to this proposed reconciliation payment limit as the stop-gain limit. This proposed stop-gain limit is parallel to the 20 percent stop-loss limit proposed for performance year 3 and beyond. We believe that a parallel stop-gain and stop-loss limit is important to provide proportionately similar protections to CMS and participant hospitals for their financial responsibilities under CCJR, as well as to protect the health of beneficiaries.

As illustrated in Figure 3 where we display results from our national model for the proposed CCJR performance year 2 policies under the assumption that utilization remains constant, we estimate that the 20 percent stop-gain limit would impact the reconciliation payment amount due to the raw NPRA of almost no hospitals. We note that a stop-gain limit of 20 percent is consistent with BPCI Model 2 policy. While Figure 3 assumes no change in utilization patterns, under the model test we expect that the proposed stop-gain limit could actually affect a few hospitals in each performance year because we expect LEJR episode care redesign incentivized by the model's financial opportunities to generally reduce unnecessary utilization, thereby reducing actual episode spending and, correspondingly, increasing any associated reconciliation payment amounts due to the raw NPRA. Nevertheless, we believe the proposed stop-gain limit of 20 percent provides substantial opportunity for hospitals to achieve savings over the target price without excessive reductions in utilization, and those savings would be paid back to hospitals fully in most cases without being affected by the stop-gain limit. We seek comment on our proposal to adopt a 20 percent stop-gain limit for all performance years of CCJR.

We note that we plan to monitor beneficiary access and utilization of services and the potential contribution of the stop-gain limit to any inappropriate reduction in episode services. We refer readers to section III.F. of this proposed rule for our proposals on monitoring and addressing hospital performance under CCJR.

c. Proposed Policies for Certain Hospitals To Further Limit Repayment Responsibility

As discussed in section III.C.3. of this proposed rule, we propose that participant hospitals would be subject to repayment responsibility for episode actual spending in excess of the applicable target price beginning in performance year 2. Hospitals participating in CCJR would not be responsible for actual episode payments greater than a ceiling set at two standard deviations above the mean regional episode payment as described earlier in this section. Additionally, we propose a 10 percent limit on the raw NPRA contribution to the repayment mount in performance year 2 and a 20 percent limit on the raw NPRA contribution to the repayment amount in performance year 3 and beyond, as described in the previous section of this proposed rule.

Though our proposals provide several safeguards to ensure that participant hospitals have limited repayment responsibility due to the raw NPRA, we are proposing additional protections for certain groups of hospitals that may have a lower risk tolerance and less infrastructure and support to achieve efficiencies for high payment episodes. Specifically, we are proposing additional protections for rural hospitals, SCHs, Medicare Dependent Hospitals and Rural Referral Centers (RCCs). We note that these categories of hospitals often have special payment protections or additional payment benefits under Medicare because we recognize the importance of preserving Medicare beneficiaries' access to care from these hospitals. In MedPAC's Report to the Congress in June 2012, MedPAC examined issues related to rural Medicare beneficiaries and found that ''The primary objective of rural special payments is to ensure that Medicare does its part to support the financial viability of rural providers that are necessary for beneficiaries' access to care. Some form of special payments will be needed to maintain access in areas with low population density where providers inevitably have low patient volumes and lack economies of scale.'' [40]

We propose that a rural hospital would have additional protections under the stop-loss limit proposal. For the purpose of this model, we are proposing to define a rural hospital as an IPPS hospital that is either located in a rural area in accordance with § 412.64(b) or in a rural census tract within an MSA defined at § 412.103(a)(1) or has reclassified to rural in accordance with § 412.103 Such rural hospitals would have additional protections under the stop-loss limit proposal. Consistent with the findings in MedPAC's June 2012 Report to the Congress, we believe rural hospitals may have a lower risk tolerance and less infrastructure and support to achieve efficiencies for high payment episodes, particularly if they are the rural hospital is the only hospital in an area.

Our preliminary analysis examining national spending for MS–DRGs 469 and 470 from October 1, 2013 to September 30, 2014 showed that MS–DRGs 469 and 470 cases represent a slightly higher proportion of cases and spending for rural hospitals than the national average (for example, MS–DRG 470 episode spending represents 12 percent of IPPS spending for rural hospitals and represents 9 percent of IPPS spending nationally).[41] Additionally, our analysis on the distribution of national spending of MS–DRGs 469 and 470 episodes by service type (that is inpatient, outpatient, SNF, Home Health, Physician Part B, DME), found that on average, inpatient services account for the most spending for an MS–DRGs 469 and 470 episode (53 percent of spending for an MS–DRG 469 episode and 55 percent of spending for MS–DRG 470 episode). SNF services account for 27 percent of spending for MS–DRG 469 and 18 percent of spending for MS–DRG 470. The spending distribution for all rural IPPS hospitals also differs from the

[40] MedPAC Report to Congress June 2012, Chapter 5, page 121.

[41] Medicare FFS Parts A and B claims, CCJR episodes as proposed, between October 1, 2013 and September 30, 2014.

national average. For rural hospitals, inpatient services for CCJR episodes account for more spending than the national average (56 percent for MS–DRG 469 and 57 percent for MS–DRG 470 for rural hospitals) and SNF spending is higher than the national average (29 percent for MS–DRG 469 and 21 percent for MS–DRG 470 for rural hospitals). It is evident that this category of hospitals has different spending patterns than the national average. Furthermore, hospitals in rural areas often face other unique challenges. Rural hospitals may be the only source of healthcare services for beneficiaries living in rural areas, and beneficiaries have limited alternatives should rural hospitals be subject to financial changes under this model. Additionally, because rural hospitals may be in areas with fewer providers including fewer physicians and PAC facilities, rural hospitals may have more limited options in coordinating care and reducing spending while maintain quality of care under this model. We believe that urban hospitals may not have similar concerns as they are often in areas with many other providers and have greater opportunity to develop efficiencies under this model. Given that rural hospitals have different episode spending patterns, have different challenges in coordinating care and reducing cost than urban hospitals and serve as a primary access to care for beneficiaries, we believe that we should have a more protective stop-loss limit policy as described later in this section.

Additionally, we propose to provide additional protections for SCHs as defined in § 412.92, Medicare Dependent Hospitals as defined in § 412.108 and RRCs as defined in § 412.96. Hospitals paid under the IPPS can qualify for SCH status if they meet one of the following criteria:

- Located at least 35 miles from other like hospitals.
- Located in a rural area, located between 25 and 35 miles from other like hospitals, and no more than 25 percent of residents or Medicare beneficiaries who become hospital inpatients in the hospital's service area are admitted to other like hospitals located within a 35-mile radius of the hospital or the hospital has fewer than 50 beds and would meet the 25 percent criterion if not for the fact that some beneficiaries or residents were forced to seek specialized care outside of the service area due to the unavailability of necessary specialty services at the hospital.
- Hospital is rural and located between 15 and 25 miles from other like hospitals but because of local topography or periods of prolonged severe weather conditions, the other like hospitals are inaccessible for at least 30 days in each of 2 out of 3 years.
- Hospital is rural and the travel time between the hospital and the nearest like hospital is at least 45 minutes.

If an IPPS hospital qualifies to be a SCH, the hospital can be paid the higher of the federal payment rate paid to IPPS hospitals or a cost-based hospital-specific rate as described in § 412.78. Under OPPS, a rural SCH can receive a 7.1 percent add on payment for most services with certain exceptions, in accordance with § 419.43(g). These criteria to qualify for SCH status demonstrate that SCHs are likely to be the sole hospital in an area. Furthermore, additional payments provided under Medicare FFS for SCHs, demonstrates Medicare's interest in ensuring these hospitals are able to provide services to the Medicare beneficiaries who may have limited access to providers in their area. As a result, we believe that we should provide SCHs additional protections from hospital responsibility for repayment in this model. We note that we propose to exclude these add-on payments for SCHs, as described in section III.C.3.a of this proposed rule.

MDHs are defined as a hospital that meets the following criteria:

- Located in a rural area.
- Has 100 beds or less.
- Is not a SCH.
- Sixty percent of the hospital's inpatient days or discharges were attributable to individuals entitled to Medicare Part A benefits during specified time periods as provided in § 412.108.

MDHs also qualify for special additional payments under the IPPS where an MDH can receive the higher of a payment under the federal standard rate for IPPS hospitals or the payment under federal standard rate for IPPS hospitals plus 75 percent of the difference in payments between a cost based hospital-specific rate and the federal standard rate as described in § 412.108(c). These criteria demonstrate that MDHs are small, rural hospitals that have a high Medicare case mix percentage and receive additional payments under the IPPS to ensure financial stability and preserve beneficiary access to care to these hospitals. Thus, we believe these factors demonstrate that we should provide additional safeguards from hospital responsibility for repayment in order to preserve access to care. We note that we propose to exclude these payment enhancements for MDHs, as described in section III.C.3.a. of this proposed rule.

RRCs are defined as IPPS hospitals with at least 275 beds that meet the following criteria:

- Fifty percent of the hospital's Medicare patients are referred from other hospitals or from physicians who are not on the staff of the hospital.
- At least 60 percent of the hospital's Medicare patients live more than 25 miles from the hospital.
- At least 60 percent of all services the hospital furnishes to Medicare patients are furnished to patients who live more than 25 miles from the hospital.

If a hospital does not meet the criteria described previously, a hospital can also qualify for RRC status if a hospital meets the following criteria:

- For specified period of time, the hospital has a case-mix that equals the lower of the median case mix index (CMI) value for all urban hospitals nationally; or the median CMI value for urban hospitals located in its region, excluding those hospitals receiving indirect medical education payments.
- Its number of discharges is at least—

++ 5,000 (or 3,000 for an osteopathic hospital); or

++ The median number of discharges for urban hospitals in the census region in which it is located, set by the CMS through IPPS rulemaking.

- Additionally, a hospital must meet one of the following criteria:

++ More than 50 percent of its active medical staff are specialists who meet the conditions specified at § 412.96(c)(3).

++ At least 60 percent of all discharges are for inpatients who reside more than 25 miles from the hospital.

++ At least 40 percent of all inpatients treated are referred from other hospitals or from physicians who are not on the hospital's staff.

As an RRC, a hospital can qualify for several additional payments under the IPPS. For example, an RRC is not subject to the 12 percent cap on Medicare Disproportionate Share Hospital payments that a rural hospital would otherwise be subject to, in accordance with § 412.106(d). Although RRCs are larger and have a higher Medicare patient mix, they often serve as the sole provider to treat higher acuity cases, as demonstrated by the RRC qualification criteria. As a result of these unique characteristics of these hospitals, RRCs can receive additional payments under Medicare FFS. Thus, it is also important to provide additional protections for RRCs such that participation in this model does not

result in significant financial loss that may reduce access for Medicare beneficiaries.

For these reasons, we propose a stop-loss limit of 3 percent of episode payments for these categories of hospitals in performance year 2 and a stop-loss limit of 5 percent of episode payments for performance years 3 through 5. More specifically, in performance year 2, a rural hospital, SCH, RRC or MDH that is a participant hospital would owe Medicare due to the raw NPRA no more than 3 percent of the hospital's target price for the anchor MS–DRG multiplied by the number of the hospital's CCJR episodes with that anchor MS–DRG in the performance year. Additionally, in performance years 3 through 5, a rural hospital, SCH, RRC or MDH that is a participant hospital would owe Medicare due to the raw NPRA no more than 5 percent of the hospital's target price for the anchor MS–DRG multiplied by the number of the hospital's CCJR episodes with that anchor MS–DRG in the performance year. We believe a different stop-loss limit policy is warranted given the different spending patterns and the unique hospital characteristics for these groups of hospitals as described earlier. We believe this proposal strikes an appropriate balance between protecting hospitals that often serve as the only access of care for Medicare beneficiaries and having these hospitals meaningfully participate in the model. We note that this proposal does not impact the proposed stop-gain policy for these categories of hospitals. Rural hospitals, SCHs, MDHs and RRCs still have the opportunity to participate in full gains at 20 percent similar to other hospitals.

Hospitals can apply for SCH, MDH and RRC status through their MACs and Regional Office at any time. MACs maintain the list of SCHs, MDHs, and RRCs in the CMS Provider Specific File, which they update on a quarterly basis. The special hospital designations recorded in the Provider Specific File are used in Medicare claims pricing to ensure that these hospitals are paid according to their special hospital designation. Additionally, CMS can identify which hospitals are considered rural for the purpose of this policy, using the Provider Specific File to identify physical geographic location of a hospital and the MACs to identify whether an urban hospital has reclassified to rural under 42 CFR 412.103 or located in a rural census tract of an MSA defined under 42 CFR 412.103(a)(1). Thus, we propose to identify rural hospitals, MDHs, SCHs and RRCs at the time of reconciliation using the Provider Specific File updated in December of the end of the performance year and information from the MACs, and those hospitals would be subject to the 3 percent stop-loss limit policy for that performance year 2, and 5 percent stop-loss limit policy in performance years 3 through 5. For example, to identify the hospitals that would receive a 3 percent stop-loss limit for performance year 2, we would use the Provider Specific File updated in December 2017. We note that the special Medicare payment designation of MDH status has been extended through FY 2017 by legislation under the Medicare Access and CHIP Reauthorization Act of 2015. As a result, the proposed additional protections for hospital responsibility for repayment for MDHs would only apply to the extent that MDH status exists under Medicare. In other words, should MDH expire on or after September 30, 2017, we would not identify hospitals as MDHs to receive the 5-percent stop-loss limit policy for performance year 3. Though MDH status is set to expire after the third quarter of 2017, we would still identify MDHs to receive the 3-percent stop loss limit policy for all of performance year 2.

We note that we also considered excluding rural hospitals, SCHs, MDHs and RRCs from the CCJR model altogether due to our concerns of placing significant responsibility for actual episode payment above the target price on these hospitals. Additionally, we were also concerned that from an evaluation perspective, we would not have sufficient sample size of CCJR episodes from these categories of hospitals to have significant results of how these groups of hospitals perform under this model. We weighed our reasons for excluding these hospitals with the potential qualitative information we would gain from payment innovation tests on rural hospitals in this model. We concluded that because the CCJR model strives to test episode payment for a broad variety of hospitals, it would be preferable to include these hospitals in the CCJR model and provide additional protections from a large repayment responsibility. We welcome public comment on our proposed stop-loss limit for rural hospitals, SCHs, MDHs and RRCs and on our alternative consideration to exclude these hospitals entirely from the CCJR model.

d. Proposed Hospital Responsibility for Increased Post-Episode Payments

We noted that while the proposed CCJR episode would extend 90-days post-discharge from the anchor hospitalization, some hospitals may have an incentive to withhold or delay medically necessary care until after an episode ends to reduce their actual episode payments. We do not believe this would be likely, especially given the relatively long episode duration. However, in order to identify and address such inappropriate shifting of care, we propose to calculate for each performance year the total Medicare Parts A and B expenditures in the 30-day period following completion of each episode for all services covered under Medicare Parts A and B, regardless of whether or not the services are included in the proposed episode definition (section III.B of this proposed rule), as is consistent with BPCI Model 2. Because we base the proposed episode definition on exclusions, identified by MS–DRGs for readmissions and ICD–9–CM diagnosis codes for Part B services as discussed in section III.B. of this proposed rule, and Medicare beneficiaries may typically receive a wide variety of related (and unrelated) services during the CCJR episode that extends 90 days following discharge from the anchor hospitalization, there is some potential for hospitals to inappropriately withhold or delay a variety of types of services until the episode concludes, without attending carefully to the episode definition, especially for Part B services where diagnosis coding on claims may be less reliable. This inappropriate shifting could include both those services that are related to the episode (for which the hospital would bear financial responsibility as they would be included in the actual episode spending calculation) and those that are unrelated (which would not be included in the actual episode spending calculation), because a hospital engaged in shifting of medically necessary services outside the episode for potential financial reward may be unlikely to clearly distinguish whether the services were related to the episode or not in the hospital's decisions.

This calculation would include prorated payments for services that extend beyond the episode as discussed in section III.C.3.b. of this proposed rule. Specifically, we would identify whether the average 30-day post-episode spending for a participant hospital in any given performance year is greater than three standard deviations above the regional average 30-day post-episode spending, based on the 30-day post-episode spending for episodes attributed to all CCJR eligible hospitals in the same region as the participant hospital. We propose that beginning in performance year 2, if the hospital's average post-episode spending exceeds

this threshold, the participant hospital would repay Medicare for the amount that exceeds such threshold, subject to the stop-loss limits proposed elsewhere in this proposed rule. We seek comment on this proposal to make participant hospitals responsible for making repayments to Medicare based on high spending in the 30 days after the end of the episode and for our proposed methodology to calculate the threshold for high post-episode spend.

9. Proposed Appeal Procedures

Under the CCJR model, we propose that we would determine target prices for episodes of care using the methodology described in section III.C. of this proposed rule. We propose to institute a reconciliation payment process as described in section III.C.6, of this proposed rule, and we propose to retrospectively calculate a participant hospital's actual episode performance relative to its target price after the completion of each performance year. The difference between the actual episode spending of each CCJR episode and the target price of that episode (calculated as target price subtracted by CCJR actual episode payment) would be aggregated for all episodes initiated at a participant hospital during each performance year. This calculation for a participant hospital would be adjusted for post-episode payment increases and stop gain and stop loss limits, as described in section III.C.6.a. of this proposed rule. We propose to use quality measure percentiles to determine hospital eligibility to receive the reconciliation payment and use the successful reporting of the voluntary PRO THA/TKA data to adjust the reconciliation payment, as described in section III.C.5. of this proposed rule. The NPRA would be reflected in a report sent to the participant hospital called the CCJR Reconciliation Report.

We also propose to institute appeals processes for the CCJR model that would allow participant hospitals to appeal matters related to reconciliation and payment (that are previously discussed in this section), as well as non-payment related issues, such as enforcement matters detailed in section III.C.12.

a. Payment Processes

The proposed processes with regard to reconciliation, payment, use of quality measures to determine payment, and stop-loss and stop-gain policies are set forth in detail in sections III.C.5–8. In this section, we propose an appeals processes that will apply to the matters addressed in sections III.C.5–8, as well as matters not related to payment or reconciliation. These appeals processes will apply to the following payment and reconciliation processes:

- Starting with the CCJR Reconciliation Report for performance year 1, if the CCJR Reconciliation Report indicates the reconciliation amount is positive, CMS would issue a payment, in a form and manner specified by CMS, for that amount to the awardee within 30 calendar days from the issue date of the CCJR Reconciliation Report, unless the participant hospital selects to pursue the calculation error and reconsideration review processes, in which case payment will be delayed as detailed later in this section.
- For performance year 1, if the CCJR reconciliation report indicates a repayment amount, the participant hospital would not be required to make payment for that amount to CMS, as we have proposed not to hold hospitals financially responsible for negative NPRAs for the first performance year. In addition, if it is determined that a CCJR hospital has a positive NPRA for performance year 1, and the subsequent calculation for performance year 1 the following year, as described in section III.C.6. of this proposed rule, determines that in aggregate the performance year 1 NPRA and the subsequent calculation amount for performance year 1 is a negative value (adding together the NPRA amount from the reconciliation for performance year 1 as well as the amount determined in the subsequent calculation, which would be detailed on the CCJR reconciliation report for performance year 2), the hospital would only be financially responsible for a repayment amount that would net the performance year 1 NPRA and subsequent calculation for year 1 to zero. This would be true for performance year 1 only, given our proposal to begin phasing in financial responsibility in year 2 of the model as discussed in section III.C.2.c. of this proposed rule. For performance years 2 through 5 of the model, for example, if the NPRA for performance year 1 for a given hospital were $3,000, and the subsequent calculation performed in Q2 2018 to account for claims run-out and overlaps determined a repayment amount of $3,500 for claims incurred and overlap during performance year 1, $3,000 would be applied to the CCJR reconciliation report for performance year 2. If the NPRA for performance year 2 were $5,000, the repayment amount of $3,000 would be netted against the $5,000, and the reconciliation payment for performance year 2 would be $2,000. Given that downside risk has been waived for performance year 1, the remaining $500 would not be added to the CCJR reconciliation report for performance year 2. However, beginning with the reconciliation process for performance year 3, any repayment amounts generated through the subsequent calculation process detailed in section III.C.6.b. would be netted against any repayment or reconciliation amount on the respective CCJR reconciliation reports for performance years 2, 3, 4, and 5. Starting with the reconciliation for performance year 2, if the CCJR Reconciliation Report indicates the NPRA is negative, the participant hospital would make payment for the absolute value of that amount to CMS within 30-calendar days from the issue date of the CCJR Reconciliation Report, in a form and manner specified by CMS. Where the participant hospital does not issue payment within 30-calendar days, we will issue a demand letter requiring payment be made immediately.
- The reconciliation or repayment amount may include adjustments, arising from matters from the previous performance year, as necessary to account for subsequent calculations performed for performance years that were specified in earlier CCJR Reconciliation Reports, as discussed in section III.C.6. of this proposed rule. For example, we would potentially make determinations of additional monies owed by Medicare to participant hospitals or vice versa in subsequent periods based on the availability of updated Medicare administrative data. These subsequent calculations would be contained in the succeeding reconciliation report. For example, the subsequent calculations applicable to performance year 1 would be contained in the reconciliation report for performance year 2.
- If the participant hospital fails to pay CMS the amount owed by the date indicated in the demand letter, CMS will recoup owed monies from participant hospital's present and future Medicare payments to collect all monies due to CMS. While we propose that a participant hospital may enter into financial arrangements with CCJR collaborators that allow for some risk-sharing, as discussed in section III.C. of this proposed rule, the participant hospital would be solely liable for the repayment of the negative repayment amount to CMS. Where the participant hospital fails to repay CMS in full for all monies owed, CMS would invoke all legal means to collect the debt, including referral of the remaining debt to the United States Department of the Treasury, pursuant to 31 U.S.C. 3711(g).

b. Calculation Error

We propose the following calculation error process for participant hospitals to contest matters related to payment or reconciliation, of which the following is a non-exhaustive list: The calculation of the participant hospital's reconciliation amount or repayment amount as reflected on a CCJR reconciliation report; the calculation of NPRA; the calculation of the percentiles of quality measure performance to determine eligibility to receive a reconciliation payment; and the successful reporting of the voluntary PRO THA/TKA data to adjust the reconciliation payment. Participant hospitals would review their CCJR reconciliation report and be required to provide written notice of any error, in a calculation error form that must be submitted in a form and manner specified by CMS. Unless the participant provides such notice, the reconciliation report would be deemed final within 30 calendar days after it is issued, and CMS would proceed with payment or repayment. If CMS receives a timely notice of an error in the calculation, CMS would respond in writing within 30 calendar days to either confirm or refute the calculation error, although CMS would reserve the right to an extension upon written notice to the participant hospital. We propose that if a participant hospital does not submit timely notice of calculation error in accordance with the timelines and processes specified by CMS, the participant hospital would be precluded from later contesting any of the following matters contained in the CCJR reconciliation report for that performance year: any matter involving the calculation of the participant hospital's reconciliation amount or repayment amount as reflected on a CCJR reconciliation report; any matter involving the calculation of NPRA; the calculation of the percentiles of quality measure performance to determine eligibility to receive a reconciliation payment; and the successful reporting of the voluntary PRO THA/TKA data to adjust the reconciliation payment.

c. Dispute Resolution

(1) Limitations on Review

In accordance with section 1115A(d) of the Act, there is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

- The selection of models for testing or expansion under section 1115A of the Act.
- The selection of organizations, sites or participants to test those models selected.
- The elements, parameters, scope, and duration of such models for testing or dissemination.
- Determinations regarding budget neutrality under subsection 1115A(b)(3).
- The termination or modification of the design and implementation of a model under subsection 1115A(b)(3)(B).
- Decisions about expansion of the duration and scope of a model under subsection 1115A(c), including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such subsection.

(2) Matters Subject to Dispute Resolution

We propose that a participant hospital may appeal an initial determination that is not precluded from administrative or judicial review by requesting reconsideration review by a CMS official. The request for review must be submitted for receipt by CMS within 10 days of the notice of the initial determination. Initial determinations that are not precluded from administrative or judicial review would include the involuntary termination of a participant hospital's participation in the CCJR model.

(3) Dispute Resolution Process

We propose the following dispute resolution process. First, we propose that only a participant hospital may utilize the dispute resolution process. Second, in order to access the dispute resolution process a participant hospital must have timely submitted a calculation error form, as previously discussed, for any matters related to payment. We propose these matters would include any amount or calculation indicated on a CCJR reconciliation report, including calculations not specifically reflected on a CCJR reconciliation report but which generated figures or amounts reflected on a CCJR reconciliation report. The following is a non-exhaustive list of the matters we propose would need to be first adjudicated by the calculation error process as previously detailed: calculations of reconciliation or repayment amounts; calculations of NPRA; and any calculations or percentile distribution involving quality measures that we propose could affect reconciliation or repayment amounts. If a participant hospital wants to engage in the dispute resolution process with regard to one of these matters, we propose it would first need to submit a calculation error form. Where the participant hospital does not timely submit a calculation error form, we propose the dispute resolution process would not be available to the participant hospital with regard to those matters for the reconciliation report for that performance year.

If the participant hospital did timely submit a calculation error form and the participant hospital is dissatisfied with CMS's response to the participant hospital's notice of calculation error, the hospital would be permitted to request reconsideration review by a CMS reconsideration official. The reconsideration review request would be submitted in a form and manner and to an individual or office specified by CMS. The reconsideration review request would provide a detailed explanation of the basis for the dispute and include supporting documentation for the participant hospital's assertion that CMS or its representatives did not accurately calculate the NPRA or post-episode spending amount in accordance with CCJR rules. The following is a non-exhaustive list of representative payment matters:

- Calculations of NPRA, post-episode spending amount, target prices or any items listed on a reconciliation report.
- The application of quality measures to a reconciliation payment, including the calculation of the percentiles thresholds of quality measure performance to determine eligibility to receive reconciliation payments, or the successful reporting of the voluntary PRO THA/TKA data to adjust the reconciliation payment.
- Any contestation based on the grounds that CMS or its representative made an error in calculating or recording such amounts.

Where the matter is unrelated to payment, such as termination from the model, the participant hospital need not submit a calculation error form. We propose to require the participant hospital to timely submit a request for reconsideration review, in a form and manner to be determined by CMS. Where such request is timely received, we propose CMS would process the request as discussed later in this section.

We propose that the reconsideration review would be an on-the-record review (a review of briefs and evidence only). The CMS reconsideration official would make reasonable efforts to notify the hospital in writing within 15 calendar days of receiving the participant hospital's reconsideration review request of the date and time of the review, the issues in dispute, the review procedures, and the procedures (including format and deadlines) for submission of evidence (the ''Scheduling Notice''). The CMS reconsideration official would make reasonable efforts to schedule the

review to occur no later than 30 days after the date of the Scheduling Notice. The provisions at § 425.804(b), (c), and (e) (as in effect on the publication date of this proposed rule) would apply to reviews conducted pursuant to the reconsideration review process for CCJR. The CMS reconsideration official would make reasonable efforts to issue a written determination within 30 days of the review. The determination would be final and binding.

We solicit comment on our proposals related to appeals rights under this model. The two-step appeal process for payment matters—(1) calculation error form, and (2) reconsideration review—is used broadly in other CMS models. We seek comment on whether we should develop an alternative appeal process. We are also interested in whether there should be appeal rights for reductions or eliminations of NPRA as a result of enforcement actions, as discussed in section III.C.12 of this proposed rule, and if so, whether the process for such appeals should differ from the processes proposed here.

In accordance with section 1115A of the Act, we are proposing to codify these proposals in regulation in the new proposed part 510 of the CFR.

10. Proposed Financial Arrangements and Beneficiary Incentives

a. Financial Arrangements and Beneficiary Incentives

As discussed earlier in this proposed rule, we propose that CCJR would be a retrospective episode payment model, under which Medicare payments for services included in an episode of care would continue to be made to all providers and suppliers under the existing payment systems, and episode payment would be based on later reconciliation of episode actual spending under those Medicare payment systems to the episode target price. If the episode actual spending is less than the target price, the participant hospital would receive a reconciliation payment, assuming quality performance thresholds are met and the stop-gain threshold is not exceeded. If the episode actual spending exceeds the target price, beginning in performance year 2 hospitals would repay the difference to Medicare up to the stop-loss threshold.

We believe that participant hospitals may wish to enter into financial arrangements with providers and suppliers caring for beneficiaries in CCJR episodes in order to align the financial incentives of those providers and suppliers with the model goals of improving quality and efficiency for LEJR episodes. For example, given that the proposed episode duration is 90 days following discharge from the anchor hospital stay and the episodes are broadly defined (see section III.B of this proposed rule), many providers and suppliers other than the participant hospital will furnish related services to beneficiaries during episodes. Those providers and suppliers may include physicians, physician group practices, skilled nursing facilities (SNFs), home health agencies (HHAs), inpatient rehabilitation facilities (IRFs), long term care hospitals (LTCHs), outpatient therapy providers, and others. We expect that participant hospitals will identify key providers and suppliers for CCJR beneficiaries in their communities and then establish close partnerships with them to assist the hospital in redesigning care for LEJR episodes to improve quality and efficiency, coordinating and managing care for beneficiaries, monitoring episode performance, and refining care pathways. These providers and suppliers may invest substantial time and other resources in these activities, yet they would neither be the direct recipients of any reconciliation payments from Medicare, nor directly responsible for repaying Medicare for excess episode spending. Therefore, we believe it is possible that a participant hospital that may receive a reconciliation payment from Medicare or may need to repay Medicare may want to enter into financial arrangements with other providers and suppliers to share risks and rewards under CCJR.

In addition to providers and suppliers with which the participant hospital may want to enter into financial arrangements to share risks and reward, we expect that participant hospitals may choose to engage with organizations that are neither providers nor suppliers to assist with matters such as: episode data analysis; local provider and supplier engagement; care redesign planning and implementation; beneficiary outreach; CCJR beneficiary care coordination and management; monitoring participant hospital compliance with the terms and conditions of the CCJR model; or other model-related activities. These organizations may play important roles in a hospital's plans to implement the CCJR model based on the experience these organizations may bring to the hospital's successful participation in the model, such as prior experience with bundled payment initiatives, care coordination expertise, familiarity with the local community, and knowledge of Medicare claims data. We expect that all relationships established between participant hospitals and these organizations for purposes of the CCJR model would only be those permitted under existing law and regulation, including any relationships that would include the participant hospital's sharing of CCJR model risks and rewards with these organizations. We would expect that all of these relationships would solely be based on the level of engagement of the organization's resources to directly support the participant hospitals' CCJR model implementation.

Additionally, because the proposed broadly defined LEJR episodes extend 90-days post-discharge from the anchor hospital stay, we believe that participant hospitals caring for CCJR beneficiaries may want to offer beneficiary incentives to encourage beneficiary adherence to recommended treatment and active patient engagement in recovery. Such incentives should be closely related to the provision of high quality care during the episode and advance a clinical goal for a CCJR beneficiary, and should not serve as inducements to beneficiaries to seek care from the participant hospital or other specific suppliers and providers. Such incentives may help participant hospitals reach their quality and efficiency goals for CCJR episodes, while benefitting beneficiaries' health and the Medicare Trust Fund if hospital readmissions and complications are reduced while recovery continues uninterrupted or accelerates.

(1) Financial Arrangements Under the CCJR Model

As previously noted, we believe that given the financial incentives of episode payment in CCJR, participant hospitals in the model may want to engage in financial arrangements to share reconciliation payments or hospital internal cost savings or both, as well as responsibility for repaying Medicare, with providers and suppliers making contributions to the hospital's episode performance on spending and quality. Such arrangements would allow the participant hospitals to share all or some of the reconciliation payments they may be eligible to receive from CMS, or the participant hospital's internal cost savings that result from care for beneficiaries during a CCJR episode. Likewise, such arrangements could allow the participant hospitals to share the responsibility for the funds needed to repay Medicare with providers and suppliers engaged in caring for CCJR beneficiaries, if those providers and suppliers have a role in the hospital's episode spending or quality performance. We propose to use the term ''CCJR collaborator'' to refer to

such providers and suppliers, who may include the following:

- SNFs.
- HHAs.
- LTCHs.
- IRFs.
- Physician Group Practices (PGPs).
- Physicians, nonphysician practitioners, and outpatient therapy providers.

We believe that CCJR collaborators should have a role in the participant hospital's episode spending or quality performance. Accordingly, we propose that the CCJR collaborator would directly furnish related items or services to a CCJR beneficiary during the episode and/or specifically participate in CCJR model LEJR episode care redesign activities, such as attending CCJR meetings and learning activities; drafting LEJR episode care pathways; reviewing CCJR beneficiaries' clinical courses; developing episode analytics; or preparing reports of episode performance, under the direction of the participant hospital or another CCJR collaborator that directly furnishes related items and services to CCJR beneficiaries. Note that we propose later in this section a limit on Gainsharing Payments (as that term is defined later in this section) to physician or nonphysician CCJR collaborators, as well as to physician group practices, related to PFS payments for services furnished to CCJR beneficiaries. Therefore, in addition to playing a role in the participant hospital's episode spending or quality performance, physician, nonphysician, and physician group practice CCJR collaborators must additionally directly furnish services to CCJR beneficiaries in order to receive a Gainsharing Payment as result of their financial arrangement with the participant hospital. We seek comment on our proposed definition of CCJR collaborators, as well as our proposed definition of a provider's or supplier's role in the participant hospital's episode spending or quality performance.

We propose that certain financial arrangements between a participant hospital and a CCJR collaborator be termed a ''CCJR Sharing Arrangement,'' and that the terms of each CCJR Sharing Arrangement be set forth in a written agreement between the participant hospital and the CCJR collaborator. We propose to use the term ''Participation Agreement'' to refer to such agreements. We propose that a ''CCJR Sharing Arrangement'' would be a financial arrangement contained in a Participation Agreement to share only the following: (1) CCJR reconciliation payments (as that term is defined in section III.C of this proposed rule); (2) the participant hospital's internal cost savings (as that term is defined later in this section); and (3) the participant hospital's responsibility for repayment to Medicare, as discussed later in this section. Where a payment from a participant hospital to a CCJR collaborator is made pursuant to a CCJR Sharing Arrangement, we propose to define that payment as a ''Gainsharing Payment.'' A Gainsharing Payment may only be only composed of the following: (1) Reconciliation payments; (2) internal cost savings; or (3) both. Where a payment from a CCJR collaborator to a participant hospital is made pursuant to a CCJR Sharing Arrangement, we propose to define that payment as an ''Alignment Payment.'' We propose that CCJR Sharing Arrangements that provide for Alignment Payments would not relieve the participant hospital of its ultimate responsibility for repayment to CMS. Many of the programmatic requirements discussed later in this proposed rule for Gainsharing Payments and Alignment Payments are similar to those in Model 2 of the BPCI initiative.

The CCJR Sharing Arrangements between participant hospitals and CCJR collaborators must be solely related to the contributions of the CCJR collaborators to care redesign that achieve quality and efficiency improvements under this model for CCJR beneficiaries. All Gainsharing Payments or Alignment Payments between participant hospitals and CCJR collaborators resulting from these arrangements must be auditable by HHS, as discussed later in this section, to ensure their financial and programmatic integrity. We emphasize that any CCJR collaborator that receives a Gainsharing Payment or makes an Alignment Payment must have furnished services included in the episode to CCJR beneficiaries. Furthermore, the payment arrangements for Gainsharing Payments or Alignment Payments contained in a CCJR Sharing Arrangement must be actually and proportionally related to the care of beneficiaries in a CCJR episode, and the CCJR collaborator must be contributing to the care redesign strategies of the participant hospital.

We considered whether CCJR collaborators should be termed ''participants'' in this model, or whether the term ''participant'' should refer only to the participant hospitals located in MSAs selected for participation. If CCJR collaborators are participants in the model, we propose that their activities with regard to CCJR beneficiaries would be regulated directly by CMS. However, if CCJR collaborators are not participants, but rather are participating entities and individuals in the CCJR model through signed agreements with participant hospitals, their activities with regard to CCJR beneficiaries would be governed by the Participation Agreement between a CCJR collaborator and a participant hospital. Given the large number of potential CCJR collaborators, the expected varied nature of their respective arrangements with participant hospitals, and the potential administrative burden in reporting information to CMS, we believe the activities of CCJR collaborators with regard to CCJR beneficiaries would be best managed by participant hospitals. As we discussed earlier in this proposed rule, one justification for proposing that acute care hospitals be the provider type financially responsible under the CCJR model is the position of the hospital with respect to other providers and suppliers, in terms of coordinating care for CCJR beneficiaries. Given that position, we propose that where participant hospitals enter into Participation Agreements that contain CCJR Sharing Arrangements with CCJR collaborators, the participant hospital must also be responsible for ensuring that those providers and suppliers comply with the terms and requirements of this proposed rule. We seek comments on this proposal; specifically, whether CCJR collaborators should be termed participants in this model and subject to the applicable requirements, or whether the responsibility for compliance with the model's requirements is better managed by participant hospitals. We are particularly interested in comments that address the advantages and disadvantages of making CCJR collaborators participants in the model, and whether there are certain provider or supplier types that CMS should consider including as ''participants'' in the model.

The following discussion outlines our proposed requirements and responsibilities of participant hospitals that engage in such CCJR Sharing Arrangements. We believe these proposed requirements and responsibilities are essential to ensuring that all CCJR Sharing Arrangements are for the sole purpose of aligning the financial incentives of collaborating providers and suppliers with those of the participant hospital toward the CCJR model goals of improved LEJR episode care quality and efficiency. We believe that the rationale for and details of these arrangements must be documented and auditable by HHS, with a direct tie between the arrangements and the

participant hospital's episode performance. Finally, we believe that the proposed limitations to the arrangements, as described later in this section, are necessary to ensure the integrity of the CCJR model by minimizing incentives for problematic behaviors, such as patient steering. We seek comments on all proposed requirements regarding CCJR Sharing Arrangements.

With respect to whether certain entities or individuals should be prevented from participating in the CCJR model, either as participant hospitals or CCJR collaborators, we considered whether CMS should conduct screening for program integrity purposes. Many CMS models conduct screening during the application process and periodically thereafter. These screenings examine provider and supplier program integrity history, including any history of Medicare program exclusions or other sanctions and affiliations with individuals or entities that have a history of program integrity issues. Where a screening reveals that a provider or supplier has a history of program integrity issues or affiliations with individuals or entities that have a history of program integrity issues, we may remove that provider or supplier from the model. We utilize these screening processes for many CMS models, including the BPCI initiative.

For several reasons, we believe that this type of screening for participant hospitals is inapplicable to the CCJR model. Most importantly, this model seeks to evaluate the performance in the model of hospitals located in a particular MSA. We believe it is important that all hospitals that meet the criteria for participation in the model be included, even if those hospitals have a history of program integrity issues. Further, we propose that CMS would evaluate the quality of care and institute beneficiary protections in ways that would go beyond some of the efforts of previous or existing CMS models. We solicit comments on this proposal, including whether screening of participant hospitals or CCJR collaborators might be appropriate or useful in aiding HHS' program integrity efforts and identifying untrustworthy parties or parties with program integrity history problems.

(a) CCJR Sharing Arrangement Requirements

We propose that each CCJR Sharing Arrangement must include and set forth in writing at a minimum—

- A specific methodology and accounting formula for calculating and verifying internal cost savings, if the participant hospital elects to share internal cost savings through Gainsharing Payments with CCJR collaborators. We propose to define internal cost savings as the measurable, actual, and verifiable cost savings realized by the participant hospital resulting from care redesign undertaken by the participant hospital in connection with providing items and services to beneficiaries within specific CCJR episodes of care. Internal cost savings would not include savings realized by any individual or entity that is not the participant hospital. Each CCJR Sharing Arrangement must include specific methodologies for accruing and calculating internal cost savings of the participant hospital, where the hospital intends to share internal cost savings through a CCJR Sharing Arrangement with a CCJR collaborator. The specific methodologies for accruing and calculating internal cost savings must be transparent, measurable, and verifiable in accordance with Generally Accepted Accounting Principles (GAAP) and Government Auditing Standards (The Yellow Book). The methodology must set out the specific care redesign elements to be undertaken by the participant hospital or the CCJR collaborator or both;
- A description of the methodology and accounting formula for calculating the percentage or dollar amount of a reconciliation payment received from CMS that will be paid as a Gainsharing Payment from the participant hospital to the CCJR collaborator;
- A description of the methodology, frequency or dates of distribution, and accounting formula for distributing and verifying any and all Gainsharing Payments;
- A description of the arrangement between the participant hospital and the CCJR collaborator regarding Alignment Payments, where the hospital and CCJR collaborator agree through a CCJR Sharing Arrangement to share risk for repayment amounts due to CMS, as reflected on a CCJR reconciliation report. The description of this arrangement must include safeguards to ensure that such Alignment Payments are made solely for purposes related to sharing responsibility for funds needed to repay Medicare in the CCJR model. This description should also include a methodology, frequency of payment, and accounting formula for payment and receipt of any and all Alignment Payments;
- A provision requiring the participant hospital to recoup Gainsharing Payments paid to CCJR collaborators if Gainsharing Payments were based on the submission of false or fraudulent data;
- Plans regarding care redesign, changes in care coordination or delivery that are applied to the participant hospital or CCJR collaborators or both, and any description of how success will be measured;
- Management and staffing information, including type of personnel or contactors that will be primarily responsible for carrying out changes to care under the model;
- The participant hospital must maintain records identifying all CCJR collaborators, and the participant hospital's process for determining and verifying the eligibility of CCJR collaborators to participate in Medicare; and
- All CCJR Sharing Arrangements must require compliance, from both the participant hospital and the CCJR collaborator, with the proposed polices regarding beneficiary notification set forth in section III.F of this proposed rule.

With respect to these requirements for Participation Agreements and CCJR Sharing Arrangements, we considered whether we should require participant hospitals and CCJR collaborators to periodically report this information to CMS for purposes of enforcement of these proposed regulations. However, we are mindful of the administrative burden in reporting this information as well as the challenges associated with creating a universal collection tool that would account for all the various iterations of financial arrangements into which participant hospitals and CCJR collaborators may enter. Therefore, we are proposing to require participant hospitals to retain this documentation as previously described, as well as in section III.C.10(d) of this proposed rule. We seek comment on this proposal as well as whether CMS should require participant hospitals and CCJR collaborators to periodically report data such as: Gainsharing Payments and/or Alignment Payments distributed and received; name and identifier (NPI, CCN, TIN) of all CCJR collaborators; and any other relevant information related to Participation Agreements and CCJR Sharing Arrangements that would assist HHS with enforcement of these regulations.

We solicit comments about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

(b) Participation Agreement Requirements

We propose that the Participation Agreement must obligate the parties to comply, and must obligate the CCJR collaborator to require any of its employees, contractors or designees to comply, without limitation, to with the following requirements:

• Each individual's or entity's participation in the CCJR Sharing Arrangement is voluntary and without penalty for nonparticipation.

• Any Gainsharing Payments made pursuant to a CCJR Sharing Arrangement must be made only from the participant hospital to the CCJR collaborator with whom the participant hospital has signed a Participation Agreement containing a CCJR Sharing Arrangement. Additionally, we propose to require the following for all CCJR Sharing Arrangements between a participant hospital and a CCJR collaborator that is a physician group practice:

++ Where a Gainsharing Payment is made to a CCJR collaborator that is a physician group practice, all monies contained in such a Gainsharing Payment must be shared only with physician or nonphysician practitioners that furnished a service to a CCJR beneficiary during an episode of care in the calendar year from which the Net Payment Reconciliation Amount (NPRA), as that term is defined in section III.C.6. of this proposed rule, or internal cost savings was generated, either or both of which are the only permitted sources of funds for a Gainsharing Payment. We further propose that each CCJR Sharing Arrangement between a participant hospital and a CCJR collaborator that is physician group practice must stipulate that the physician group practice may not retain any portion of a Gainsharing Payment or distribute, by any method, any portion of a Gainsharing Payment to physician or nonphysician practitioners who did not furnish a service to a CCJR beneficiary during an episode of care in the calendar year from which the NPRA or internal cost savings was generated.

• Any Alignment Payments made pursuant to a CCJR Sharing Arrangement may be made only to the participant hospital from the entity or individual with whom the participant hospital has signed a Participation Agreement containing a CCJR Sharing Arrangement.

• Each CCJR Sharing Arrangement must require that the CCJR collaborator be in compliance with all Medicare provider enrollment requirements at § 424.500 *et seq.,* including having a valid and active TIN or NPI.

• Any internal cost savings or reconciliation payments that the participant hospital seeks to share through CCJR Sharing Arrangements must meet the requirements set forth in the final CCJR rule (as finalized) and be administered by the participant hospital in accordance with GAAP. In no event may the participant hospital distribute any amounts pursuant to a CCJR Sharing Arrangement that are not comprised of either internal cost savings or a reconciliation payment, as those terms are defined in this proposed rule. All amounts determined to be internal cost savings by the participant hospital must reflect actual, internal cost savings achieved by the participant hospital through implementation of care redesign elements identified and documented by the participant hospital. In no case may internal cost savings reflect ''paper'' savings from accounting conventions or past investment in fixed costs.

• Any Alignment Payments that the participant hospital receives through a CCJR Sharing Arrangement must meet the requirements set forth in the final CCJR rule (as finalized) and be administered by the participant hospital in accordance with GAAP.

• CCJR Sharing Arrangements must not include any amounts that are not Alignment Payments or Gainsharing Payments.

• Further, we propose that each Participation Agreement—

++ Between the participant hospital and a CCJR collaborator must obligate the CCJR collaborator to provide the participant hospital and HHS access to the CCJR collaborator's records, information, and data for purposes of monitoring and reporting and any other lawful purpose. Records, information, and data regarding the CCJR Sharing Arrangement must have sufficient detail to verify compliance with all material terms of the CCJR Sharing Arrangement and the terms of the CCJR model;

++ Must require the participant hospital and the CCJR collaborator to include in their compliance programs specific oversight of their CCJR participation agreements and compliance with the requirements of the CCJR mode;

++ Must require compliance, from both the participant hospital and the CCJR collaborator, with the proposed polices regarding beneficiary notification set forth in section III.F; and

++ Must require the board or other governing body of the participant hospital to have responsibility for overseeing the participant hospital's participation in the model, its arrangements with CCJR collaborators, its payment of Gainsharing Payments and receipt of Alignment Payments, and its use of beneficiary incentives in the CCJR model.

• Participation Agreements must require all CCJR collaborators to comply with any evaluation, monitoring, compliance, and enforcement activities performed by HHS or its designees for the purposes of operating the CCJR model.

• Each Participation Agreement must require the CCJR collaborator to permit site visits from CMS, or one of its designees, for purposes of evaluating the model.

We solicit comments about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

(c) Gainsharing Payment and Alignment Payment Conditions and Restrictions

We propose the following conditions and restrictions concerning Gainsharing Payments and Alignment Payments made pursuant to a CCJR Sharing Arrangement:

• No entity or individual, whether or not a party to a Participation Agreement, may condition the opportunity to receive Gainsharing Payments in CCJR on the volume or value of past or anticipated referrals or other business generated to, from, or among a participant hospital, any CCJR collaborators, and any individual or entity affiliated with a participant hospital or CCJR collaborator.

• Participant hospitals would not be required to share reconciliation payments, internal cost savings, or responsibility for repayment to CMS with other providers and suppliers. However, where a participant hospital elects to engage in those activities, we propose that such activities be limited to the provisions prescribed in this proposed rule.

• We propose that Gainsharing Payments must be distributed on an annual basis, and are required to meet the following criteria:

++ Must be clearly identified and comply with all provisions in this proposed rule, as well as all applicable laws, statutes, and rules;

++ Must not be a loan, advance payments, or payments for referrals or other business; and

++ Must be made by electronic funds transfer (EFT).

• We propose that Alignment Payments from a CCJR collaborator to a

participant hospital may be made at any interval, and are required to meet the following criteria:

++ Must be clearly identified and comply with all provisions in this proposed rule, as well as all applicable laws, statutes, and rules;

++ Must not be issued, distributed, or paid prior to the calculation by CMS of a reconciliation report reflecting a negative Net Payment Reconciliation Amount (NPRA);

++ Must not be a loan, advance payments, or payments for referrals or other business; and

++ Must be made by electronic funds transfer (EFT).

• We propose that each CCJR Sharing Arrangement stipulate that any CCJR collaborator that is subject to any action involving noncompliance with the provisions of this propose rule, engaged in fraud or abuse, providing substandard care, or have other integrity problems not be eligible to receive any Gainsharing Payments related to NPRA generated during the time that coincides with the action involving any of the issues previously listed until the action has been resolved.

• No entity or individual, as whether or not a party to a Participation Agreement, may condition the opportunity to make or receive Alignment Payments in CCJR on the volume or value of past or anticipated referrals or other business generated to, from, or among a participant hospital, any CCJR collaborators, and any individual or entity affiliated with a participant hospital or CCJR collaborator.

• In a calendar year, the aggregate amount of the total Gainsharing Payments distributed by the participant hospital that are derived from a CCJR reconciliation payment may not exceed the amount of the reconciliation payment that the participant hospital received from CMS.

• In a calendar year, the aggregate amount of the total Alignment Payments received by the participant hospital may not exceed 50 percent of the participant hospital's repayment amount due to CMS. If no repayment amount is due, then no Alignment Payments may be received by the participant hospital.

• We propose that the participant hospital must retain at least 50 percent of its responsibility for repayment to CMS, pursuant to the repayment amount reflected in each annual reconciliation report, under the CCJR model. Given that the participant hospital will be responsible for developing and coordinating care redesign strategies in response to its participation in the CCJR model, we believe it is important that the participant hospital retain a significant portion of its responsibility for repayment to CMS. For example, upon receipt of a reconciliation report indicating that the participant hospital owes $100 to CMS, the participant hospital would be permitted to receive no greater than $50 in Alignment Payments, in the aggregate, from its CCJR collaborators.

• Further, we propose that a CCJR Sharing Arrangement must limit the amount a single CCJR collaborator may make in Alignment Payments to a single participant hospital. We propose that a single CCJR collaborator not make an Alignment Payment to a participant hospital that represents an amount greater than 25 percent of the repayment amount reflected on the participant hospital's annual reconciliation report. For example, upon receipt of a reconciliation report indicating that the participant hospital owes $100 to CMS, the participant hospital would be permitted to receive no more than $25 in an Alignment Payment from a single entity or individual who is a CCJR collaborator of the participant hospital.

• Gainsharing Payments and Alignment Payments must not induce the participant hospital, CCJR collaborators, or the employees, contractors, or designees of the participant hospital or CCJR collaborators to reduce or limit medically necessary services to any Medicare beneficiary.

• Individual physician and nonphysician practitioners, whether or not a party to a CCJR Sharing Arrangement, must retain their ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

• Entities furnishing services to beneficiaries during a CCJR episode, whether or not a party to a CCJR Sharing Arrangement, must retain their ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

• Gainsharing methodologies for calculating Gainsharing Payments and Alignment Payments must not directly account for volume or value of referrals, or business otherwise generated, between or among a participant hospital, any CCJR collaborators, and any individual or entity affiliated with a participant hospital or CCJR collaborator.

• Gainsharing Payments must be derived solely from reconciliation payments or internal cost savings or both.

• The total amount of Gainsharing Payments for a calendar year paid to an individual physician or nonphysician practitioner who is a CCJR collaborator must not exceed a cap. The cap is 50 percent of the total Medicare approved amounts under the Physician Fee Schedule (PFS) for services furnished to the participant hospital's CCJR beneficiaries during a CCJR episode by that physician or nonphysician practitioner. This cap of 50 percent on Gainsharing Payments to individual physician or nonphysician practitioner is consistent with the same policy for the BPCI initiative. The purpose of this cap is to limit the amount of Gainsharing Payments an individual practitioner may receive due to his/her provision of services included in the CCJR model.

• The total amount of Gainsharing Payments for a calendar year paid to an physician group practice that is a CCJR collaborator must not exceed a cap. The cap is 50 percent of the sum of the total Medicare approved amounts under the Physician Fee Schedule (PFS) for services furnished by physician or nonphysician practitioner members of the physician group practice to the participant hospital's CCJR beneficiaries during a CCJR episode by those physicians or nonphysician practitioners.

We solicit comments about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

(d) Documentation and Maintenance of Records

We propose to require participant hospitals and CCJR collaborators to comply with audit and document retention requirements similar to those required by the Medicare Shared Savings Program, BPCI Model 2, and other Innovation Center models. Specifically, with respect to all Participation Agreements and CCJR Sharing Arrangements, the participant hospital and CCJR collaborator must:

• Comply with the retention requirements regarding Participation Agreements and CCJR Sharing Arrangements set forth in subsection III.C.10(a)–(d).

• Maintain and give CMS, the Office of Inspector General of the Department of Health and Human Services (OIG), and the Comptroller General or their designee(s) access to all books, contracts, records, documents, and other evidence (including data related to utilization and payments, quality performance measures, billings, and CCJR Sharing Arrangements related to

CCJR) sufficient to enable the audit, evaluation, inspection, or investigation of the participant hospital's compliance, as well as the compliance of any CCJR collaborator that has a CCJR Sharing Arrangement with the participant hospital, with CCJR requirements, the Participation Agreement, the quality of services furnished, the obligation to repay any reconciliation payments owed to CMS, the calculation, distribution, receipt, or recoupment of Gainsharing Payments or Alignment Payments.

• Maintain such books, contracts, records, documents, and other evidence for a period of 10 years from the last day of the participant hospital's participation in the CCJR model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

++ CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the participant hospital or CCJR collaborator at least 30 calendar days before the normal disposition date; or

++ There has been a dispute or allegation of fraud or similar fault against the participant hospital or any CCJR collaborator in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

• Notwithstanding any CCJR Sharing Arrangements between the participant hospital and CCJR collaborators, the participant hospital must have ultimate responsibility for adhering to and otherwise fully complying with all provisions of the CCJR model.

• OIG Authority is not limited or restricted by the provisions of the CCJR model, including the authority to audit, evaluate, investigate, or inspect the participant hospital, CCJR collaborators, or any other person or entity or their records, data, or information, without limitation.

• None of the provisions of the CCJR model limits or restricts any other government authority permitted by law to audit, evaluate, investigate, or inspect the participant hospital, CCJR collaborators, or any other person or entity or their records, data, or information, without limitation.

We solicit comments about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

(2) Beneficiary Incentives Under the CCJR Model

We believe that the CCJR model will incent participant hospitals to furnish directly and otherwise coordinate services throughout the episode that lead to higher quality care for the beneficiary and lower episode spending. We believe that one mechanism that may be useful to the participant hospital in achieving these goals is the provision of certain items and services to the beneficiary during the episode of care. We also considered whether this policy on beneficiary incentives should extend to providers and suppliers, other than the participant hospital, that furnish services during the CCJR episode of care. However, as discussed in section III.A, given our belief that the participant hospital is best positioned to coordinate the care of beneficiaries, we believe they are also better suited than other providers and suppliers to provide beneficiary incentives. Thus, we propose to include in the CCJR model certain in-kind patient engagement incentives to the beneficiary, subject to the following conditions:

• The incentive must be provided by the participant hospital to the beneficiary during CCJR episode of care.

• There must be a reasonable connection between the item or service and the beneficiary's medical care.

• The item or service must be a preventive care item or service or an item or service that advances a clinical goal for a CCJR beneficiary, including the following: Increasing the beneficiary's engagement in the management of his or her own health care; adherence to a treatment or drug regimen; adherence to a follow-up care plan; reduction of readmissions and complications resulting from LEJR procedures; and management of chronic diseases and conditions that may be affected by the LEJR procedure.

• Items of technology comply with certain safeguards regarding value, as discussed later in this section.

• The participant hospital must maintain contemporaneous documentation of the incentives provided to beneficiaries for a period of 10 years.

• The cost of the incentives is not shifted to another federal health care program.

For example, under this proposal, participant hospitals could provide incentives such as post-surgical monitoring equipment to track patient weight and vital signs for post-surgical patients discharged directly to home, but they could not provide theater tickets, which would bear no reasonable connection to the patient's medical care. Similarly, we are proposing that participant hospitals might provide post-surgical monitoring equipment, but not broadly used technology that is more valuable to the beneficiary than equipment that is reasonably necessary for the patient's post-surgical care. In such circumstances, a reasonable inference arises that the technology would not be reasonably connected to the medical care of the patient. Among other things, this safeguard precludes incentives that might serve to induce beneficiaries inappropriately to receive other medical care that is not included in the episode.

We propose that participant hospitals would be required to maintain contemporaneous documentation of such items and services furnished that exceed $10, including the date and identity of the beneficiary to whom the item or service was provided. We further propose that the required documentation be maintained for a period of 10 years.

We propose that items and services involving technology provided to beneficiaries may not exceed $1,000 in retail value at the time of donation for any one beneficiary in any one CCJR episode. Items of technology exceeding $50 in retail value at the time of donation must remain the property of the participant hospital and must be retrieved from the beneficiary at the end of the episode, with the documentation of the date of retrieval. In addition, the amount and nature of the technology must be the minimum necessary to achieve the goals previously noted earlier in this section. Finally, we propose that beneficiary incentives may not be tied to the receipt of services outside the episode of care and that the cost of the incentives cannot be shifted to a federal health care program. The aforementioned proposals regarding beneficiary incentives are consistent with the policies on beneficiary incentives in other CMS models, such as the BPCI initiative.

We seek comment on our proposal for beneficiary incentives under CCJR. In addition to general comments on the proposal, we are interested in comments on whether the $1,000 limit on technology items and services is necessary, reasonable, and appropriate. We also solicit comment on whether retrieving technology valued at more than $50 is too burdensome and whether elimination of that requirement will prevent abuse. We also solicit comment on the documentation requirement for items and services furnished that exceed $10, or whether a different amount would be more

appropriate and less burdensome. We welcome comments on additional program integrity safeguards for these arrangements.

(3) Compliance With Fraud and Abuse Laws

Certain arrangements between and among participant hospitals and third parties or beneficiaries may implicate the civil monetary penalty (CMP) law (sections 1128A(a)(5), (b)(1) and (b)(2) of the Act), the Federal Anti-kickback statute (section 1128B(b)(1) and (2) of the Act), or the physician self-referral prohibition (section 1877 of the Act). In many cases, arrangements that implicate these laws can be structured to comply with them by using existing safe harbors and exceptions. Section 1115A(d)(1) of the Act authorizes the Secretary to waive certain specified fraud and abuse laws as may be necessary solely for purposes of testing of payment models under section 1115A(b) of the Act. A waiver is not needed for an arrangement that does not implicate the fraud and abuse laws or that implicates the fraud and abuse laws but either fits within an existing exception or safe harbor, as applicable, or does not otherwise violate the law. Accordingly, pursuant to section 1115A(d)(1) of the Act, the Secretary will consider whether waivers of certain fraud and abuse laws are necessary to test the CCJR model as the model develops. The vehicle for promulgating waivers, if any, is under consideration. Such waivers, if any, would be promulgated separately from this proposed regulation by OIG (as to sections 1128A and 1128B of the Act) and CMS (as to section 1877 of the Act), to which the respective authorities have been delegated.

The requirements of the CCJR final rule will bear on the need for and scope of any fraud and abuse waivers that might be granted for the CCJR model. Because of the close nexus between the final regulations governing the structure and operations of the CCJR model and the development of any fraud and abuse waivers necessary to carry out the provisions of the model, CMS and OIG may, when considering the need for or scope of any waivers, consider comments submitted in response to this proposed rule and the provisions of the CCJR final rule.

11. Proposed Waivers of Medicare Program Rules

a. Overview

We believe it may be necessary and appropriate to provide additional flexibilities to hospitals participating in CCJR, as well as other providers that furnish services to beneficiaries in CCJR episodes. The purpose of such flexibilities would be to increase LEJR episode quality and decrease episode spending or internal costs or both of providers and suppliers that results in better, more coordinated care for beneficiaries and improved financial efficiencies for Medicare, providers, and beneficiaries. These possible additional flexibilities could include use of our waiver authority under section 1115A of the Act, which provides authority for the Secretary to waive such requirements of title XVIII of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act. This provision affords broad authority for the Secretary to waive statutory Medicare program requirements as necessary to carry out the provisions of section 1115A of the Act.

As we have stated elsewhere in sections I.B and III.A of this proposed rule, our previous and current efforts in testing episode payment models have led us to believe that models where entities bear financial responsibility for total Medicare spending for episodes of care hold the potential to incentivize the most substantial improvements in episode quality and efficiency. As discussed in section III.C of this proposed rule, we are proposing that hospitals participating in this model be eligible for reconciliation payments based on improved performance starting in performance year 1, and we would phase-in repayment responsibility for excess episode spending starting in performance year 2. We believe that where participant hospitals bear repayment responsibility for excess episode spending beyond the target price while high quality care is valued, they will have an increased incentive to coordinate care furnished by the hospital and other providers and suppliers throughout the episode to improve the quality and efficiency of care. With these incentives present, there may be a reduced likelihood of over-utilization of services that could otherwise result from waivers of Medicare program rules. Given these circumstances, waivers of certain program rules for providers and suppliers furnishing services to CCJR beneficiaries may be appropriate to offer more flexibility than under existing Medicare rules for such providers and suppliers, so that they may provide appropriate, efficient care for beneficiaries. An example of such a program rule that could be waived to potentially allow more efficient LEJR episode care would be the 3-day inpatient hospital stay requirement prior to a covered SNF stay for beneficiaries who could appropriately be discharged to a SNF after less than a 3-day inpatient hospital stay.

In addition, we believe that waivers of certain Medicare program rules are necessary to make reconciliation payments to or recoup payments from participant hospitals as a result of the Net Payment Reconciliation Amount (NPRA) for each performance year as discussed in section III.C.6.a. of this proposed rule, as well as to exclude beneficiary cost-sharing from these reconciliation payments or recoupments.

We welcome comments on possible waivers under section 1115A of the Act of certain Medicare program rules beyond those specifically discussed in this proposed rule that might be necessary to test this model. We will consider the comments that are received during the public comment period and our early model implementation experience and may make future proposals regarding program rule waivers during the course of the model test. We are especially interested in comments explaining how such waivers could provide providers and suppliers with additional ways that are not permitted under existing Medicare rules to increase quality of care and reduce unnecessary episode spending, but that could be appropriately used in the context of CCJR where participant hospitals bear full responsibility for total episode spending by performance year 3. We are also interested in receiving comments regarding the timing and manner in which such waivers, were they to be offered, would be implemented. For example, would it be necessary and appropriate to offer program waivers early in the model test to allow providers and suppliers adequate time to adjust their care coordination strategies to implement changes permitted by the waivers, despite there being no full repayment responsibility for excess episode spending until performance year 3? What program integrity and beneficiary protection risks could be introduced by waivers of the program rules described later in this section of this proposed rule and how could we mitigate those risks? What other issues should be considered when making use of waiver authority with respect to program rules? What operational issues do CMS and providers and suppliers furnishing services to beneficiaries in the model need to consider and what processes would need to be in place to implement these alternative program policies?

What implications would there be for provider and supplier infrastructure, including IT and other systems and processes? What provider education would be needed? We note that any waivers included in a final rule would be offered to participant hospitals, but depending on the specifics of each waiver, might be applied to services furnished by providers and suppliers other than the hospital. Where that is the case, we seek input on how we may best educate and disseminate information using methods effective in reaching providers and suppliers. Additionally, we seek comment on how we would appropriately and accurately track the use of waivers by providers and suppliers other than participant hospitals.

Specific program rules for which we propose waivers under the CCJR model to support provider and supplier efforts to increase quality and decrease episode spending and for which we invite comments are included in the sections that follow. We propose that these waivers of program rules would apply to the care of beneficiaries who are in CCJR episodes at the time when the waiver is used to bill for a service that is furnished to the beneficiary, even if the episode is later cancelled as described in section III.B.3.b of this proposed rule. If a service is found to have been billed and paid by Medicare under circumstances only allowed by a program rule waiver for a beneficiary not in the CCJR model at the time the service was furnished, CMS would recoup payment for that service from the provider or supplier who was paid, and require that provider and supplier to repay the beneficiary for any coinsurance previously collected.

We also generally seek comment on any additional Medicare program rules that it may be necessary to waive using our authority under section 1115A of the Act in order to effectively test the CCJR model that we could consider in the context of our early model implementation experience to inform any future proposals we may make.

b. Post-Discharge Home Visits

We expect that the broadly defined LEJR episodes with a duration of 90 days following hospital discharge as we propose in section III.B. of this proposed rule will result in participant hospitals redesigning care by increasing care coordination and management of beneficiaries following surgery. This will require participant hospitals to pay close attention to any underlying medical conditions that could be affected by the anchor hospitalization and improving coordination of care across care settings and providers. Beneficiaries may have substantial mobility limitations during LEJR episodes following discharge to their home or place of residence that may interfere with their ability to travel easily to physicians' offices or other health care settings. Adopting new strategies to increase beneficiary adherence to and engagement with recommended treatment and follow-up care following discharge from the hospital or PAC setting will also be important to high quality episode care. Scientific evidence exists [42] to support the use of home nursing visits among Medicare beneficiaries in improving care coordination following hospital discharge. In addition, we believe the financial incentives in this episode payment model will encourage hospitals to closely examine the most appropriate PAC settings for beneficiaries so that the clinically appropriate setting of the lowest acuity is recommended following discharge from the anchor hospitalization. We expect that all these considerations will lead to greater interest on the part of hospitals and other providers and suppliers caring for CCJR beneficiaries in furnishing services to beneficiaries in their home or place of residence. Such services could include visits by licensed clinicians other than physicians and nonphysician practitioners

In order for Medicare to pay for home health services, a beneficiary must be determined to be ''home-bound''. Specifically, sections 1835(a) and 1814(a) of the Act require that a physician certify (and recertify) that in the case of home health services under the Medicare home health benefit, such services are or were required because the individual is or was ''confined to the home'' and needs or needed skilled nursing care on an intermittent basis, or physical or speech therapy or has or had a continuing need for occupational therapy. A beneficiary is considered to be confined to the home if the beneficiary has a condition, due to an illness or injury, that restricts his or her ability to leave home except with the assistance of another individual or the aid of a supportive device (that is, crutches, a cane, a wheelchair or a walker) or if the beneficiary has a condition such that leaving his or her home is medically contraindicated. While a beneficiary does not have to be bedridden to be considered confined to the home, the condition of the beneficiary must be such that there exists a normal inability to leave home and leaving home requires a considerable and taxing effort by the beneficiary. Absent this condition, it would be expected that the beneficiary could typically get the same services in an outpatient or other setting. Thus, the homebound requirement provides a way to help differentiate between patients that require medical care at home versus patients who could more appropriately receive care in a less costly outpatient setting. Additional information regarding the homebound requirement is available in the Medicare Benefit Manual (Pub 100–02); Chapter 7, ''Home Health Services,'' Section 30.1.1, ''Patient Confined to the Home.''

We considered whether a waiver of the homebound requirement would be appropriate under the CCJR model, particularly beginning in performance year 2, where hospitals begin to bear repayment responsibility for excess episode spending. Waiving the homebound requirement would allow additional beneficiaries to receive home health care services in their home or place of residence. As previously discussed, physician certification that a beneficiary meets the homebound requirement is a prerequisite for Medicare coverage of home health services, and waiving the homebound requirement could result in lower episode spending in some instances. For example, if a beneficiary is allowed to have home health care visits, even if the beneficiary is not considered homebound, the beneficiary may avoid a hospital readmission. All other requirements for the Medicare home health benefit would remain unchanged. Thus, under such a waiver, only beneficiaries who otherwise meet all program requirements to receive home health services would be eligible for coverage of home health services without being homebound.

However, we are not proposing to waive the homebound requirement under CCJR for several reasons. Based on the typical clinical course of beneficiaries after LEJR procedures, we believe that many beneficiaries would meet the homebound requirement for home health services immediately following discharge from the anchor hospitalization or following discharge to their home or place of residence from a SNF that furnished PAC services immediately following the hospital discharge, so they could receive medically necessary home health services under existing program rules. Home health episodes are 60 days in duration, and payment adjustments are made for beneficiaries who require only a few visits during the episode or who

[42] Naylor MD, Brooten D, Campbell R, Jacobsen BS, Mezey MD, Pauly MV, Schwartz JS. JAMA. 1999:281(7):613–620. doi:10/1001/jama.281.7.613

are discharged during the episode. For those CCJR beneficiaries who could benefit from home visits by a licensed clinician for purposes of assessment and monitoring of their clinical condition, care coordination, and improving adherence with treatment but who are not homebound, we do not believe that paying for these visits as home health services under Medicare is necessary or appropriate, especially given that Medicare payments for home health services are set based on the clinical care furnished to beneficiaries who are truly homebound. Finally, in other CMS episode payment models, such as BPCI, we have not waived the homebound requirement for home health services.

In BPCI, we have provided a waiver of the ''incident to'' rule to allow a physician or nonphysician practitioner participating in care redesign under a participating BPCI provider to bill for services furnished to a beneficiary who does not qualify for Medicare coverage of home health services as set forth under § 409.42 where the services are furnished in the beneficiary's home during the episode after the beneficiary's discharge from an acute care hospital. The ''incident to'' rules are set forth in § 410.26(b)(5), which requires services and supplies furnished incident to the service of a physician or other practitioner must be provided under the direct supervision (as defined at § 410.32(b)(3)(ii)) of a physician or other practitioner.

In BPCI, the waiver is available only for services that are furnished by licensed clinical staff under the general supervision (as defined at § 410.32(b)(3)(i)) of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner), or of the same entity that employs or contracts with the physician (or other practitioner), and while the services may be furnished by licensed clinical staff they must be billed by the physician (or other practitioner) in accordance with CMS instructions using a Healthcare Common Procedures Coding System (HCPCS) G-code created by CMS specifically for the BPCI initiative. As discussed in section III.B of this proposed rule, participants in the BPCI initiative are permitted to select the duration of an episode as either 30 days, 60 days or 90 days. In the case of the incident to waiver under BPCI, the waiver allows physician and nonphysician practitioners to furnish the services not more than once in a 30-day episode, not more than twice in a 60-day episode, and not more than three times in a 90-day episode. All other Medicare coverage and payment criteria must be met.

For the CCJR model, we propose to waive the ''incident to'' rule set forth in § 410.26(b)(5), to allow a CCJR beneficiary who does not qualify for home health services to receive post-discharge visits in his or her home or place of residence any time during the episode. The waiver would not apply for beneficiaries who would qualify for home health services under the Medicare program, as set forth under § 409.42. Therefore these visits could not be billed for such beneficiaries. We propose to allow licensed clinicians, such as nurses, either employed by a hospital or not, to furnish the service under the general supervision of a physician, who may be either an employee or a contractor of the hospital. We propose to allow services furnished under such a waiver to be billed under the PFS by the physician or nonphysician practitioner or by the hospital to which the supervising physician has reassigned his or her benefits. In the latter scenario, we note that the post-discharge home visit services would not be ''hospital services,'' even when furnished by clinical staff of the hospital.

We propose that up to 9 post-discharge home visits could be billed and paid during each 90-day post-anchor hospitalization CCJR episode. Given the average PAC length of stay of approximately 45 days for these episodes and the incentives under CCJR to improve efficiency, which may shorten PAC stays, 9 visits would represent a home visit on average of once per week for two-thirds of the 90-day episode duration, the period of time when the typical beneficiary may have concluded PAC in an efficient episode. We believe that a home visit of once a week to a non-homebound beneficiary who has concluded PAC and who could also receive services in the physician's office or hospital outpatient department as needed, along with telehealth visits in the home from a physician or NPP as proposed in the next section, should be sufficient to allow comprehensive assessment and management of the beneficiary throughout the LEJR episode. We propose that the service be billed with HCPCS code GXXXX (Coordinated quality care—joint replacement model home visit for patient assessment performed by a qualified health care professional for an individual not considered homebound, including, but not necessarily limited to patient assessment of clinical status, safety/fall prevention, functional status/ambulation, medication reconciliation/management, compliance with orders/plan of care, performance of activities of daily living, and making beneficiary connections to community and other services; (for use only in the Medicare-approved coordinated quality care—joint replacement model); may not be billed for a 30-day period covered by a transitional care management code) and paid at approximately $50 under the PFS. The standard PFS ratesetting methodologies establish relative value units (RVUs) based on the resources required to furnish the typical service. Final RVUs under the CY 2016 PFS for the proposed new HCPCS code for CCJR home visits will be included in the CCJR final rule. In addition, we propose to update the values each year to correspond to final values established under the PFS.

The waiver would not apply with respect to a CCJR beneficiary who has qualified, or would qualify, for home health services when the visit was furnished. We expect that the visits by licensed clinicians could include patient assessment, monitoring, assessment of functional status and fall risk, review of medications, assessment of adherence with treatment recommendations, patient education, communication and coordination with other treating clinicians, care management to improve beneficiary connections to community and other services, etc. These post-discharge home visits would remove barriers to follow-up care outside of the home with providers and suppliers and allow the beneficiary to be treated in his or her home environment or place of residence, where potential safety concerns, such as tripping hazards, could quickly be identified and remediated. Given these occasions for further patient assessment and intervention, we believe that where such post-discharge home visits are furnished, there are opportunities to increase patient-centered care coordination and decrease episode spending, potentially resulting in higher quality care for beneficiaries and increased episode efficiency which may benefit the beneficiaries, the Medicare Trust Fund, and participant hospitals.

We also propose to waive current Medicare billing rules in order to allow the separate reporting of these post-discharge home visits during surgical global periods. The PFS payment for the surgical procedure includes 90 days of post-operative care furnished by the surgeon. Post-operative follow-up care is not separately billable by the surgeon or, unless there is a transfer of care, by another practitioner. The current construction of the global packages included in PFS payments reflects a

narrow view of surgical follow-up care that does not encompass broader, more comprehensive models of post-operative care, such as an episode model like CCJR. As we have noted in the past, it is also difficult to determine the appropriate valuation of the various components of the current global packages (2015 Physician Fee Schedule 79 FR 67584). We do not believe that the CCJR post-discharge home visits, which can include nursing assessments for chronic conditions for which care may be affected by the surgery, would replace or substantially duplicate the kind of post-operative visits involved in furnishing post-operative follow-up care for the global surgery procedure under the PFS. Instead, we anticipate that the work of these post-discharge visits will be similar to the work furnished by the physician coordinating the patient's overall episode care. Therefore, we propose to waive the global surgery billing rules to allow the surgeon or other practitioners to furnish and bill for the post-discharge home visits during surgical global periods.

We plan to monitor utilization patterns of post-discharge home visits under CCJR to monitor for overutilization and significant reductions in medical home health services. We seek comments on the proposed waiver of the ''incident to'' rule to pay for a maximum number of post-discharge home visits to beneficiaries who do not qualify for home health services by licensed clinicians under the general supervision of a physician.

c. Billing and Payment for Telehealth Services

As discussed in the previous section, we expect that the CCJR model design features will lead to greater interest on the part of hospitals and other providers and suppliers caring for CCJR beneficiaries in furnishing services to beneficiaries in their home or place of residence, including physicians' professional services. While physicians may furnish and be paid by Medicare for home visits under the PFS, few visits are actually furnished to Medicare beneficiaries because of the significant physician resources required for such visits and the general structure of most physician office-based practices. For example, in 2014 only 2.6 million physician or nonphysician practitioner home visits were furnished to Medicare beneficiaries in contrast to almost 250 million office or other outpatient evaluation and management visits furnished by physicians or nonphysician practitioners. CCJR would create new incentives for comprehensive episode care management for beneficiaries, including early identification and intervention regarding changes in health status following discharge from the anchor hospitalization. We understand that participant hospitals may want to engage physicians in furnishing timely visits to homebound or non-homebound CCJR beneficiaries in their homes or places of residence to address concerning symptoms or observations raised by beneficiaries themselves, clinicians furnishing home health services, or licensed clinicians furnishing post-discharge home visits, while physicians committed to LEJR care redesign may not be able to revise their practice patterns to meet this home visit need for CCJR beneficiaries.

Under section 1834(m) of the Act, Medicare pays for telehealth services furnished by a physician or practitioner under certain conditions even though the physician or practitioner is not in the same location as the beneficiary. The telehealth services must be furnished to a beneficiary located in one of the eight types of originating sites specified in section 1834(m)(4)(C)(ii) of the Act and the site must satisfy at least one of the requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act. Generally, for Medicare payment to be made for telehealth services under the Physician Fee Schedule several conditions must be met, as set forth under § 410.78(b). Specifically, the service must be on the Medicare list of telehealth services and meet all of the following other requirements for payment:

- The service must be furnished via an interactive telecommunications system.
- The service must be furnished to an eligible telehealth individual.
- The individual receiving the services must be in an eligible originating site.

When all of these conditions are met, Medicare pays a facility fee to the originating site and provides separate payment to the distant site practitioner for the service. Section 1834(m)(4)(F)(i) of the Act defines Medicare telehealth services to include professional consultations, office visits, office psychiatry services, and any additional service specified by the Secretary, when furnished via a telecommunications system. For the list of approved Medicare telehealth services, see the CMS Web site at *www.cms.gov/Medicare/Medicare-General-information/telehealth/*. Under section 1834(m)(4)(F)(ii) of the Act, CMS has an annual process to consider additions to and deletions from the list of telehealth services. We do not include any services as telehealth services when Medicare does not otherwise make a separate payment for them.

Some literature suggests that technologies that enable health care providers to deliver care to patients in locations remote from providers are being increasingly used to complement face-to-face patient-provider encounters in both urban and rural areas.[43] In these cases, the use of remote access technologies may improve the accessibility and timeliness of needed care, increase communication between providers and patients, enhance care coordination, and improve the efficiency of care. We note that certain professional services that are commonly furnished remotely using telecommunications technology are paid under the same conditions as in-person physicians' services, and thus do not require a waiver to be considered as telehealth services. Such services that do not require the patient to be present in person with the practitioner when they are furnished are covered and paid in the same way as services delivered without the use of telecommunications technology when the practitioner is in person at the medical facility furnishing care to the patient.

In other CMS episode payment models, such as BPCI Models 2 and 3, we determined it was necessary to waive the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act. This waiver allows telehealth services to be furnished to eligible telehealth individuals when they are located at one of the eight originating sites at the time the service is furnished via a telecommunications system but without regard to the site meeting one of the geographic site requirements. For CCJR, we propose a waiver of this same provision as well as waiver of the requirement that the eligible telehealth individual be in an originating site when the otherwise eligible individual is receiving telehealth services in his or her home or place of residence. This waiver would allow providers and suppliers furnishing services to CCJR beneficiaries to utilize telemedicine for beneficiaries that are not classified as rural and to allow the greatest degree of efficiency and communication between providers and suppliers and beneficiaries by allowing beneficiaries to receive telehealth services at their home or place of residence. We believe that these waivers are essential to maximize the opportunity to improve the quality of care and efficiency for LEJR episodes under CCJR.

Specifically, like the telehealth waiver for BPCI, we propose to waive the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act that limit telehealth payment to services furnished within specific types of geographic areas or in an entity participating in a federal telemedicine demonstration project approved as of December 31, 2000. Waiver of this requirement would allow beneficiaries located in any region to receive services related to the episode to be furnished via telehealth, as long as all other Medicare requirements for telehealth services are met. Any service on the list of Medicare approved telehealth services and reported on a claim with an ICD–9 principal diagnosis code that is not excluded from the proposed CCJR episode definition (see section III.B.2 of this proposed rule) could be furnished to a CCJR beneficiary, regardless of the beneficiary's geographic location. Under CCJR, this waiver would support care coordination and increasing timely access to high quality care for all CCJR beneficiaries, regardless of geography. Additionally, we propose, only for the purpose of testing the CCJR model, waiving the originating site requirements of section 1834(m)(4)(C)(ii)(I)–(VIII) of the Act that specify the particular sites at which the eligible telehealth individual must be located at the time the service is furnished via a telecommunications system. Specifically, we propose to waive the requirement only when telehealth services are being furnished in the CCJR' beneficiary's home or place of residence during the episode. Any service on the list of Medicare approved telehealth services and reported on a claim with an ICD–9 principal diagnosis code that is not excluded from the proposed CCJR episode definition (see section III.B.2 of this proposed rule) could be furnished to a CCJR beneficiary in his or her home or place of residence, unless the service's HCPCS code descriptor precludes delivering the service in the home or place of residence. For example, subsequent hospital care services could not be furnished to beneficiaries in their home since those beneficiaries would not be inpatients of the hospital.

The existing set of codes used to report evaluation and management (E/M) visits are extensively categorized and defined by the setting of the service, and the codes describe the services furnished when both the patient and the practitioner are located in that setting. Section 1834(m) of the Act provides for particular conditions under which Medicare can make payment for office visits when a patient is located in a health care setting (the originating sites authorized by statute) and the eligible practitioner is located elsewhere. However we do not believe that the kinds of E/M services furnished to patients outside of health care settings via real-time, interactive communication technology are accurately described by any existing E/M codes. This would include circumstances when the patient is located in his or her home and the location of the practitioner is unspecified. Therefore, in order to create a mechanism to report E/M services accurately under the CCJR model, we propose to create a specific set of HCPCS G-codes to describe the E/M services furnished to CCJR beneficiaries in their homes via telehealth.

Among the existing E/M visit services, we envision these services would be most similar to those described by the office and other outpatient E/M codes. Therefore, we propose to structure the new codes similarly to the office/outpatient E/M codes but adjusted to reflect the location as the beneficiary's residence and the virtual presence of the practitioner. Specifically, we propose to create a parallel structure and set of descriptors currently used to report office or other outpatient E/M services, (CPT codes 99201 through 99205 for new patient visits and CPT codes 99212 through 99215 for established patient visits.) For example, the proposed G-code for a level 3 E/M visit for an established patient would be a telehealth visit for the evaluation and management of an established patient in the patient's home, which requires at least 2 of the following 3 key components:

- An expanded problem focused history;
- An expanded problem focused examination;
- Medical decision making of low complexity.

Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the patient's or family's needs or both. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent with the patient or family or both via real-time, audio and video intercommunications technology.

We note that we are not proposing a G-code to parallel the level 1 office/outpatient visit for an established patient, since that service does not require the presence of the physician or other qualified health professional. We also believe this would duplicate the home visits for non-homebound beneficiaries previously proposed in this section.

We propose to develop payment rates for these new telehealth G-codes for E/M services in the patient's home that are similar to the payment rates for the office/outpatient E/M services, since the codes will describe the work involved in furnishing similar services. Therefore, we propose to include the resource costs typically incurred when services are furnished via telehealth. In terms of the relative resource costs involved in furnishing these services, we believe that the efficiencies of virtual presentation generally limit resource costs other than those related to the professional time, intensity, and malpractice risk to marginal levels. Therefore, we propose to adopt work and malpractice (MP) RVUs associated with the corresponding level of office/outpatient codes as the typical service because the practitioner's time and intensity and malpractice liabilities when conducting a visit via telehealth are comparable to the office visit. Final RVUs under the CY 2016 PFS will be included in the CCJR final rule. Additionally, we propose to update these values each year to correspond to final values established under the PFS. We considered whether each level of visit typically would warrant support by auxiliary licensed clinical staff within the context of the CCJR model. The cost of such staff and any associated supplies, for example, would be incorporated in the practice expense (PE) RVUs under the PFS. For the lower level visits, levels 1 through 3 for new and 2 and 3 for established visits, we did not believe that the visit would necessarily require auxiliary medical staff to be available in the patient's home. We anticipate these lower level visits would be the most commonly furnished and would serve as a mechanism for the patient to consult quickly with a practitioner for concerns that can be easily described and explained by the patient. We do not propose to include PE RVUs for these services, since we do not believe that virtual visits envisioned for this model typically incur the kinds of costs included in the PE RVUs under the PFS. For higher level visits, we typically would anticipate some amount of support from auxiliary clinical staff. For example, wound examination and minor wound debridement would be considered included in an E/M visit and would require licensed clinical staff to be present in the beneficiary's home during the telehealth visit in order for

the complete service to be furnished. We believe it would be rare for a practitioner to conduct as complex and detailed a service as a level 4 or 5 E/M home visit via telehealth for CCJR beneficiaries in LEJR episodes without licensed clinical staff support in the home.

However, we also note that this proposed model already includes several avenues for licensed clinical staff to be in the patient's home, either through a separately paid home visit as proposed for the model or through home health services as discussed earlier in this section of this proposed rule. Therefore, although we consider support by auxiliary clinical staff to be typical for level 4 or 5 E/M visits furnished to CCJR beneficiaries in the home via telehealth, we do not propose to incorporate these costs through PE RVUs. Given the anticipated complexity of these visits, we would expect to observe level 4 and 5 E/M visits to be reported on the same claim with the same date of service as a home visit or during a period of authorized home health care. If neither of these occurs, we propose to require the physician to document in the medical record that auxiliary licensed clinical staff were available on site in the patient's home during the visit and if they were not, to document the reason that such a high-level visit would not require such personnel.

We note that because the services described by the proposed G-codes, by definition, are furnished remotely using telecommunications technology, they therefore are paid under the same conditions as in-person physicians' services and they do not require a waiver to the requirements of section 1834(m) of the Act. We also note that because these home telehealth services are E/M services, all other coverage and payment rules regarding E/M services would continue to apply.

Under CCJR, this proposal to waive the originating site requirements and create new home visit telehealth HCPCS codes would support the greatest efficiency and timely communication between providers and beneficiaries by allowing beneficiaries to receive telehealth services at their places of residence.

With respect to home health services paid under the home health prospective payment system (HH PPS), we emphasize that telehealth visits under this model cannot substitute for in-person home health visits per section 1895(e)(1)(A) of the Act. Furthermore, telehealth services by social workers cannot be furnished for CCJR beneficiaries who are in a home health episode of care because medical social services are included as home health services per section 1861(m) of the Act and paid for under the Medicare HH PPS. However, telehealth services permitted under section 1834 of the Act and furnished by physicians or other practitioners, specifically physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, nurse anesthetists, psychologists, and dieticians, can be furnished for CCJR beneficiaries who are in a home health episode of care. Finally, sections 1835(a) and 1814(a) of the Act require that the patient has a face-to-face encounter with the certifying physician or an allowed nonphysician practitioner (NPP) working in collaboration with or under the supervision of the certifying physician before the certifying physician certifies that the patient is eligible for home health services. Under § 424.22(a)(1)(v), the face-to-face encounter can be performed up to 90 days prior to the start of home health care or within 30 days after the start of home health care. Section 424.22(a)(1)(v)(A) also allows a physician, with privileges, who cared for the patient in an acute or PAC setting (from which the patient was directly admitted to home health) or an allowed NPP working in collaboration with or under the supervision of the acute or PAC physician to conduct the face-to-face encounter.

Although sections 1835(a) and 1814(a) of the Act allow the face-to-face encounter to be performed via telehealth, we are not proposing that the waiver of the telehealth geographic site requirement for telehealth services and the the originating site requirement for telehealth services furnished in the CCJR beneficiary's home or place of residence would apply to the face-to-face encounter required as part of the home health certification when that encounter is furnished via telehealth. In other words, when a face-to-face encounter furnished via telehealth is used to meet the requirement for home health certification, the usual Medicare telehealth rules apply with respect to geography and eligibility of the originating site. We expect that this policy will not limit CCJR beneficiaries' access to medically necessary home health services because beneficiaries receiving home health services during a CCJR episode will have had a face-to-face encounter with either the physician or an allowed NPP during their anchor hospitalization or a physician or allowed NPP during a post-acute facility stay prior to discharge directly to home health services.

Under the proposed waiver of the geographic site requirement and originating site requirement, all telehealth services would be required to be furnished in accordance with all Medicare coverage and payment criteria, and no additional payment would be made to cover set-up costs, technology purchases, training and education, or other related costs. The facility fee paid by Medicare to an originating site for a telehealth service would be waived if there is no facility as an originating site (that is, the service was originated in the beneficiary's home). Finally, providers and suppliers furnishing a telehealth service to a CCJR beneficiary in his or her home or place of residence during the episode would not be permitted to bill for telehealth services that were not fully furnished when an inability to provide the intended telehealth service is due to technical issues with telecommunications equipment required for that service. Beneficiaries would be able to receive services furnished pursuant to the telehealth waivers only during the CCJR LEJR episode.

We plan to monitor patterns of utilization of telehealth services under CCJR to monitor for overutilization or reductions in medically necessary care, and significant reductions in face-to-face visits with physicians and NPPs. We plan to specifically monitor the distribution of new telehealth home visits that we are proposing, as we anticipate greater use of lower level visits. Given our concern that auxiliary licensed clinical staff be present for level 4 and 5 visits, we will monitor our proposed requirement that these visits be billed on the same claim with the same date of service as a home nursing visit, during a period authorized home health care, or that the physician document the presence of auxiliary licensed clinical staff in the home or an explanation as to the specific circumstances precluding the need for auxiliary staff for the specific visit. We seek comments on the proposed waivers with respect to telehealth services, and the proposed creation of the home visit telehealth codes.

d. SNF 3-Day Rule

We expect that the CCJR model will encourage participant hospitals and their provider and supplier partners to redesign care for LEJR episodes across the continuum of care extending to 90 days post-discharge from the anchor hospital stay. We believe that hospitals will seek to develop and refine the most efficient care pathways so beneficiaries

receive the lowest intensity, clinically appropriate care at each point in time throughout the episode. We understand that in some cases, particularly younger beneficiaries undergoing total knee replacement, certain beneficiaries receiving LEJR procedures may be appropriately discharged from the acute care hospital to a SNF in less than the 3 days required under the Medicare program for coverage of the SNF stay. While total knee arthroplasty (TKA) remains payable by Medicare to the hospital only when furnished to hospital inpatients, we have heard from some stakeholders that these procedures may be safely furnished to hospital outpatients with a hospital outpatient department stay of only 24 hours. Finally, we note that the current geometric mean hospital length of stay for LEJR procedures for beneficiaries without major complications or comorbidities (MS–DRG 470) is only 3 days and that for MS–DRG 469 for beneficiaries with such complications or comorbidities is 6 days. Thus, we believe it is possible that hospitals working to increase episode efficiency may identify some CCJR beneficiaries who could be appropriately discharged from the hospital to a SNF in less than 3 days, but that early discharge would eliminate Medicare coverage for the SNF stay unless a waiver of Medicare requirements were provided under CCJR.

The Medicare SNF benefit is for beneficiaries who require a short-term intensive stay in a SNF, requiring skilled nursing or skilled rehabilitation care or both. Pursuant to section 1861(i) of the Act, beneficiaries must have a prior inpatient hospital stay of no fewer than 3-consecutive days in order to be eligible for Medicare coverage of inpatient SNF care. We refer to this as the SNF 3-day rule. We note that the SNF 3-day rule has been waived or is not a requirement for Medicare SNF coverage under other CMS models or programs, including BPCI Model 2. BPCI Model 2 awardees that request and are approved for the waiver can discharge Model 2 beneficiaries in less than 3 days from an anchor hospital stay to a SNF, where services are covered under Medicare Part A as long as all other coverage requirements for such services are satisfied.

Currently, FFS Medicare beneficiary discharge patterns to a SNF immediately following hospitalization for an LEJR procedure vary regionally across the country, from a low of approximately 10 percent of Medicare beneficiaries to a high of approximately 85 percent.[44] Additionally, a study of Medicare beneficiaries has shown that over the period of time between 1991 and 2008, as the inpatient hospital length-of-stay for total hip arthroplasty (THA) decreased from an average of 9.1 days to an average of 3.7 days, the average percentage of primary THA patients discharged directly to home declined from 68 percent to 48 percent while the proportion discharged directly to skilled care (primarily SNFs) increased from 17.8 percent to 34.3 percent.[45] During this same period of time, 30-day all-cause readmission increased from 5.8 percent to 8.5 percent. Similar to the CCJR payment policies we propose in section III.C of this proposed rule, which would require participating CCJR hospitals to repay Medicare for excess episode spending beginning in performance year 2, participants in BPCI Model 2 assume financial responsibility for episode spending for beneficiaries included in a Model 2 episode. Episode payment models like BPCI and CCJR have the potential to mitigate the existing incentives under the Medicare program to overuse SNF benefits for beneficiaries, as well as to furnish many fragmented services that do not reflect significant coordinated attention to and management of complications following hospital discharge. The removal of these incentives in an episode payment model lays the groundwork for offering participant hospitals greater flexibility around the parameters that determine SNF stay coverage. BPCI participants considering the early discharge of a beneficiary pursuant to the waiver during a Model 2 episode must evaluate whether early discharge to a SNF is clinically appropriate and SNF services are medically necessary. Next, they must balance that determination and the potential benefits to the hospital in the form of internal cost savings due to greater financial efficiency with the understanding that a subsequent hospital readmission, attributable to premature discharge or low quality SNF care, could substantially increase episode spending while also resulting in poorer quality of care for the beneficiary. Furthermore, early hospital discharge for a beneficiary who would otherwise not require a SNF stay (that is, the beneficiary has no identified skilled nursing or rehabilitation need that cannot be provided on an outpatient basis) following a hospital stay of typical length does not improve episode efficiency under an episode payment model such as BPCI or CCJR.

Because of the potential benefits we see for participating CCJR hospitals, their provider partners, and beneficiaries, we propose to waive in certain instances the SNF 3-day rule for coverage of a SNF stay following the anchor hospitalization under CCJR beginning in performance year 2 of the model when repayment responsibility for actual episode spending that exceeds the target price begins. We propose to use our authority under section 1115A of the Act with respect to certain SNFs that furnish Medicare Part A post-hospital extended care services to beneficiaries included in an episode in the CCJR model. We believe this waiver is necessary to the model test so that participant hospitals can redesign care throughout the episode continuum of care extending to 90 days post-discharge from the anchor hospital stay in order to maximize quality and hospital financial efficiency, as well as reduce episode spending under Medicare. However, we are not proposing to waive this requirement in performance year 1, when participating hospitals are not responsible for excess actual episode spending. We believe that there is some potential for early hospital discharge followed by a SNF stay to increase actual episode spending over historical patterns unless participant hospitals are particularly mindful of this potential unintended consequence. Without participant hospital repayment responsibility in performance year 1, we are concerned that Medicare would be at full risk under the model for increased episode spending because, without a financial incentive to closely manage care, hospitals might be more likely to discharge beneficiaries to SNFs early leading to increased episode spending for which the hospital would bear no responsibility. Beginning in performance year 2 and continuing through performance year 5, we propose to waive the SNF 3-day rule because participant hospitals will bear partial or full responsibility (capped at the proposed stop-loss limit described in section III.C. of this proposed rule) for excess episode actual spending, thereby providing a strong incentive in those years for participant hospitals to redesign care with both quality and efficiency outcomes as priorities. All other Medicare rules for coverage and payment of Part A-covered SNF services would continue to apply to CCJR

[44] ''Analysis of Medicare claims with admission dates from July 1, 2013 through June 30, 2014 accessed through the Chronic Conditions Warehouse.''

[45] Cram P, Lu X, Kaboli PJ, et al. Clinical Characteristics and Outcomes of Medicare Patients Undergoing Total Hip Arthroplasty, 1991–2008. JAMA. 2011;305(15):1560–1567.

beneficiaries in all performance years of the model.

In addition, because the average length of stay for Medicare beneficiaries hospitalized for LEJR procedures without major complications or comorbidities is already relatively short at 3 days and in view of our concerns over protecting immediate CCJR beneficiary safety and optimizing health outcomes, we propose to require that participant hospitals may only discharge a CCJR beneficiary under this proposed waiver of the SNF 3-day rule to a SNF rated an overall of three stars or better by CMS based on information publicly available at the time of hospital discharge. Problem areas due to early hospital discharge may not be discovered through model monitoring and evaluation activities until well after the episode has concluded, and the potential for later negative findings alone may not afford sufficient beneficiary protections. CMS created a Five-Star Quality Rating System for SNFs to allow SNFs to be compared more easily and to help identify areas of concerning SNF performance. The Nursing Home Compare Web site (*www.medicare.gov/NursingHomeCompare/*) gives each SNF an overall rating of between 1 and 5 stars. Skilled nursing facilities with 5 stars are considered to have much above average quality, and SNFs with one star are considered to have quality much below average. Published SNF ratings include distinct ratings of health inspection, staffing, and quality measures, with ratings for each of the three sources combined to calculate an overall rating. These areas of assessment are all relevant to the quality of SNF care following discharge from the anchor hospitalization initiating a CCJR episode, especially if that discharge occurs after less than three days in the hospital. A study of the clinical factors that kept patients in a Danish hospital unit dedicated to discharge in three days or fewer following total hip and knee arthroscopy procedures found that that pain, dizziness, and general weakness were the main clinical reasons for longer hospitalization, as well as problems with personal care and walking 70 meters with crutches.[46] Medicare beneficiaries discharged from the hospital to a SNF in less than three days may be at higher risk of these uncomfortable symptoms and disabling functional problems not being fully resolved at hospital discharge, although we expect that under the CCJR episode payment model participant hospitals will have a strong interest in ensuring appropriate discharge timing so that hospital readmissions and complications are minimized. Nevertheless, because of the potential greater risks following early inpatient hospital discharge, we believe it is appropriate that all CCJR beneficiaries discharged from the participant hospital to a SNF in less than 3 days be admitted to a SNF that has demonstrated that it is capable of providing quality care to patients with significant unresolved post-surgical symptoms and problems. We believe such a SNF would need to provide care of at least average overall quality, which would be represented by an overall SNF 3-star or better rating.

We propose that the waiver be available for the CCJR beneficiary's care. The SNF would insert a Treatment Authorization Code on the claim for a beneficiary in the model where the SNF seeks to the use the waiver. This process would promote coordination between the SNF and the participant hospital, as the SNF would need to be in close communication with the participant hospital to ensure that the beneficiary is in the model at the time the waiver is used. We propose that where the beneficiary would be eligible for inclusion in a CCJR episode of care at the time of hospital discharge, use of the waiver would be permitted where it is medically necessary and appropriate to discharge the beneficiary to a SNF prior to a 3-day inpatient stay.

Beneficiaries would be eligible to receive services furnished under the 3-Day Rule waiver only during the CCJR episode. We plan to monitor patterns of SNF utilization under CCJR, particularly with respect to hospital discharge in less than 3 days to a SNF, to ensure that beneficiaries are not being discharged prematurely to SNFs and that they are able to exercise their freedom of choice without patient steering. We seek comment on our proposal to waive the SNF 3-day stay rule for stays in SNFs rated overall as three stars or better following discharge from the anchor hospitalization in CCJR episodes.

e. Waivers of Medicare Program Rules To Allow Reconciliation Payment or Repayment Actions Resulting From the Net Payment Reconciliation Amount

In order to make reconciliation payment to or carry out recoupment from a participant hospital that results from the NPRA calculation for each performance year as discussed in section III.C.6.a. of this proposed rule, we believe we would need to waive certain Medicare program rules. Therefore, in accordance with the authority granted to the Secretary in section 1115A(d)(1) of the Act, we would waive requirements of the Act for all Medicare Part A and Part B payment systems only to the extent necessary to make reconciliation payments or receive repayments based on the NPRA that reflect the episode payment methodology under this proposed payment model for CCJR participant hospitals selected in accordance with CMS's proposed selection methodology. In addition, we do not propose that reconciliation payments or repayments change beneficiary cost-sharing from the regular Medicare program cost-sharing for the related Part A and Part B services that were paid for CCJR beneficiaries and aggregated to determine actual episode spending in the calculation of the NPRA. We therefore would waive the requirements of sections 1813 and 1833(a) of the Act to the extent that they would otherwise apply to reconciliation payments or repayments from a participant hospital under the CCJR model. We seek comment on our proposed waivers related to repayment and recoupment actions as a result of the NRPA calculated.

12. Proposed Enforcement Mechanisms

CMS must have certain mechanisms to enforce compliance with the requirements of the model, either by the participant hospital, or by an entity or individual participating in the CCJR model by furnishing a service to a beneficiary during a CCJR episode. The following discussion details the enforcement mechanisms we propose to make available to CMS for the CCJR model.

We propose an enforcement structure that would be consistent with other CMMI models. We believe that Model 2 of the BPCI initiative is an appropriate model for comparison, given that Model 2 and CCJR share many of the same policy characteristics, particularly with respect to episode definition. For example, the participation agreement between CMS and a participant (called an Awardee) in BPCI Model 2 provides that CMS may immediately or with advance notice terminate the awardee's participation in the model or require the Awardee to terminate its agreement (''participant agreement'') with a participating provider or supplier that is not in compliance with BPCI requirements. In such circumstances, CMS may direct the Awardee to terminate its participant agreement with a participating provider or supplier because the Awardee has a participation agreement with CMS, whereas the participating provider or supplier does

[46] Husted H, Lunn TH, Troelsen A, Gaarm-Larsen L, Kristensen BB, Kehlet H. Why still in hospital after fast-track hip and knee arthroplasty? Acta Orthopaedica. 2011; 82(6)679–684.

not. CMS may require termination of the Awardee or a participating provider or supplier if—

• CMS determines that it no longer has the funds to support the BPCI model;

• CMS terminates the model pursuant to section 1115A(b)(3)(B) of the Act; or

• The BPCI awardee or an individual or entity participating in BPCI under the awardee does any of the following:

++ Takes any action that threatens the health or safety of patients; avoids at-risk Medicare beneficiaries, as this term is defined in § 425.20; or avoids patients on the basis of payer status.

++ Is subject to sanctions or final actions of an accrediting organization or federal, state or local government agency that could lead to the inability to comply with the requirements and provisions of the BPCI agreement.

++ Takes or fails to take any action that CMS determines for program integrity reasons is not in the best interests of the BPCI initiative.

++ Is subject to action by HHS (including OIG and CMS) or the Department of Justice to redress an allegation of fraud or significant misconduct, including intervening in a False Claims Act qui tam matter, issuing a pre-demand or demand letter under a civil sanction authority, or similar actions.

Under the terms of the BPCI agreement, upon CMS's termination of the agreement for any of the reasons previously listed in this section, CMS may immediately cease the distribution of positive reconciliation payments to the awardee and the awardee must immediately cease the distribution of any gainsharing payments.

Many CMMI models also allow for CMS to impose remedial actions to address noncompliance by either a participant that has a direct relationship (participation agreement) with CMS, or by any individual or entity participating in the CMMI model pursuant to an agreement with the participant hospital. For example, with respect to the BPCI Model 2, where CMS determines that there may be noncompliance, CMS may take any or all of the following actions:

• Notify the BPCI awardee of the specific performance problem.

• Require the awardee to provide additional data to CMS or its designees.

• Require the awardee to stop distributing funds to a particular individual or entity.

• Require the awardee to forego the receipt of any positive reconciliation payments from CMS.

• Request a corrective action plan from the awardee.

++ If CMS requests a corrective action plan, then the following requirements apply to awardees in the BPCI initiative:

— The awardee must submit a corrective action plan for CMS approval by the deadline established by CMS.

— The corrective action plan must address what actions the awardee will take within a specified time period to ensure that all deficiencies are corrected and that it remains in compliance with the BPCI agreement.

Under the CCJR model, we propose that CMS would have the enforcement mechanisms detailed in this section available for use against participant hospitals and any entity or individual furnishing a service to a beneficiary during a CCJR episode, where the participant hospital or such entity or individual: (1) Does not comply with the CCJR model requirements; or (2) are identified as noncompliant via CMS' monitoring of the model or engage in behavior related to any of the reasons previously described that apply to the BPCI initiative. These mechanisms will support the goals of CCJR to maintain or improve quality of care. Given that participant hospitals may receive reconciliation payments, and choose to distribute or share those payments with other providers or suppliers (''CCJR collaborators'') we believe that enhanced scrutiny and monitoring of participant hospitals and CCJR collaborators under the model is necessary and appropriate. Participant hospitals and CCJR collaborators will also be subject to all existing requirements and conditions for Medicare participation not otherwise waived under section 1115A(d)(1) of the Act.

We propose that CMS would have the option to use any one or more of the following enforcement mechanisms for participant hospitals in CCJR. We further propose that these enforcement mechanisms could be instituted and applied in any order, as is consistent with other CMMI models:

• Warning letter—We propose to give CMS the authority to issue a warning letter to participant hospitals to put them on notice of behavior that may warrant additional action by CMS. This letter would inform participant hospitals of the issue or issues identified by CMS leading to the issuance of the warning letter.

• Corrective Action Plan—We propose to give CMS the authority to request a corrective action plan from participant hospitals. We propose the following requirements for corrective action plans:

++ The participant hospital would be required to submit a corrective action plan for CMS approval by the deadline established by CMS.

++ The corrective action plan would be required to address what actions the participant hospital will take within a specified time period to correct the issues identified by CMS.

++ The corrective action plan could include provisions requiring that the participant hospital terminate Participation Agreements with CCJR collaborators that are determined by HHS to be engaging in activities involving noncompliance with the provisions of this proposed rule, engaged in fraud or abuse, providing substandard care, or experiencing other integrity problems.

++ The participant hospital's failure to comply with the corrective action plan within the specified time period could result in additional enforcement action, including: (1) Termination; (2) automatic forfeiture of all or a portion of any reconciliation payments as that term is defined in section III.C. of this proposed rule; (3) CMS's discretionary reduction or elimination of all or a portion of the hospital's reconciliation payment; or (4) a combination of such actions.

• Reduction or elimination of reconciliation amount—We propose to give CMS the authority to reduce or eliminate a participant hospital's reconciliation amount based on noncompliance with the model's requirements, negative results found through CMS' monitoring activities, or the participant hospital's noncompliance associated with a corrective action plan (as noted previously). For example, where CMS requires a participant hospital to submit a corrective action plan, the result of the participant hospital's failure to timely comply with that requirement could be a 50 percent reduction in the reconciliation amount due to the participant hospital at the end a performance year, where the participant hospital's reconciliation report reflects a positive reconciliation amount. We solicit comments on whether negative monitoring results and noncompliance with program requirements or corrective action plans should result in automatic forfeiture of all or a portion of positive NPRA, the amount that could be forfeited or reduced, the number of performance periods over which NPRA may be forfeited or reduced per instance or episode of noncompliance, whether the amount should be a fixed percentage of NPRA or a variable amount depending on the nature and severity of the noncompliance, and the criteria

CMS should use in deciding the severity of noncompliance.

Where the participant hospital's reconciliation report reflects a repayment amount, forfeiture of a reconciliation amount would not be an option for that performance year. In such a case, we considered whether CMS would require the participant hospital to forfeit a certain percentage of a reconciliation amount in the reconciliation report for a future performance year. However, in the case of a failure to comply with the model's requirements, presence of negative results found through CMS's monitoring activities, or noncompliance associated with a corrective action plan, we believe a policy that would increase the amount of repayment amount on the reconciliation report for the performance year in which the noncompliance occurred by the participant hospital is more likely to result in compliance from the hospital. Therefore, we propose to add 25 percent to a repayment amount on a reconciliation report, where the participant hospital fails to timely comply with a corrective action plan or is noncompliant with the model's requirements, We seek comments on this forfeiture policy, including the percentage to be added to a repayment amount on a reconciliation report; the number of performance periods over which a reconciliation amount may be forfeited or reduced per instance or episode of noncompliance; whether the amount should be a fixed percentage of a reconciliation amount or repayment amount, as applicable, or a variable amount depending on the nature and severity of the noncompliance; and the criteria CMS should use in deciding the severity of noncompliance.

• Termination from the model—Given the provisions we have proposed outlining the participation of hospitals in the model, we believe that, in contrast to other CMS models, termination from the CCJR model would contradict the model's design. As a result, in some circumstances termination from the model may be unlikely to be a sufficient mechanism to deter noncompliance by participant hospitals. While we believe termination is a remedy unlikely to be frequently used by CMS in this model, we nonetheless leave open the possibility that in extremely serious circumstances termination might be appropriate, and for that reason, we propose to include it as an available enforcement option. Where a participant hospital is terminated from the CCJR model, we propose that the hospital would remain liable for all negative NPRA generated from episodes of care that occurred prior to termination. We propose that CMS may terminate the participation in CCJR of a participant hospital when the participant hospital, or a CCJR collaborator that has a Participation Agreement with a participant hospital and performs functions or services related to CCJR activities, fails to comply with any of the requirements of the CCJR model. We further propose that CMS could terminate the participant hospital's participation in the model, or require a participant hospital to terminate a Participation Agreement with a CCJR collaborator for reasons including, but not limited to the following:

• CMS determines that it no longer has the funds to support the CCJR model.

• CMS terminates the model pursuant to section 1115A(b)(3)(B) of the Act.

• The CCJR participant hospital, or an individual or entity participating in CCJR under the participant hospital does any of the following:

++ Takes any action that threatens the health or safety of patients; avoids at-risk Medicare beneficiaries, as this term is defined in § 425.20; or avoids patients on the basis of payor status.

++ Is subject to sanctions or final actions of an accrediting organization or federal, state or local government agency that could lead to the inability to comply with the requirements and provisions of this proposed rule.

++ Takes or fails to take any action that CMS determines for program integrity reasons is not in the best interests of the CCJR model.

++ Is subject to action by HHS (including OIG and CMS) or the Department of Justice to redress an allegation of fraud or significant misconduct, including intervening in a False Claims Act qui tam matter, issuing a pre-demand or demand letter under a civil sanction authority, or similar actions.

++ Is subject to action involving violations of the physician self-referral prohibition, civil monetary penalties law, federal anti-kickback statute, antitrust laws, or any other applicable Medicare laws, rules, or regulations that are relevant to the CCJR model

• Other Enforcement Mechanisms—We seek to incorporate policies regarding enforcement mechanisms that are necessary and appropriate to test the CCJR model. Thus, we seek public comment on additional enforcement mechanisms that would contribute to the following goals:

++ Allow CMS to better operate or monitor the model.

++ Appropriately engage and encourage all entities and individuals furnishing a service to a beneficiary during a CCJR episode to comply with the requirements and provisions of the CCJR model.

++ Preserve the rights of Medicare beneficiaries to receive medically necessary care, to not be endangered by providers and suppliers engaging in noncompliant activities, and to be able to choose from whom they want to receive care.

We seek public comment on these proposals and invite commenters to propose additional safeguards we should consider in this proposed rule.

D. Quality Measures and Display of Quality Metrics Used in the CCJR Model

1. Background

a. Purpose of Quality Measures in the CCJR Model

The priorities of the National Quality Strategy [47] include making care safer and more affordable, promoting effective communication and coordination as well as engaging patients and families in their care. We believe quality measures that encourage providers to focus on the National Quality Strategy priorities will ultimately improve quality of care and cost efficiencies. As described earlier in section III.C.5 of this proposed rule, we are proposing that in order for a hospital in the CCJR model to receive a reconciliation payment for the applicable performance year, the participant hospital's measure results must meet or exceed certain thresholds compared to the national hospital measure results calculated for all HIQR-participant hospitals for all three measures for each performance period. More specifically, for performance years 1 through 3, a participant hospital's measure results must be at or above the 30th percentile of the national hospital measure results calculated for all hospitals under the HIQR Program for each of the three measures for each performance period (for a detailed discussion see section III.C.5.b of this proposed rule. For performance years 4 and 5, a participant hospital's measure results must be at or above the 40th percentile of the national hospital measure results (for a detailed discussion see section III.C.5.b. of this proposed rule). In this section, we fully describe the proposed quality measures that will be used for public reporting and to determine whether a participant

[47] National Quality Strategy. Working for Quality: About the National Quality Strategy. Available at: *http://www.ahrq.gov/workingforquality/about.htm#develnqs.* Accessed on April 15, 2015.

hospital is eligible for the reconciliation payment under the CCJR model. We are proposing a complication measure, readmission measure, and a patient experience survey measure for the CCJR model. We note that these measures will assess the priorities of safer care, transitions of care and effective communication, and engagement of patients in their care, respectively. Specifically, we are proposing the following three CMS outcome measures:

- The Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1550) (as referred to as THA/TKA Complications measure (NQF #1550)).
- The Hospital-level 30-day, all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1551) (as referred to as THA/TKA Readmissions measure (NQF #1551)).
- HCAHPS Survey (NQF #0166).

For the inpatient hospital settings, these fully developed measures are endorsed by the National Quality Forum (NQF), and recommended by the NQF Measure Application Partnership (MAP) with subsequent implementation in the HIQR Program, HVBP Program, and the HRRP (see FY 2015 IPPS/LTCH final rule 79 FR 50031, 50062, 50208 and 50209, and 50259). These measures are also publicly reported on Hospital Compare.

An important purpose of the proposed quality measures for the CCJR model is to provide transparent information on hospital performance for the care of patients undergoing eligible elective joint replacement surgery and to ensure that care quality is either maintained or improved. The proposed measures assess the following key outcomes for patients undergoing elective joint replacement surgery:

- Serious medical and surgical complications.
- Unplanned readmissions.
- Patient experience.

We note that complications and unplanned readmissions result in excess inpatient and post-acute spending, and reductions in these undesirable events will improve patient outcomes while simultaneously lowering healthcare spending. The THA/TKA Complications measure (NQF #550) will inform quality improvement efforts targeted towards minimizing medical and surgical complications during surgery and the postoperative period. The THA/TKA Readmission measure (NQF #1551) captures the additional priorities of care provided in the transition to outpatient settings and communication with patients and providers during and immediately following inpatient admission. Improved quality of care, specifically achieved through coordination and communication among providers and with their patients and their caregivers, can favorably influence performance on these measures. We believe improvement in measure performance will also mean improved quality of care and reduced cost.

Additionally, we continue to focus on patient experience during hospitalizations, and believe that the HCAHPS Survey measure provides not only the opportunity for patients to share their lower extremity joint replacement hospital experience, but also for hospitals to improve quality of care based on patient experience. For example, the HCAHPS Survey ''categories of patient experience'' specifically provides areas (for example, communication with doctors and nurses, responsiveness of hospital staff, pain management) in which a hospital could improve transition of care and increase patient safety (for detailed description of patient experience areas covered by HCAHPS surveys see section III.D.2.c. of this proposed). Additionally, the survey includes measures related to nurse and physician communication, pain management, timeliness of assistance, explanation of medications, discharge planning and cleanliness of the hospitals to provide specific areas for hospitals to improve on.[48] Specific questions on provider communication include the following:

- How often the patient believed providers listened carefully to his or her questions?
- Whether the purpose of medications and associated adverse events were explained?
- Whether discussions on post-discharge instructions and plans occurred so that the patient had a clear understanding of how to take medications and an understanding of his or her responsibilities in managing his or her health post-discharge?

All of these areas of patient experience would be invaluable to improving hospital quality of care. We note that Manary, *et al.*[2] suggest that by focusing on patient outcomes we can improve patient experience and that timeliness of measuring patient experience is important due to the potential for recall inaccuracies; survey administration for HCAHPS surveys must begin between 2 and 42 days after discharge from a hospital.

We are aware that there is concern whether there is a relationship between patient satisfaction and quality of surgical care. To address this question Tsai *et al.*[49] recently assessed patient satisfaction using the HCAHPS Survey results and correlated quality performance using nationally implemented structural, process and outcome surgical measures (that is, structural, process and outcome surgical measures in the Hospital Value Based Purchasing, and the Hospital Readmission Reduction Programs). The study found a positive relationship between patient experience of care and surgical quality of care, among the 2,953 hospitals that perform six high cost and high frequency surgical procedures that are also associated with morbidity and mortality in Medicare beneficiaries. The study included hip replacement procedures, and specifically noted that those hospitals with high patient satisfaction also had high performance on nationally implemented surgical quality measures (such as the Surgical Care Improvement Project measures and 30-day risk-adjusted readmission and peri-operative mortality outcome measures). Finally, we note that although the HCAHPS Survey measure is not specific to joint replacements, the survey provides all patients the opportunity to comment on their hospital experience, including patients who have received lower extremity joint replacements, which helps to inform hospitals on areas for improvement. While HCAHPS scores are aggregated at the hospital level, the surgical service line is one of three service lines encompassed by the survey.[50]

We strive to align as many measures and programs as is feasibly possible. We believe proposing fully developed measures that are used in other CMS hospital quality programs will minimize the burden on participant hospitals for having to become familiar with new measures and will allow us to appropriately capture quality data for the CCJR model.

[48] Manary MP, Boulding W, Staelin R, Glickman SW. The Patient Experience and Health Outcomes. New England Journal of Medicine. Jan 2013; 368(3):201–203.

[49] Tsai TC, Orav EJ, Jha AK. Patient Satisfaction and quality of surgical care in US hospitals. Annals of Surgery. 2015; 261:2–8.

[50] Giordano LA, Elliott MN, Goldstein E, Lehrman WG, Spencer PA. Development, Implementation, and Public Reporting of the HCAHPS Survey. Medical Care Research and Review. 2010;67(1):27–37.

b. Public Display of Quality Measures in the CCJR Model

We believe that the display of measure results is an important way to educate the public on hospital performance and increase the transparency of the model. As discussed later in this section of this proposed rule, for the CCJR model, we are proposing to display quality measure results on the Hospital Compare Web site (*http://www.hospitalcompare.hhs.gov/*). We believe that the public and hospitals are familiar with this Web site and how the information is displayed. The proposed measures have been displayed on Hospital Compare over the past few years. Finally, while also aligning the display of data for the CCJR model with other CMS hospital quality programs, we believe that the public and 'hospitals' familiarity with the Hospital Compare Web site will make it simpler to access data.

2. Proposed Quality Measures for Performance Year 1 (CY 2016) and Subsequent years

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

(1) Background

THA and TKA are commonly performed procedures for the Medicare population that improve quality of life. Between 2009 and 2012, there were 337,419 total hip arthroplasty (THA) procedures and 750,569 total knee arthroplasty (TKA) procedures for Medicare FFS patients 65 years and older.[51] The post-operation complications of these procedures are high considering these are elective procedures, and usually, the complications are devastating to patients. For example, rates for periprosthetic joint infection, a rare but devastating complication, have been reported at 2.3 percent for THA/TKA patients with rheumatoid arthritis after 1 year of follow-up [52] and 1.6 percent in Medicare patients undergoing TKA after 2 years of follow up.[53] Two studies reported 90-day death rates following THA at 0.7 percent [54] and 2.7 percent, respectively.[55] Reported rates for pulmonary embolism following TKA range from 0.5 percent to 0.9 percent.[56 57 58] Reported rates for septicemia range from 0.1 percent, during the index admission[59] to 0.3 percent, 90 days following discharge for primary TKA.[60] Rates for bleeding and hematoma following TKA have been reported at 0.94 percent [61] to 1.7 percent.[62] Combined, THA and TKA procedures account for the largest payments for procedures under Medicare.[63] Both hip and knee arthroplasty procedures improve the function and quality of life of patients with disabling arthritis, and the volume and cost associated with these procedures are very high. We believe it is important to assess the quality of care provided to Medicare beneficiaries who undergo one or both of these procedures.

The proposed measure developed by CMS, and currently implemented in the Hospital IQR and Hospital Value-Based Purchasing Program, assesses a hospital's risk standardized complication rate, which is the rate of complications occurring after elective primary THA and TKA surgery. The measure outcome is the rate of complications occurring after THA and TKA during a 90-day period that begins with the date of the index admission for a specific hospital; an index admission is the hospitalization to which the complications outcome is attributed. The following outcomes (either one or more) are considered complications in this measure: Acute myocardial infarction, pneumonia, or sepsis/septicemia within 7 days of admission; surgical site bleeding, pulmonary embolism or death within 30 days of admission; or mechanical complications, periprosthetic joint infection or wound infection within 90 days of admission. The data indicated that the median hospital-level risk-standardized complication rate for 2008 was 4.2 percent, with a range from 2.2 percent to 8.9 percent in hospitals. The variation in complication rates suggests that there are important differences in the quality of care delivered across hospitals, and that there is room for quality improvement. In 2010, we developed the proposed measure of hospital-level risk-standardized complication rate (RSCR) following elective primary THA and TKA surgery, which was later endorsed by the NQF (NQF #1550). In its Pre-Rulemaking Report for 2012,[64] the Measure Application Partnership (MAP) also recommended the inclusion of this measure in the HIQR Program; we have not submitted this measure for use in the post-acute care settings as the measure was developed for the acute care hospital setting. This measure has been publicly reported on Hospital Compare since FY 2014 and in the HIQR Program since FY 2015 (FY 2015 IPPS/LTCH final rule 79 FR 50062). Finally, we note a comparison of the median hospital-level risk-standardized complication rates for hospitals between April 1, 2011 and March 31, 2014 illustrates a performance gap (median RSCR of 3.1 percent with a range from 1.4 percent to 6.9 percent) indicating

[51] Suter L, Grady JL, Lin Z et al.: 2013 Measure Updates and Specifications: Elective Primary Total Hip Arthroplasty (THA) And/Or Total Knee Arthroplasty (TKA) All-Cause Unplanned 30-Day Risk-Standardized Readmission Measure (Version 2.0). 2013. *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[52] Bongartz, T, Halligan CS, Osmon D, et al. Incidence and risk factors of prosthetic joint infection after total hip or knee replacement in patients with rheumatoid arthritis. Arthritis Rheum. 2008; 59(12): 1713–1720.

[53] Kurtz S, Ong K, Lau E, Bozic K, Berry D, Parvizi J. Prosthetic joint infection risk after TKA in the Medicare population. Clin Orthop Relat Res. 2010;468:5.

[54] Cram P, Vaughan-Sarrazin MS, Wolf B, Katz JN, Rosenthal GE. A comparison of total hip and knee replacement in specialty and general hospitals. J Bone Joint Surg Am. Aug 2007;89(8):1675–1684. Soohoo NF, Farng E, Lieberman JR, Chambers L, Zingmond, DS. Factors That Predict Short-term Complication Rates After Total Hip Arthroplasty. Clin Orthop Relat Res. Sep 2010;468(9):2363–2371.

[55] Soohoo NF, Farng E, Lieberman JR, Chambers L, Zingmond, DS. Factors That Predict Short-term Complication Rates After Total Hip Arthroplasty. Clin Orthop Relat Res. Sep 2010;468(9):2363–2371. Cram P, Vaughan-Sarrazin MS, Wolf B, Katz JN, Rosenthal GE. A comparison of total hip and knee replacement in specialty and general hospitals. J Bone Joint Surg Am. Aug 2007;89(8):1675–1684.

[56] Mahomed NN, Barrett JA, Katz JN, et al. Rates and outcomes of primary and revision total hip replacement in the United States medicare population. J Bone Joint Surg Am. Jan 2003;85–A(1):27–32.

[57] Khatod M, Inacio M, Paxton EW, et al. Knee replacement: epidemiology, outcomes, and trends in Southern California: 17,080 replacements from 1995 through 2004. Acta Orthop. Dec 2008;79(6):812–819.

[58] Solomon DH, Chibnik LB, Losina E, et al. Development of a preliminary index that predicts adverse events after total knee replacement. Arthritis & Rheumatism. 2006;54(5):1536–1542.

[59] Browne, JA, Cook C, Hofmann A, Bolognesi MP. Postoperative morbidity and mortality following total knee arthroplasty with computer navigation. Knee. 2010;17(2): 152–156.

[60] Cram P, Vaughan-Sarrazin MS, Wolf B, Katz JN, Rosenthal GE. A comparison of total hip and knee replacement in specialty and general hospitals. J Bone Joint Surg Am. Aug 2007;89(8):1675–1684.

[61] Browne, JA, Cook C, Hofmann A, Bolognesi MP. Postoperative morbidity and mortality following total knee arthroplasty with computer navigation. Knee. 2010;17(2): 152–156.

[62] Huddleston JI, Maloney WJ, Wang Y, Verzier N, Hunt DR, Herndon JH. Adverse Events After Total Knee Arthroplasty: A National Medicare Study. The Journal of Arthroplasty. 2009;24(6, Supplement 1): 95–100.

[63] Bozic KJ, Rubash HE, Sculco TP, Berry DJ., An analysis of Medicare payment policy for total joint arthroplasty. J Arthroplasty. Sep 2008; 23(6 Suppl 1):133–138.

[64] National Quality Forum. MAP Final Reports. Available at: *http://www.qualityforum.org/Publications/2012/02/MAP_Pre-Rulemaking_Report__Input_on_Measures_Under_Consideration_by_HHS_for_2012_Rulemaking.aspx.* Accessed on April 1 6, 2015, page 78.

there is still room for quality improvement.[65]

(2) Data Sources

We propose to use Medicare Part A and Part B FFS claims submitted by the participant hospital as the data source to calculate the measure. Index admission diagnoses and in-hospital comorbidities are assessed using Medicare Part A claims. Additional comorbidities prior to the index admission are assessed using Part A inpatient, outpatient, and Part B office visit Medicare claims in the 1 to 2 months prior to the index (initial) admission. Enrollment and post-discharge mortality status are obtained from Medicare's enrollment database which contains beneficiary demographic, benefits/coverage, and vital status information.

(3) Cohort

The THA/TKA Complication measure (NQF #1550) includes Medicare FFS beneficiaries, aged 65 years or older, admitted to non-federal acute care hospitals for elective primary THA or TKA. THA and TKA procedures eligible for inclusion are defined using ICD–9–CM codes 81.51 and 81.54, respectively. We propose that the cohort will include all hospitals included in the CCJR model, but the CCJR model cohort may differ slightly from the hospital cohort that is currently captured in the measures through the HIQR program. That is, the CCJR model cohort is a randomly selected group of acute care hospitals and therefore may not include all of the HIQR program acute care hospitals (for a detailed discussion on selection of hospitals for the model see section III.A.4. of this proposed rule).

(4) Inclusion and Exclusion Criteria

An index admission is the hospitalization to which the complication outcome is attributed. The measure includes the following index admissions for patients:

- Enrolled in Medicare FFS.
- Aged 65 or over.
- Enrolled in Part A and Part B Medicare for the 12 months prior to the date of index admission and during the index admission.
- Having a qualifying elective primary THA/TKA procedure; elective primary THA/TKA procedures are defined as those procedures without any of the following:

++ Femur, hip, or pelvic fractures coded in principal or secondary discharge diagnosis fields of the index admission.

++ Partial hip arthroplasty (PHA) procedures with a concurrent THA/TKA.

++ Revision procedures with a concurrent THA/TKA.

++ Resurfacing procedures with a concurrent THA/TKA.

++ Mechanical complication coded in the principal discharge diagnosis field.

++ Malignant neoplasm of the pelvis, sacrum, coccyx, lower limbs, or bone/bone marrow or a disseminated malignant neoplasm coded in the principal discharge diagnosis field.

++ Removal of implanted devices/prostheses.

++ Transfer from another acute care facility for the THA/TKA.

The following admissions would be excluded from the measure:

- Admissions for patients discharged against medical advice (AMA).
- Admissions for patients with more than two THA/TKA procedure codes during the index hospitalization.
- Consistent with the FY 2016 IPPS/LTCH proposed rule, admissions for patients without at least 90 days post-discharge enrollment in FFS Medicare; this exclusion is an update to the measure signaled in the HIQR program section of the FY2016 IPPS/LTCH proposed rule (80 FR 24572 through 24574) to ensure that disproportionate Medicare FFS disenrollment does not bias the measure results.

After applying these exclusion criteria, we randomly select one index admission for patients with multiple index admissions in a calendar year. Therefore, we exclude the other eligible index admissions in that year. Identification and use of a single index admission in a calendar year is done because this measure includes mortality as an outcome and the probability of death increases with each subsequent admission, preventing each episode of care from being mutually independent. Therefore only one index admission is selected to maintain measure integrity.

We note that THA/TKA Complication measure (NQF #1550) does not capture patients undergoing partial hip arthroplasty procedures. We excluded partial hip arthroplasty procedures primarily because partial hip arthroplasty procedures are done for hip fractures. Therefore, they are not elective procedures. Also, partial hip arthroplasty procedures are typically performed on patients who are older, frailer, and have more comorbid conditions. Although this exclusion is not fully harmonized with MS–DRG 469 and 470, which includes partial hip arthroplasty procedures, this measure will still provide strong incentive for improving and maintaining care quality across joint replacement patients as hospitals typically develop protocols for lower extremity joint arthroplasty that will address peri-operative and post-operative care for both total and partial hip arthroplasty procedures. As previously cited in the Episode Definition of the CCJR model (section III.B. of this proposed rule) the frequency of administrative claims data using ICD–9 codes for 2014 indicated that partial hip arthroplasty (ICD–9 code: 81.52) accounted for 12 percent of the administrative claims, while Total Hip replacement (ICD–9 code: 81.51) and Total Knee replacement (ICD–9 code: 81.54) accounted for 87 percent of the administrative claims for 2014. We also note that the same surgeons and care teams frequently perform both procedures. Therefore, quality improvement efforts initiated in response to the THA/TKA Complication measure (NQF #1550) are likely to benefit patients undergoing similar elective procedures, such as partial hip arthroplasty and revision THA/TKA procedures, and possibly even non-elective THA/TKA procedures, such as fracture-related THA.

(5) Risk-Adjustment

We note that CCJR-we chose to align this measure with the risk-adjustment methodologies adopted for the HIQR program and the HRRP in accordance with section 1886(b)(3)(B)(viii)(VIII) of the Act (FY 2013 IPPS/LTCH final rule 77 FR 53516 through 53518 and FY 2015 IPPS/LTCH final rule; 79 FR 50024, 50031, and 50202). We note that the risk-adjustment takes into account the patient case-mix to assess hospital performance. The patient risk factors are defined using the Hierarchical Condition Categories (CC), which are clinically relevant diagnostic groups of ICD–9–CM codes.[66] The CCs used in the risk adjustment model for this measure, are provided on the CMS QualityNet *Web site* (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=Qnet Public%2FPage%2FQnetTier4&cid=1228772783162*). We note that the measure uses all Part A and B administrative claims ICD–9 codes for the year prior to and including the index admission. The Part A and B administrative claims ICD–9 codes are

[65] Suter L, Zang W, Parzynski C, et al. 2015 Procedure-Specific Complication Measures Update and Specifications: Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Risk-Standardized Complication Measure (Version 4.0). 2015.

[66] Pope G, Ellis R, Ash A, *et al.*, Principal Inpatient Diagnostic Cost Group Models for Medicare Risk Adjustment. Health Care Financing Review. 2000;21(3):26.

used to inform the risk prediction for each patient; diagnostic codes from post-acute care settings are included in the measure, but this information is only used to identify a hospital's patient case mix in order to adequately adjust for differences in case mix across hospitals. Use of the Part A and B data does not mean the measures are applicable to post-acute care settings, only that they use comprehensive data to predict the risk of the outcome and adjust for hospital patient case mix. The measure would meet the requirement if it applied since risk-adjustment adjusts for hospital patient mix, including age and comorbidities, to ensure that hospitals that care for a less healthy patient population are not penalized unfairly. The measure methodology defines ''complications'' as acute myocardial infarction (AMI); pneumonia; sepsis/septicemia; pulmonary embolism; surgical site bleeding; death; wound infection; periprosthetic joint infection; and mechanical complication within 0 to 90 days post the index date of admission, depending on the complication. The decision on the appropriate follow-up period of 0 to 90 days was based on our analysis of 90-day trends in complication rates using the 2008 Medicare FFS Part A Inpatient Data. We found that rates for mechanical complications are elevated until 90 days post the date of index admission. We found that the rates for four other complications—death, surgical site bleeding, wound infection, and pulmonary embolism—are elevated for 30 days, and that rates for AMI, pneumonia, and sepsis/septicemia level off 7 days after the date of index admission.

(6) Calculating the Risk-Standardized Complication Rate and Performance Period

Analogous to how we calculate hospital risk-standardized readmission rates with all readmission measures and risk-standardized mortality rates with the mortality measures used in CMS hospital quality programs, we calculate the hospital risk-standardized complication rate by producing a ratio of the number of ''predicted'' complications (that is, the adjusted number of complications at a specific hospital based on its patient population) to the number of ''expected'' complications (that is, the number of complications if an average quality hospital treated the same patients) for each hospital and then multiplying the ratio by the national raw complication rate. The 3-year rolling performance period would be consistent with that used for HIQR (FY 2015 IPPS/LTCH final rule 79 FR 50208 and 50209). For performance year-one of the CCJR model, we propose that the performance period for the THA/TKA Complication measure (NQF #1550) we propose to be April 2013 through March 2016. As noted in this proposed rule, the THA/TKA Readmissions measure (NQF #1551) uses a 30-day window of follow-up, which is different from the 90-day window of follow-up used in the THA/TKA Complications measure (NQF #1550). Section III.D.4. of this proposed rule, Form and Manner, summarizes performance periods for years 1 through 5 of the CCJR JR model.

We seek public comment on this proposal to assess quality performance through implementation of the Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1550) measure.

b. Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551)

(1) Background

The objective of CMS's Hospital-level 30-day, all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1551) (as referred to as THA/TKA Readmission measure (NQF #1551)) measure is to assess readmission from any cause within 30 days of discharge from the hospital following elective primary THA and TKA. As previously stated, outcome measures such as complications and readmissions are the priority areas for the HIQR Program. Elective primary THA and TKA are commonly performed procedures that improve quality of life. THA and TKA readmissions are disruptive to patients' quality of life, costly to the Medicare program, and data support that readmission rates can be improved through better care coordination and other provider actions.[67] Furthermore, we believe that there is an opportunity for hospitals to improve quality of life for the patient. From July 1, 2011 to June 30, 2014, Medicare FFS claims data indicate that 30-day hospital-level risk-standardized readmission rates ranged from 2.6 percent to 8.5 percent among hospitals with a median rate of 4.8 percent. The mean risk-standardized readmission rate was 4.9 percent.[68] This variation suggests there are important differences in the quality of care received across hospitals, and that there is room for improvement. A measure that addresses readmission rates following THA and TKA provides an opportunity to provide targets for efforts to improve the quality of care and reduce costs for patients undergoing these elective procedures. The measure also increases transparency for consumers and provides patients with information that could guide their choices. We believe that a risk-adjusted readmission outcome measure can provide a critical perspective on the provision of care, and support improvements in care for the Medicare patient population following THA/TKA hospitalization. We note that the THA/TKA Readmission measure (NQF #1551) has wide stakeholder support, with NQF endorsement in January 2012, and support by the MAP for the HIQR Program (2012 Pre-Rulemaking report [19]), and for HRRP (2013 Pre-Rulemaking report [69]). Finally, THA/TKA Readmission Measure (NQF #1551) has been publicly reported since FY 2014 (79 FR 50062), and was implemented in both the HIQR program (77 FR 53519 through 53521) and HRRP (78 FR 50663 and 50664).

(2) Data Sources

We propose to use Medicare Part A and Part B FFS claims submitted by the participant hospital as the data source for calculation of the THA/TKA Readmission measure (NQF #1551). Index admission diagnoses and in-hospital comorbidity data are assessed using Medicare Part A claims. Additional comorbidities prior to the index admission are assessed using Part A inpatient, outpatient, and Part B office visit Medicare claims in the 12 months prior to index (initial) admission. Enrollment status is obtained from Medicare's enrollment database which contains beneficiary demographic,

[67] Mistiaen P, Francke AL, Poot E. Interventions aimed at reducing problems in adult patients discharged from hospital to home: a systematic meta-review. *BMC Health Services Research.* 2007;7:47.

[68] Suter L, Desai N, Zang W, *et al.* 2015 2015 Procedure-Specific Readmission Measures Updates and Specifications Report: Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Risk-Standardized Readmission Measure (Version 4.0), Isolated Coronary Artery Bypass Graft (CABG) Surgery—Version 2.0. 2015; *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[69] National Quality Forum. MAP Final Reports. Available at: *http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx.* Accessed on April 16, 2015, page 143.

benefit/coverage, and vital status information.

(3) Cohort

The THA/TKA Readmission measure (NQF #1551) includes Medicare FFS beneficiaries, aged 65 years or older, admitted to non-federal acute care hospitals for elective primary THA or TKA. THA and TKA procedures eligible for inclusion are defined using ICD–9–CM codes 81.51 and 81.54, respectively. We propose that the cohort will include all hospitals included in the CCJR model, but the CCJR model cohort may differ slightly from the hospital cohort that is currently captured in the measures through the HIQR program. That is, the CCJR model cohort is a randomly selected group of acute care hospitals and therefore may not include all of the HIQR program acute care hospitals (for a detailed discussion on selection of hospitals for the model see section III.A. of this proposed rule.)

(4) Inclusion and Exclusion Criteria

We propose that an index admission is the anchor hospitalization to which the readmission outcome is attributed. The measure includes index admissions for patients:

- Enrolled in Medicare FFS.
- Aged 65 or over.
- Discharged from non-federal acute care hospitals alive.
- Enrolled in Medicare Part A and Part B for the 12 months prior to the date of index admission and during the index admission.
- Having a qualifying elective primary THA/TKA procedure; elective primary THA/TKA procedures are defined as those procedures without any of the following:

++ Femur, hip, or pelvic fractures coded in principal or secondary discharge diagnosis fields of the index admission.

++ Partial hip arthroplasty (PHA) procedures with a concurrent THA/TKA.

++ Revision procedures with a concurrent THA/TKA.

++ Resurfacing procedures with a concurrent THA/TKA.

++ Mechanical complication coded in the principal discharge diagnosis field.

++ Malignant neoplasm of the pelvis, sacrum, coccyx, lower limbs, or bone/bone marrow or a disseminated malignant neoplasm coded in the principal discharge diagnosis field.

++ Removal of implanted devices/prostheses.

++ Transfer from another acute care facility for the THA/TKA.

- This measure excludes index admissions for patients:

++ Without at least 30 days post-discharge enrollment in FFS Medicare.

++ Discharged against medical advice (AMA).

++ Admitted for the index procedure and subsequently transferred to another acute care facility.

++ With more than two THA/TKA procedure codes during the index hospitalization.

Finally, for the purpose of this measure, admissions within 30 days of discharge from an index admission are not eligible to also be index admissions. Thus, no hospitalization will be counted as both a readmission and an index admission in this measure.

This measure does not capture patients undergoing partial hip arthroplasty procedures, as partial hip arthroplasties are primarily done for hip fractures and are typically performed on patients who are older, frailer, and have more comorbid conditions. Although this exclusion is not fully harmonized with MS–DRG 469 and 470, which includes partial hip arthroplasty procedures, this measure would still provide strong incentive for improving and maintaining care quality across joint replacement patients. We believe the THA/TKA Readmission measure (NQF #1551) provides strong incentive for quality improvement because hospitals typically develop protocols for lower extremity joint arthroplasty that will address peri-operative and post-operative care for both total and partial hip arthroplasties, and the same surgeons and care teams frequently perform both procedures. Therefore, quality improvement efforts initiated in response to the THA/TKA Readmission measure (NQF #1551) are likely to benefit patients undergoing similar elective procedures, such as partial hip arthroplasty and revision THA/TKA procedures, and possibly even non-elective THA/TKA procedures, such as fracture-related THA.

(5) Risk-Adjustment

We note that CCJR-we chose to align this measure with the risk-adjustment methodologies adopted for Readmission measure (NQF #1551) under the HIQR Program in accordance with section 1886(b)(3)(B)(viii)(VIII) of the Act, as finalized in FY 2013 IPPS/LTCH PPS final rule (77 FR 53519 through 53521). We also note that the measure risk-adjustment takes into account patient age and comorbidities to allow a fair assessment of hospital performance. The measure defines the patient risk factors for readmission using diagnosis codes collected from all patient claims 1 year prior to patient index hospitalization for THA and TKA. As previously noted in the THA/TKA Complication measure (NQF #1550), Part A and B administrative claims ICD–9 codes are used to inform the risk prediction for each patient; diagnostic codes from post-acute care settings are included in the measure, but this information is only used to identify a hospital's patient case mix in order to adequately adjust for differences in case mix across hospitals. Use of the Part A and B data does not mean the measures are applicable to post-acute care settings, only that they use comprehensive data to predict the risk of the outcome and adjust for hospital patient case mix. We note that the patient diagnosis codes are grouped using Hierarchical Condition Categories (CCs), which are clinically relevant diagnostic groups of ICD–9–CM codes.[70] The CCs used in the risk adjustment model for this measure, are provided on the CMS QualityNet *Web site* (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069856694*). In summary, age and comorbidities present at the time of admission are adjusted for differences in hospital case mix (patient risk factors). The measure uses the hierarchical logistic regression model (HLM) statistical methodology for risk adjustment.

(6) Calculating the Risk-Standardized Readmission Rate and Performance period

We propose to calculate hospital risk-standardized readmission rates consistent with the methodology used to risk standardize all readmission measures and mortality measures used in CMS hospital quality programs. Using HLM, we calculate the hospital-level elective primary THA/TKA risk-standardized readmission rate by producing a ratio of the number of ''predicted'' readmissions (that is, the adjusted number of readmissions at a specific hospital) to the number of ''expected'' readmissions (that is, the number of readmissions if an average quality hospital treated the same patients) for each hospital and then multiplying the ratio by the national raw readmission rate. The 3-year rolling performance period would be consistent with that used for the HIQR program (FY 2015 IPPS/LTCH final rule 79 FR 50208 and 50209). For performance year-one of the CCJR model, we propose that the performance period for the THA/TKA Readmission measure (NQF

[70] Pope G, Ellis R, Ash A, *et al.*, Principal Inpatient Diagnostic Cost Group Models for Medicare Risk Adjustment. Health Care Financing Review. 2000;21(3):26.

#1551) would be July 2013 through June 2016. As noted in this proposed rule for the section on the THA/TKA Complications measure (NQF #1550), there is a 90-day window of follow-up which is different from the THA/TKA Readmissions measure (NQF #1551). Section III.D.4.Form and Manner, of this proposed rule summarizes performance periods for years 1 through 5 of the CCJR model years.

We invite public comments on this proposal to include Hospital-level 30-day, all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1551) or both in the CCJR model to assess quality performance. We also invite public comment on inclusion of other potential quality measures in the model.

c. Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey

(1) Background

The HCAHPS Survey (NQF #0166) is a CMS survey and a national, standardized, publicly reported survey of patients' experience of hospital care. The HCAHPS Survey is endorsed by the NQF (#0166); CMS is the measure steward. The HCAHPS survey, also known as CAHPS® Hospital Survey, is a survey instrument and data collection methodology for measuring patients' perceptions of their hospital experience. The HCAHPS Survey asks recently discharged patients 32 questions about aspects of their hospital experience that they are uniquely suited to address. The core of the survey contains 21 items that ask ''how often'' or whether patients experienced a critical aspect of hospital care. The survey also includes four items to direct patients to relevant questions, five items to adjust for the mix of patients across hospitals, and two items that support Congressionally-mandated reports (see 77 FR 53513 through 53515). Eleven HCAHPS measures (seven composite measures, two individual items and two global items) are currently publicly reported on the Hospital Compare Web site for each hospital participating in the HIQR Program (see 79 FR 50259.) Each of the seven currently reported composite measures is constructed from two or three survey questions. The seven composites summarize the following:

- How well doctors communicate with patients.
- How well nurses communicate with patients.
- How responsive hospital staff are to patients' needs.
- How well hospital staff helps patients manage pain.
- How well the staff communicates with patients about medicines.
- Whether key information is provided at discharge.
- How well the patient was prepared for the transition to post-hospital care.

Lastly, the two individual items address the cleanliness and quietness of patients' rooms, while the two global items report patients' overall rating of the hospital, and whether they would recommend the hospital to family and friends. We propose to adopt a measure in the CCJR model that uses HCAHPS survey data to assess quality performance and capture patient experience of care.

(2) Data Sources

The HCAHPS Survey is administered to a random sample of adult inpatients between 48 hours and 6 weeks after discharge. As previously discussed in section III.D.5. of this proposed rule, the HCAHPS survey data is collected on inpatient experience, is not limited to Medicare beneficiaries, and does not distinguish between types of Medicare beneficiaries. Patients admitted in the medical, surgical and maternity care service lines are eligible for the survey; the survey is not restricted to Medicare beneficiaries. Hospitals may use an approved survey vendor, or collect their own HCAHPS data (if approved by CMS to do so) (for a detailed discussion see 79 FR 50259). To accommodate hospitals, the HCAHPS Survey can be implemented using one of the following four different survey modes:

- Mail.
- Telephone.
- Mail with telephone follow-up.
- Active Interactive Voice Recognition (IVR).

Regardless of the mode used, hospitals are required to make multiple attempts to contact patients. Hospitals may use the HCAHPS Survey alone, or include additional questions after the 21 core items discussed previously. Hospitals must survey patients throughout each month of the year, and hospitals participating in the HIQR Program must target at least 300 completed surveys over 4 calendar quarters in order to attain the reliability criterion CMS has set for publicly reported HCAHPS scores (see 79 FR 50259). The survey itself and the protocols for sampling, data collection, coding, and file submission can be found in the current HCAHPS Quality Assurance Guidelines manual, available on the HCAHPS Web site located at: *http://www.hcahpsonline.org.* (The HCAHPS Survey is available in several languages, and all official translations of the HCAHPS Survey instrument are available in the current HCAHPS Quality Assurance Guidelines at *http://www.hcahpsonline.org/qaguidelines.aspx.*)

(3) Cohort

Hospitals, or their survey vendors, submit HCAHPS data in calendar quarters (3 months). Consistent with other quality reporting programs, we propose that HCAHPS scores would be publicly reported on Hospital Compare based on 4 consecutive quarters of data. For each public reporting, the oldest quarter of data is rolled off, and the newest quarter is rolled on (see 79 FR 50259).

(4) Inclusion and Exclusion Criteria

The HCAHPS Survey is broadly intended for patients of all payer types who meet the following criteria:

- Eighteen years or older at the time of admission.
- Admission includes at least one overnight stay in the hospital.
- Non-psychiatric MS–DRG/principal diagnosis at discharge.
- Alive at the time of discharge.

There are a few categories of otherwise eligible patients who are excluded from the sample frame as follows:

- ''No-Publicity'' patients—Patients who request that they not be contacted.
- Court/Law enforcement patients (that is, prisoners); patients residing in halfway houses are included.
- Patients with a foreign home address (U.S. territories—Virgin Islands, Puerto Rico, Guam, American Samoa, and Northern Mariana Islands are not considered foreign addresses and are not excluded).
- Patients discharged to hospice care (Hospice-home or Hospice-medical facility).
- Patients who are excluded because of state regulations.
- Patients discharged to nursing homes and skilled nursing facilities.

The HCAHPS Survey is intended for short-term, acute care hospitals. Both IPPS and Critical Access Hospitals participate in the survey; specialty hospitals, psychiatric hospitals and children's hospitals do not.

(5) Case-Mix-Adjustment

To ensure that HCAHPS scores allow fair and accurate comparisons among hospitals, CMS adjusts for factors that are not directly related to hospital performance but which affect how patients answer survey items. This includes the mode of survey administration and characteristics of

patients that are out of a hospital's control. Patient-mix adjustments (also known as case-mix adjustment) control for patient characteristics that affect ratings and that are differentially distributed across hospitals. Most of the patient-mix items are included in the ''About You'' section of the survey, while others are taken from hospital administrative records. Based on the HCAHPS mode experiment,[71] and consistent with previous studies of patient-mix adjustment in HCAHPS and in previous hospital patient surveys, we employ the following variables in the patient-mix adjustment model:

- Self-reported general health status (specified as a linear variable).
- Education (specified as a linear variable).
- Type of service (medical, surgical, or maternity care).
- Age (specified as a categorical variable).
- Admission through emergency room (discontinued in 2010).
- Lag time between discharge and survey.
- Age by service line interaction.
- Language other than English spoken at home.

Once the data are adjusted for patient-mix, there is a fixed adjustment for the mode of survey administration (mail, telephone, mail with telephone follow-up, and active Interactive Voice Response).

Information on patient-mix adjustment (risk adjustment) and survey mode adjustment of HCAHPS scores can be found at *http://www.hcahpsonline.org/modeadjustment.aspx.*

(6) HCAHPS Scoring

Regarding the HCAHPS survey measure, we identified the methodology used to assess hospitals in the HIQR program as reasonable for use in the CCJR model since this is a survey that many hospitals and patients are familiar with. In determining HCAHPS performance, we propose to utilize the HCAHPS Linear Mean Roll-up (HLMR) score. The HLMR summarizes performance across the 11 publicly reported HCAHPS measures for IPPS hospitals with 100 or more completed HCAHPS surveys in a 4-quarter period. The HLMR is calculated by taking the average of the linear mean scores (LMS) for each of the 11 publicly reported HCAHPS measures. The LMS, which was created for the calculation of HCAHPS Star Ratings, summarizes all survey responses for each HCAHPS measure; a detailed description of LMS can be found in HCAHPS Star Rating Technical Notes, at *http://www.hcahpsonline.org/StarRatings.aspx.*

We propose that hospitals participating in the CCJR model also have at least 100 completed HCAHPS surveys over a given 4-quarter period to be evaluated on HCAHPS for the CCJR model.

The responses to the survey items used in each of the 11 HCAHPS measures described previously are combined and converted to a 0 to 100 linear-scaled score (LMS) as follows:

- ''Never'' = 0; ''Sometimes'' = 33⅓; ''Usually'' = 66⅔; and ''Always'' = 100 (For HCAHPS Survey items 1–9, 11, 13–14, and 16–17).
- ''No'' = 0; and ''Yes'' = 100 (For items 19 and 20).
- Overall Rating ''0'' = 0; Overall Rating ''1'' = 10; Overall Rating ''2'' = 20; . . .; Overall Rating ''10'' = 100 (For item 21).
- ''Definitely No'' = 0; ''Probably No'' = 33⅓; ''Probably Yes'' = 66⅔; and ''Definitely Yes'' = 100 (For item 22).
- ''Strongly Disagree'' = 0; ''Disagree'' = 33⅓; ''Agree'' = 66⅔; and ''Strongly Agree'' = 100 (For items 23, 24, and 25).

The 0 to 100 linear-scaled HCAHPS scores are then adjusted for patient mix, survey mode, and quarterly weighting, see *http://www.hcahpsonline.org/files/HCAHPS_Stars_Tech_Notes_Apr2015.pdf.*

The HLMR summarizes performance across the 11 HCAHPS measures by taking an average of each of the LMS of the 11 HCAHPS measures, using a weight of 1.0 for each of the 7 HCAHPS composite measures, and a weight of 0.5 for each of the single item measures (Cleanliness, Quietness, Overall Hospital Rating and Recommend the Hospital). The HLMR is calculated to the second decimal place. Once the HLMR score is determined for a participant hospital, the hospital's percentile of performance can be determined based on the national distribution of hospital performance on the score.

(7) Performance Period

We propose to be consistent with the HIQR program, which uses four quarters of data (79 FR 50259). For the CCJR model, we propose to use the most recently available HCAHPS 4-quarter roll-up to calculate the HLMR score for the initial year of the CCJR model. The performance period would assess data on patients discharged from July 1, 2015 through June 30, 2016. Section III.D.4 of this proposed rule, Form and Manner, summarizes performance periods for years 1 through 5 of the CCJR model years.

We invite public comments on this proposal to include HCAHPS Survey in the CCJR model to assess quality performance and capture patient experience of care.

d. Applicable Time Period

In order to align as much as is reasonably possible with other CMS hospital quality and public reporting programs in which these three measures are implemented, we propose for the THA/TKA Complication measure (NQF #1550) and the THA/TKA Readmission measure (NQF #1551) performance time periods to be consistent with the HIQR, HVBP and HRRP programs. These programs use a 3-year rolling performance (see section III.D.2.b.(6). of this proposed rule) or applicable period for the Hospital-level 30-day, all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1551) and the Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1550) measures. We similarly propose a 3-year rolling performance period for the THA/TKA Complication measure (NQF #1550) and the THA/TKA Readmission measure (NQF #1551) because a 3-year performance period yields the most consistently reliable and valid measure results. We also propose the 3-year rolling performance periods for the THA/TKA Complication measure (NQF #1550) and the THA/TKA Readmission measure (NQF #1551) because hospitals are intimately familiar with these measures. We note that reconciliation payments to hospitals as part of the CCJR are dependent upon both cost and quality outcome measures, and that making reconciliation payments solely based on cost has the potential to lead to reduced access and stinting of care. In order to address these possibilities the inclusion of performance on outcome measures is critical to ensure access and high quality care for patients undergoing these procedures. The only way to include reliable quality measures in the model upon which to base reconciliation payments for 2016 is to use measures that have a performance period that precedes the effective date of the model. Furthermore, from a measure reliability and validity perspective, it is imperative to have at least 4 quarters of data for HCAHPS survey measures and

[71] The Effects of Survey Mode, Patient Mix, and Nonresponse on CAHPS Hospital Survey Scores.'' M.N. Elliott, A.M. Zaslavsky, E. Goldstein, W. Lehrman, K. Hambarsoomian, M.K. Beckett and L. Giordano. *Health Services Research,* 44 (2): 501–518. 2009.

3 years of data for the THA/TKA readmission and complications measures. We intentionally chose outcome and patient experience measures for which hospitals that are already financially accountable in other IPPS programs. Consequently, the performance periods are the same periods for the THA/TKA readmission and complications measures between the CCJR model, HIQR, HVBP and HRRP programs. For the HCAHPS survey measures, there is overlap with the performance periods for the CCJR model and HIQR. Given that there is no downward payment adjustment associated with the CCJR model, that hospitals are already familiar with these measures as part of the Hospital IQR program, Hospital VBP program, and the Hospital readmission reduction program, and that hospitals are already held financially accountable for these measures, we believe it is appropriate and necessary to use performance periods that precede the effective date of the CCJR model. For the HCAHPS Survey measure, we would continue to use a 4 quarter performance period as in the HIQR program, but would not align with the Hospital IQR program performance period. We initially considered using the same Hospital IQR program performance period for the HCAHPS survey measures but realized that should we use the same Hospital IQR program performance periods for the CCJR model, other CCJR model timeframes and policy goals would not be met. Such policy goals like calculating reconciliation payment adjustments in a timely fashion during the 2nd quarter of each year. We note that HCAPHS survey results are not available until the 3rd quarter of each year. For this reason, we are not proposing that the HCAHPS survey performance period follow the HIQR program performance periods. We also propose that HCAHPS survey scores be calculated from 4 consecutive quarters of survey data; publicly reported HCAHPS results are also based on 4 quarters of data (79 FR 50259).

3. Possible New Outcomes for Future Measures

a. Hospital-Level Performance Measure(s) of Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty

(1) Background

As part of our goal to move towards outcome measures that assess patient reported outcomes, we have begun development on a measure to assess improvement in patient-reported outcomes following THA/TKA procedures. The Hospital-Level Performance Measure(s) of Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (hereinafter referred to as ''THA THA/TKA patient-reported outcome-based measure'') is currently under development. We specifically chose to focus on THA/TKA procedures since THA/TKAs are important, effective procedures performed on a broad population, and the patient outcomes for these procedures (for example, pain, mobility, and quality of life) can be measured in a scientifically sound way and are also influenced by a range of improvements in care.[72] [73] [74] We also note that THA/TKA procedures are specifically intended to improve function and reduce pain, making patient-reported outcomes the most meaningful outcome metric to assess for these common, costly procedures. Patient-reported outcomes will be assessed separately for THA and TKA procedures, though these results may be combined into a single composite measure for reporting. Therefore, we will refer to a single measure, but acknowledge the possibility of two measures, one for THA patients and one for TKA patients.

During measure development, we discovered that in order to complete measure development, we would need access to a nationally representative sample of THA and TKA inpatient surgical procedure patient-reported outcome data set that is also consistently collected at the hospital-level and contains risk variables identified by orthopedists. The rationale for requesting access to a national THA and TKA inpatient surgical procedures patient-reported data source are twofold: (1) A national data source would provide us with hospital-level data representative of the total number of THA and TKA procedures performed in hospitals, as well as representative data on hospital-level case-mix; and (2) access to a national THA and TKA inpatient surgical procedures patient-reported data source would allow us to assess and identify a set of parsimonious data elements that will minimize the data collection burden by patients, physicians and hospitals. We believe access to such data would allow for completion and testing of the current measure under development that can be appropriately used for nationwide hospital performance evaluation. We also believe the CCJR model provides a unique opportunity to resolve these measure development issues through the collection of THA and TKA patient—reported outcome data. Access to this data through the CCJR Model would address the following:

- Current data sources are not consistently collected nor collected in a uniform process and in a standardized format (that is, data elements are not consistently defined across different data sources). We note that currently available data sources tend to be limited to single hospitals or regional registries which are associated with complex data access sharing requirements.
- Current lack of uniform hospital-level data that can be used in measure development.
- Lack of incentive for physicians and hospitals to collect patient-reported outcome data such as that through the model's financial incentives associated with voluntary data submission.
- Current lack of a technically simple and feasible mechanism for hospitals to submit patient-reported data to CMS. This model would help create and optimize such a mechanism, potentially enabling future measure implementation.

In summary, the voluntary data collection initiative in the CCJR model would provide data from the patient's perspective that is necessary to finalize and test the measure specifications, including the risk model. Access to this national representative voluntarily submitted data would enable us to do the following:

- Determine a parsimonious set of risk factors that are statistically adequate for risk adjustment for patient-reported outcome.
- Examine the differences in hospital performance related to different components in the patient-reported outcome (such as functional status, pain, etc.) to finalize the statistical modeling methodology for risk adjustment.
- Evaluate the reliability of the patient-reported outcome measure.
- Examine validity of the patient-reported outcome measure upon finalization of the risk adjustment

[72] Monticone M, Ferrante S, Rocca B, et al. Home-based functional exercises aimed at managing kinesiophobia contribute to improving disability and quality of life of patients undergoing total knee arthroplasty: a randomized controlled trial. *Archives of physical medicine and rehabilitation.* Feb 2013;94(2):231–239.

[73] Galea MP, Levinger P, Lythgo N, et al. A targeted home- and center-based exercise program for people after total hip replacement: a randomized clinical trial. *Archives of physical medicine and rehabilitation.* Aug 2008;89(8):1442–1447.

[74] Moffet H, Collet JP, Shapiro SH, Paradis G, Marquis F, Roy L. Effectiveness of intensive rehabilitation on functional ability and quality of life after first total knee arthroplasty: A single blind randomized controlled trial. *Archives of physical medicine and rehabilitation.* Apr 2004;85(4):546–556.

model via potential testing methods such as face validity testing with national experts, comparing the measure results to similar results based on other data sources if feasible, etc.

In order to encourage participation with voluntary data submission of patient-reported outcome data, we are proposing to seek and reward voluntary participation in submission of THA/TKA patient-reported outcome-based measure data as outlined in section III.D.5.b. of this proposed rule. We note that we would not publicly report the THA/TKA voluntary data.

Finally, we intend to use a fully tested and completed THA/TKA patient-reported outcome-based measure in CMS models or programs when appropriate. If there is a decision to implement the fully developed THA/TKA patient-reported outcome-based measure, such as in the CCJR model, we would propose to adopt the measure through notice and comment rulemaking. We refer reviewers to draft measure specifications in the downloads section of the Measure Methodology Web page at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

(2) Data Sources

As previously discussed, this measure is under development, and we are proposing to reward participant hospitals that volunteer to submit provider- and patient- level data elements. We note that there is currently little uniformity across hospitals regarding collection of specific provider- and patient-level data elements that are used to assess patient outcomes after THA and TKA inpatient procedures. In the voluntary data submission for the THA/TKA patient-reported outcome-based measure, we are trying to identify a uniform set of provider- and patient-level data elements that are accurate, valid, and reliable pieces of information that can be used in the determination of improvement in various patient characteristics like those previously listed (that is, pain, mobility, and quality of life). Furthermore, in order to minimize provider and hospital burden associated with data collection and submission of provider- and hospital-level data elements, we propose using a variety of data sources for measure development. We anticipate using the following data sources are:

- Patient-reported data;
- Administrative claims-based data; and
- One or both physician-reported and electronic health record data.

Through this voluntary data submission proposal, we hope to identify a uniform set of provider- and patient-level data elements while also identifying data sources that are the least burdensome for the patients, providers, and hospitals. We propose to request that participant hospitals provide administrative claims-based data whenever possible, in order to minimize burden on patients, providers, and hospitals. Additionally, we propose to request that participant hospitals submit either hospital documentation, chart abstraction, or abstraction from the electronic health records. We propose to request submission of the following data elements:

- Pre-operative Assessments (to be collected between 90 and 0 days prior to THA/TKA procedure):

++ Age.
++ Date of Birth.
++ Gender.
++ Ethnicity.
++ THA or TKA procedure.
++ Date of admission to anchor hospitalization.
++ Date of discharge from anchor hospitalization.
++ Date of eligible THA/TKA procedure.
++ Medicare Health Insurance Claim Number.

—PROMIS Global (all items).
++ VR–12 (all items.)
++ For TKA patients Knee injury and Osteoarthritis Outcome Score (*KOOS*[75]) (all items).
++ For THA patients Hip disability and Osteoarthritis Outcome Score (*HOOS*[76]) (all items).
++ Body Mass Index.
++ Presence of live-in home support, including spouse.
++ Use of chronic (≥ 90 day) narcotics.

—American Society of Anesthesiologists (ASA) physical status classification.
++ Charnley Classification.
++ Presence of retained hardware.

—Total painful joint count.
—Quantified spinal pain.
++ Joint range of motion in degrees (specify hip or knee).
++ Use of gait aides.
++ For THA patients abductor muscles strength.
++ For THA patients presence of Trendelenberg gait.
++ For THA patients history of congenital hip dysplasia or other congenital hip disease.
++ For THA patients presence of angular, translational, or rotational deformities of the proximal femur (in degrees).
++ For TKA patients anatomic angle (femoro-tibial angle) in degrees with varus/valgus.
++ For TKA patients knee extensor strength.
++ Single Item Health Literacy Screening (SILS2) questionnaire.[77]

- Post-operative Assessments (To be collected between 270 and 365 days following THA/TKA procedure):

++ Age.
++ Date of Birth.
++ Gender.
++ Date of admission to anchor hospitalization.
++ Date of discharge from anchor hospitalization.
++ Date of eligible THA/TKA procedure
++ Medicare Health Insurance Claim Number

—PROMIS Global (all items).
++ VR–12 (all items).

—For TKA patients, Knee injury and Osteoarthritis Outcome Score (*KOOS*[78]) (all items).

—For THA patients, Hip disability and Osteoarthritis Outcome Score (*HOOS*[79]) (all items).

Finally, we note that as the measure continues to undergo development that the list of data elements may be simplified. As stated earlier in this section entitled Data Sources, we intend identify a uniform set of provider- and patient-level data elements that are accurate, valid and reliable pieces of information that can be used in the determination of improvement in various patient-reported outcomes like those previously listed (that is, pain, mobility, and quality of life). We anticipate, via public comment and experience with the voluntary data submission, that the set of data elements listed previously will be simplified.

In accordance with, and to the extent permitted by, the HIPAA Privacy Rule and other applicable law, we propose to request that participant hospitals submit

[75] What is the KOOS? Available at: *http://www.koos.nu/koospresentation.html.* Accessed on April 15, 2015.

[76] What is the HOOS? Available at: *http://www.koos.nu/hoospres.html.* Accessed on April 15, 2015.

[77] Wallace LS, Rogers ES, Roskos SE., Holiday DB, Weiss BD. Screening items to identify patients with limited health literacy skills. J Gen Intern Med. 2006;21:874–7.

[78] Roos EM, Roos HP, Lohmander LS, Ekdahl C, Beynnon BD. Knee Injury and Osteoarthritis Outcome Score (KOOS)—development of a self-administered outcome measure. J Orthop Sports Phis There. 1998 Aug;28(2):88–96.

[79] What is the HOOS? Available at: *http://www.koos.nu/hoospres.html.* Accessed on April 15, 2015.

the data specified in the request, which we would limit to the minimum data necessary for us to conduct quality assessment and improvement activities. Regarding the process for data collection, we propose the THA/TKA voluntary data will be submitted to and collected by a CMS contractor in a manner and format similar to existing CMS data submission processes. For example, CMS would supply applicable hospitals with a file template and instructions for populating the file template with data and submitting the data; the hospitals will populate the template, log in to a secure portal, and transmit the file to the appropriate CMS contractor; the CMS contractor would also match the submitted data to Medicare administrative claims-based data and calculate completeness for determination of the reconciliation payment as noted in section III.C.5 of this proposed rule (or validated subscales or abbreviated versions of these instruments). We believe that participation in the submission of THA/TKA—voluntary data will provide the minimum information we would need that would inform us on how to continuously improve the currently specified measure in development.

We note that some of these data elements are closely aligned with data elements in e-clinical measures submitted by eligible professionals for the Medicare EHR Incentives Program for Eligible Professionals. Specifically these EHR Incentives Program measures for eligible professionals are: (1) Functional Status Assessment for Knee replacement (CMS 66); and (2) Functional Status Assessment for Hip replacement (CMS 56). We refer reviewers to CMS.gov EHR Incentives Program 2014 Eligible Professional June 2015 zip file update at *http://cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/eCQM_2014_EP_June2015.zip* for full measure specifications. We believe it is possible that many health IT vendors are already certified to capture, calculate and report these provider-level measures of functional status on total knee and total hip arthroplasty, and therefore we anticipate that the provider-level data elements that are identical to the THA/TKA patient-reported outcome voluntary data elements previously listed may not be as burdensome for the CCJR model participant hospitals to voluntarily submit.

(3) Cohort

The measure cohort(s) includes Medicare FFS beneficiaries, aged 65 years or older, admitted to non-federal acute care hospitals for elective primary THA or TKA. We would exclude from the cohort patients with fractures and mechanical complications or those undergoing revision procedures. THA and TKA patient-reported outcomes will be assessed separately but may be combined into a single composite measure for reporting.

(4) Inclusion and Exclusion Criteria

The measure cohort inclusion criteria are all patients undergoing elective primary THA/TKA procedures. Exclusion criteria will consist of patients undergoing non-elective procedures (that is, patients with fractures resulting in THA/TKA), as it is unfeasible to routinely capture pre-operative patient-reported assessments in these patients; patients with mechanical complications of prior hip and knee joint procedures and those undergoing revision THA/TKA will also be excluded, as their patient-reported outcomes may be influenced by prior care experiences and therefore may not adequately represent care quality of the hospital performing the revision procedure.

(5) Outcome

The measure will assess change between pre- and post-operative patient-reported outcomes for THA and TKA separately or as a composite measure for both procedures. The measure will use one or more of the following patient-reported outcome instruments (or validated subscales or abbreviated versions of these instruments) to calculate the measure score: the Patient Reported Outcomes Measurement Information Systems (PROMIS)-Global or the Veterans Rand 12 Item Health Survey (VR–12), and the Hip dysfunction and Osteoarthritis Outcome Score/Knee injury and Osteoarthritis Outcome Score (HOOS/KOOS) instruments to measure pre- and postoperative improvement or both. These candidate instruments were selected by a Technical Expert Panel based upon their meaningfulness to patients and clinicians, performance characteristics such as reliability, responsiveness and validity, and their perceived burden to both patients and providers. The pre-operative data collection timeframe will be 90 to 0 days before surgery, and the post-operative data collection timeframe will be 270 to 365 days following surgery. The approach to calculating the improvement or worsening of patient outcomes represented by the pre- and postoperative patient-reported survey results has not yet been determined, but will use one or more surveys to define the improvement or worsening of patient-reported outcomes to reliably identify differences between hospitals of varying performance.

(6) Risk-Adjustment (If Applicable)

We note that the measure's risk model has yet to be developed. In order to develop the risk model, final risk variable selection for the risk model will involve empirical testing of candidate risk variables as well as consideration of the feasibility and reliability of each variable. The risk model will account for the hospital level response rate as well as measureable patient-level factors relevant to patient-reported outcomes following elective THA/TKA procedures. To the extent feasible, the risk model methodology will adhere to established statistical recommendations.[80]

(7) Calculating the Risk-Standardized Rate

We note that the approach to reporting this measure(s) has yet to be developed. The measure will assess change in patient-reported outcomes between the pre-operative (90 to 0 days prior to the elective primary THA/TKA procedure) and post-operative (270–365 days following the elective primary THA/TKA procedure) periods.

We invite public comments on this proposal to seek voluntary participation in submitting data for a Hospital-Level Performance Measure of Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty. We also welcome comments on the appropriateness of this voluntary data collection for this model and the specific data collection requirements (see section III.D.3.a.(9) of this proposed rule) and data elements proposed.

(8) Performance Period

We propose defining performance periods for each year of the model as outlined in Table 16. A performance period for the voluntary THA/TKA data submission, are those timeframes in which an anchor hospital admission occurs for eligible THA/TKA voluntary data submission procedure. For the first year of the CCJR model, hospitals voluntarily submitting data will only be

[80] Ash AS, Fiengerg SE., Louis TA, Normand ST, Stukel TA, Utts J. STATISTICAL ISSUES IN ASSESSING HOSPITAL PERFORMANCE, Commissioned by the Committee of Presidents of Statistical Societies. Original report submitted to CMS on November 28, 2011, Revised on January 27, 2012. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Statistical-Issues-in-Assessing-Hospital-Performance.pdf.* Accessed on April 15, 2015.

asked to submit data for a 3-month period. The 3-month period for THA/TKA voluntary data reporting was identified due to data processing and coordination of other proposed timelines in this model. Data submitted for the first year would be for cases that fulfill the measure specifications described in section III.D.3.a. of this proposed rule, and would be restricted to the pre-operative data elements on cases performed between April 1, 2016 and June 30, 2016. The proposed timing allows matching of the patient-reported data with relevant administrative claims-based data in order to accurately calculate the percent of eligible elective primary THA/TKA patients for which THA/TKA voluntary data was successfully submitted. The April 1st date acknowledges the measure requirement of the 90-day window prior to surgery during which hospitals can collect pre-operative data. The June 30th end date was selected because it correlates with the THA/TKA readmission measure performance period end date currently implemented for the HIQR program and the HRRP. Both of these dates provide the greatest feasibility for data collection.

For year 2, THA/TKA voluntary data reporting would be 3 months of post-operative data for cases performed between April 1, 2016 and June 30, 2016, and 12 months of pre-operative data for cases performed between July 1, 2016 and June 30, 2017.

For year 3 and subsequent years of the model, the performance periods for submission of voluntary data will consist of 12-month time periods.

TABLE 16—EXAMPLE OF POTENTIAL PERFORMANCE PERIODS FOR PRE- AND POST-OPERATIVE THA/TKA VOLUNTARY DATA SUBMISSION

CCJR model year	Performance period	Patient population eligible for THA/TKA voluntary data submission	Requirements for successful THA/TKA voluntary data submission *
2016	April 1, 2016 through June 30, 2016.	All patients undergoing elective primary THA/TKA procedures performed between April 1, 2016 and June 30, 2016.	Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between April 1, 2016 and June 30, 2016.
2017	April 1, 2016 through June 30, 2016.	All patients undergoing elective primary THA/TKA procedures performed between April 1, 2016 and June 30, 2016.	Submit POST-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between April 1, 2016 and June 30, 2016.
2017	July 1, 2016 through June 30, 2017.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2016 and June 30, 2017.	Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2016 and June 30, 2017.
2018	July 1, 2016 through June 30, 2017.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2016 and June 30, 2017.	Submit POST-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2016 and June 30, 2017.
2018	July 1, 2017 through June 30, 2018.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2017 and June 30, 2018.	Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2017 and June 30, 2018.
2019	July 1, 2017 through June 30, 2018.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2017 and June 30, 2018.	Submit POST-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2017 and June 30, 2018.
2019	July 1, 2018 through June 30, 2019.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2018 and June 30, 2019.	Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2018 and June 30, 2019.
2020	July 1, 2018 through June 30, 2019.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2018 and June 30, 2019.	Submit POST-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2018 and June 30, 2019.
2020	July 1, 2019 through June 30, 2020.	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2019 and June 30, 2020.	Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2019 and June 30, 2020.
2016	3 months	All patients undergoing elective primary THA/TKA procedures performed between April 1, 2016 and June 30, 2016.	Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between April 1, 2016 and June 30, 2016.
2017	15 months	All patients undergoing elective primary THA/TKA procedures performed between April 1, 2016 and June 30, 2017.	1. Submit POST-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between April 1, 2016 and June 30, 2016. 2. Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2016 and June 30, 2017.
2018	24 months	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2016 and June 30, 2018.	1. Submit POST-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2016 and June 30, 2017.

TABLE 16—EXAMPLE OF POTENTIAL PERFORMANCE PERIODS FOR PRE- AND POST-OPERATIVE THA/TKA VOLUNTARY DATA SUBMISSION—Continued

CCJR model year	Performance period	Patient population eligible for THA/TKA voluntary data submission	Requirements for successful THA/TKA voluntary data submission *
			2. Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2017 and June 30, 2018.
2019	24 months	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2017 and June 30, 2019.	1. Submit POST-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2017 and June 30, 2018. 2. Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2018 and June 30, 2019.
2020	24 months	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2018 and June 30, 2020.	1. Submit POST-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2018 and June 30, 2019. 2. Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2019 and June 30, 2020.

* Requirements for determining successful submission of THA/TKA voluntary data are located in section III.D.3.a.(9) of this proposed rule.

The proposed performance period enables hospitals to receive incentives for data collection starting in performance year-one, even though complete pre-operative and post-operative data collection requires a minimum 9 through 12 month time period. This 9 through 12 month time period, between the procedure and post-operative data collection, was defined through clinician and stakeholder input and provides for both sufficient elapsed time for maximum clinical benefit of THA/TKA procedures on patient-reported outcomes and accommodates common clinical care patterns in which THA/TKA patients return to their surgeon one year after surgery. We invite public comments on our proposal of defining performance year-one episodes for a participating hospital as an anchor hospital admission for an eligible THA/TKA procedure between April 1, 2016 and June 30, 2016, with subsequent year performance time periods each being 12-month periods and starting every July 1st.

(9) Requirements for ''Successful'' Submission of THA/TKA Voluntary Data

In order for CMS to assess if participant hospitals are eligible for reconciliation payment after receiving the THA/TKA voluntary data, requirements to determine if the submitted data will inform measure development have been identified. We believe that the following criteria should be used to determine if a participant hospital has successfully submitted THA/TKA voluntary data. We note that successful THA/TKA voluntary data submission, as stated briefly in section III.C.5. of this proposed rule, requires completion of all of the following:

- Submission of the data elements listed in section III.D.3.a.(2).of this proposed rule.
- Data elements listed in section III.D.3.a.(2) of this proposed rule must be submitted on at least 80 percent of their eligible elective primary THA/TKA patients (as described in section III.D.3.a.(3) of this proposed rule).
- THA/TKA voluntary data submission must occur within 60 days of the end of the most recent data collection period.

To fulfill THA/TKA voluntary data collection criteria for performance year-one, only pre-operative data collection and submission on at least 80 percent of eligible elective primary THA/TKA patients is required. To successfully submit THA/TKA voluntary data for performance years 2 through 5, hospitals must submit both pre-operative and post-operative patient reported outcome data on at least 80 percent of eligible elective primary THA/TKA patients. A potential example of the performance periods for which we would like to have THA/TKA voluntary data is summarized in section III.D.3.a.of this proposed rule.

Table 16 also summarizes the performance periods for pre-operative and post-operative THA/TKA voluntary data. Finally, hospitals volunteering to submit THA/TKA data will be required to submit pre-operative data on all eligible patients and post-operative data elements only on those patients at least 366 days out from surgery. Therefore, hospitals are not expected to collect and submit post-operative THA/TKA voluntary data on patients who are fewer than 366 days from the date of surgery.

We previously described a THA/TKA eligible patient in section III.D.3.a.(2) of this proposed rule. This description is important as these patients are those in which we seek submission of voluntary data. We also selected the requirement of submitting 80 percent of eligible elective primary THA/TKA patients' data because this volume of cases will result in a high probability that we will have a have a national sample of THA/TKA patient data representative of each hospital's patient case mix. Having 80 percent of the eligible elective primary THA/TKA patients will enable an accurate and reliable assessment of patient-reported outcomes for use in measure development. We note that data used for outcome measure development must adequately represent the population that is anticipated to be measured and in this case that population would be those experiencing elective primary THA/TKA inpatient surgical procedures. Data that more accurately reflects the patient outcomes and case mix of the population to be measured will allow, during measure development, a more scientifically accurate and reliable measure. Having 80 percent of eligible elective primary THA/TKA recipient data will result in a more reliable measure that is better

able to assess hospital performance than a measure created from a less representative patient sample. Furthermore, we considered setting the requirement at 100 percent of the eligible elective primary THA/TKA patients, but concluded that a requirement of 100 percent data collection may not be feasible for all hospitals or may be excessively burdensome to achieve. Therefore we set the requirement at 80 percent of the eligible elective primary THA/TKA patients. We believe acquisition of 80 percent of the eligible elective primary THA/TKA patients will provide representative data for measure development while decreasing patient, provider and hospital burden. We seek public comment of these requirements to determine successful voluntary submission of THA/TKA data. We also seek public comment specifically on the requirement for data on 80 percent of the eligible elective primary THA/TKA patients.

b. Measure That Captures Shared Decision-Making Related to Elective Primary Total Hip and/or Total Knee Arthroplasty

In addition to the patient-reported functional status outcomes, we note that shared-decision making is an important aspect of care around elective procedures such as primary total hip and total knee arthroplasty. We also note that lower episode expenditures achieved through improved efficiency may yield the unintended consequence of a compensatory increase in the number of episodes initiated. Use of shared decision-making prior to episode initiation can serve as an important tool to ensure appropriate care. Though there are no developed measures, we seek feedback on the opportunity to capture quality data related to shared decision-making between patients and providers. Examples of such a measure could include concepts such as a trial of conservative medical therapy prior to elective procedures or broader shared decision-making measures. We invite public comment on whether such a measure concept would be appropriate for the CCJR model. If we develop a measure that captures shared decision-making related to elective primary total hip and total knee arthroplasty or both, we would propose through rulemaking or other means to add that measure to the CCJR model.

c. Future Measures Around Care Planning

The person-centered shared care plan is an important tool that can help providers across settings collaborate around a customized plan that reflects a patient's goals and offers providers critical information about all of the treatment a beneficiary has received. Health IT solutions are increasingly supporting the exchange of care plan information across settings so that providers and individuals have access to necessary information whenever and wherever it is needed. In the 2015 Edition of certification criteria for health information technology (80 FR 16842) the Office of the National Coordinator for Health Information Technology (ONC) has proposed the adoption of a new criterion to ensure health IT can capture, display, and exchange a robust care plan document in accordance with new standards released in the Consolidated Clinical Document Architecture Release 2. While further measure development is needed, we are seeking comment on the appropriateness of a future quality measure which would assess the use of shared care plans in the care of beneficiaries participating in the CCJR model.

d. Future Measures for Use of Health IT and Health Information Exchange

We believe the use of health IT tools is a critical component of effective coordination across settings of care. Under bundled payment models, in which providers across the continuum of care share accountability for the clinical management and total cost of an episode of care, the capacity to share information electronically across disparate provider systems is essential for delivering efficient, safe, high quality care. As discussed in the August 2013 Statement ''Principles and Strategies for Accelerating Health Information Exchange'' (available at *http://www.healthit.gov/sites/default/files/acceleratinghieprinciples_strategy.pdf*), we believe that all individuals, their families, their healthcare and social service providers, and payers should have consistent and timely access to health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the individual's care. ONC has released a draft document entitled ''Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap'' (available at *http://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version-1.0.pdf*), which describes barriers to interoperability across the current health IT landscape, the desired future state that will be necessary according to the industry to enable a learning health system, and a suggested path for moving forward. ONC will focus on actions that will enable a majority of individuals and providers across the care continuum to send, receive, find and use a common set of electronic clinical information at the nationwide level by the end of 2017. Under section 1833(z)(3)(D)(i)(I) of the Act, as amended by section 101(e) of the Medicare Access and CHIP Reauthorization Act, providers participating in qualifying alternative payment models under Medicare will be required to use certified EHR technology beginning in 2019. As this date approaches, we believe it will be important for providers working in these models to demonstrate adoption of health information technology.

We believe that use of certified health IT tools and the interoperable exchange of health information is a critical capability for CCJR model participants to be able to deliver the high-quality care and effective coordination across settings that will be required to demonstrate success under the model. Moreover, we believe that it will be important to incentivize adoption and use of these enabling technologies among model participants including post-acute care providers, by linking these activities to participant eligibility to receive reconciliation payments.

While we are not proposing to add a measure for certified health IT use for the program's initial performance year, we are seeking comment on how we might incorporate such a measure beginning in the 2017 performance year. We invite stakeholder comment on the following questions:

- Is successful attestation as part of the EHR Incentive Program for Medicare hospitals tin he applicable reporting year the most appropriate quality measure for assessing hospital performance on the use of health IT and interoperable health information in the CCJR model?
- Should the model include a performance measure that would be specific to the ability of hospitals to conduct electronic care coordination using certified health IT, for instance, the measure of transitions of care which hospitals currently report on as part of the EHR Incentives Program for Medicare Hospitals?
- What other measures could be used to assess hospital performance on the use of health IT and interoperable health information while minimizing program and provider collection and reporting burden?

We seek public comments on how we might incorporate an electronic measure beginning in the 2017 performance year,

and public comments on the questions posed previously in this rule.

We also seek public comment on the appropriateness of quality measures for post-acute care patients, physicians and facilities that care for THA/TKA surgical procedure patients.

4. Form, Manner and Timing of Quality Measure Data Submission

We believe it is important to be transparent and to outline the form, manner and timing of quality measure data submission so that accurate measure results are provided to hospitals, and that timely and accurate calculation of measure results are consistently produced to determine annual reconciliation payment.

We propose that data submission for Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550) and Hospital-Level Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551) (or both) be accomplished through the existing HIQR program processes. Since these measures are administrative claims based measures, hospitals will not need to submit data. We propose that the same mechanisms used in the HIQR program to collect HCAHPS survey measure data also be used in the CCJR model (79 FR 50259). For the hospitals that voluntarily submit data for the THA/TKA patient-reported outcome-based performance measure we anticipate, if it is technically feasible, for data submission processes to be broadly similar to those summarized for the HIQR program for chart abstracted and administrative claims based measures. We would create a template for hospitals to complete with the THA/TKA voluntary data, provide a secure portal for data submission, and provide education and outreach on how to use these mechanisms for data collection and where to submit the THA/TKA voluntary data. We describe potential processes for voluntary data collection in section III.D.3.a.(2) of this proposed rule, Data Sources. These processes are broadly similar to those used by the HIQR program.

We invite public comment on the proposal to collect quality measure data through mechanisms similar to those used in the Hospital IQR program.

5. Proposed Display of Quality Measures and Availability of Information for the Public From the CCJR Model

We believe display of quality data is an important way to educate the public on hospital performance. We have used several methods to report quality data to the public, including posting data on the Hospital Compare Web site and *data.medicare.gov.* Data has been available for viewing on these Web sites and in downloadable databases since 2005, and are well-known mechanisms for providing information to the public. We are proposing to post data for measures included in the CCJR model for each participant hospital on the Hospital Compare Web site in an easily understood format. The applicable time periods for the measures during the CCJR model initiative are summarized in Table 17.

TABLE 17—SUMMARY OF QUALITY MEASURE PERFORMANCE PERIODS BY YEAR OF THE CCJR MODEL

Measure title	CCJR model year				
	1st	2nd	3rd	4th	5th
THA/TKA Complication *	April 1, 2013–March 31, 2016.	April 1, 2014–March 31, 2017.	April 1, 2015–March 31, 2018.	April 1, 2016–March 31, 2019.	April 1, 2017–March 31, 2020.
THA/TKA ** Readmission	July 1, 2013–June 30, 2016.	July 1, 2014–June 30, 2017.	July 1, 2015–June 30, 2018.	July 1, 2016–June 30, 2020.	July 1, 2017–June 30, 2016.
HCAHPS ***	July 1, 2015–June 30, 2016.	July 1, 2016–June 30, 2017.	July 1, 2017–June 30, 2018.	July 1, 2018–June 30, 2019.	July 1, 2019–June 30, 2020.

* Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550).
** Hospital-Level Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551).
*** HCAHPS (NQF #0166) Survey.

The proposed time periods for the THA/TKA Complications measure (NQF #1550), and the THA/TKA Readmission measure (NQF #1551) are consistent with HIQR program performance periods for July 2017 public reporting. The HCAHPS quality information will be the measure results. We believe the public is familiar with the proposed measures, which have been publicly reported in past releases of Hospital Compare as part of the Hospital IQR Program. In order to minimize confusion and facilitate access to the data on the measures included in the CCJR model, we propose to post the data on each participant hospital's performance on each of the 3 proposed quality measures in a downloadable format in a section of the Web site specific to the CCJR model, similar to what is done for HRRP and the Hospital-Acquired Conditions Reduction Program. We also propose to post data on whether or not each participant hospital met the proposed threshold (section III.C.5.b. of this proposed rule) for receiving a reconciliation payment in the same downloadable database.

In addition, we believe information about functional status both pre- and post-operatively is important for hip and knee replacements. We are developing a functional status measure that we believe will provide this needed information. The measure, Hospital-Level Performance Measure(s) of Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (see section III.D.3 of this proposed rule for a detailed description), requires comprehensive testing before it can be used in a CMS program. As part of the effort to collect data on functional status voluntarily from hospitals, we are proposing that hospitals that voluntarily submit data for this measure be acknowledged through the use of a symbol on Hospital Compare. The data submitted voluntarily for the functional status measure would not be publicly reported along with the other measures in the program.

We invite public comments on these proposals to post data for mandatorily required measures on the Hospital Compare Web site and to acknowledge hospitals that voluntarily submit data for the functional status measure with an icon on the Hospital Compare Web site.

Finally, in accordance with section 1115A of the Act, we are proposing section III.D. in the new proposed part 510 of the Code of Federal Regulations.

E. Data Sharing

1. Overview

In this section, we propose to provide data to the hospital participants of the CCJR model. CMS has experience with a range of efforts designed to improve care coordination for Medicare beneficiaries, including the Medicare Shared Savings Program (MSSP), Pioneer Accountable Care Organization (ACO) Model, and BPCI, all of which make certain data available to participants. The CCJR model proposes in section III.C.2. of this proposed rule to financially incentivize hospitals, through retrospective bundled payments, to engage in care redesign efforts to improve quality of care and reduce spending for the aggregate Part A and B FFS (FFS) spending for beneficiaries included in the model during the inpatient hospitalization and 90 days post-discharge. Given this, we believe it is necessary to provide historical and ongoing claims data representing care furnished during episodes of care for LEJRs to hospitals so that they can, among other things, adequately structure their care pathways, coordinate care for beneficiaries, and estimate acute inpatient and post-acute spending within LEJR episodes.

As noted previously, this would not be the first instance in which we have provided claims data to entities participating in a CMS model or program. For example, participants in MSSP initially receive historical aggregate information on their financial performance as well as updated financial data throughout their tenure in the program. In addition, MSSP participants receive certain beneficiary-identifiable claims information in accordance with our regulations (see Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 FR 67844 through 67849, November 2, 2011). The MSSP regulation noted that while an ACO may have complete information for the services it provides or coordinates on behalf of its FFS beneficiary population, it may not have complete information on a FFS beneficiary who chose to receive services, medications or supplies from non-ACO providers and suppliers. Thus, we decided to provide ACOs participating in the MSSP with an opportunity to request CMS claims data on the premise that more complete beneficiary-identifiable information would enable practitioners in an ACO to better coordinate and target care strategies. Recently, we noted that the ACOs participating in the MSSP have reported how important access to real time data is for providers to improve care coordination across all sites of care, including outpatient, acute, and post-acute sites of care. Furthermore, we noted our view that providers across the continuum of care are essential partners to physicians in the management of care. (See Medicare Program: Medicare Shared Savings Program: Accountable Care Organizations: Proposed Rule, 79 FR 72779).

Similarly, participants in the Pioneer ACO model can request historical claims data of beneficiaries aligned with the particular Pioneer ACO entity, and the entities continue to receive certain ongoing data regarding the services furnished to those beneficiaries. (See *http://innovation.cms.gov/Files/fact-sheet/Pioneer-ACO-Model-Beneficiaries-Rights-Fact-Sheet.pdf*). In addition, we provide BPCI participants with the opportunity to request beneficiary-level claims data regarding their own patients, both for the historical period of 2009–2012 that was used to set baseline prices for entities participating in BPCI, as well as ongoing monthly claims feeds containing Medicare FFS claims for beneficiaries that could have initiated an episode of care for that particular BPCI participant. These monthly claims feeds provide BPCI participants with data for both acute and post-acute care spending for beneficiaries that could have initiated an episode of care at that BPCI participant.

Based on our experience with these efforts, we believe that providing a similar opportunity for hospitals participating in the CCJR model to request data is necessary for participant hospitals to have the relevant information to allow for practice changes supported by CCJR and to identify services furnished to beneficiaries receiving LEJRs under the model. Specifically, providing participant hospitals with certain claims and summary information on beneficiaries in accordance with established privacy and security protections would improve their understanding of the totality of care provided during an episode of care. With this greater understanding, we anticipate that hospitals would be better equipped to evaluate their practice patterns and actively manage care delivery so that care for beneficiaries is better coordinated, quality and efficiency are improved, and payments aligned more appropriately to the medically necessary services beneficiaries have a right to receive. We also expect that providing this data to CCJR participants will benefit beneficiaries by allowing providers to use the data to improve care coordination activities in areas that may be currently lacking. However, we also expect that CCJR hospitals are able to, or will work toward, independently identifying and producing their own data, through electronic health records, health information exchanges, or other means that they believe are necessary to best evaluate the health needs of their patients, improve health outcomes, and produce efficiencies in the provision and use of services.

Accordingly, we believe that making certain data available to CCJR hospitals, as we do with ACOs participating in the MSSP and Pioneer model, would help them to monitor trends and make needed adjustments in their practice patterns. In order for CCJR participants to understand and track their care patterns, we propose to provide the participants with beneficiary-level claims data for the historical period used to calculate a CCJR hospital's target price as well as ongoing quarterly beneficiary-identifiable claims data in response to their request for such data in accordance with our regulations. Given that the CCJR model also proposes to incorporate regional pricing in the calculation of target prices, we also propose to provide participants with aggregate regional data.

2. Beneficiary Claims Data

Based on our experience with BPCI participants, we recognize that hospitals vary with respect to the kinds of beneficiary claims information that would be most helpful. While many hospitals located in MSAs that are selected for participation in CCJR model may have the ability to analyze raw claims data, other hospitals may find it more useful to have a summary of these data. Given this, we are proposing to make beneficiary claims information available through two formats.

First, for participant hospitals that lack the capacity to analyze raw claims data, we propose to provide summary beneficiary claims data reports on beneficiaries' use of health care services during the baseline and performance periods. These reports would allow participant hospitals to assess summary data on their relevant beneficiary population without requiring sophisticated analysis of raw claims data. Such summary reports will provide tools to monitor, understand, and manage utilization and expenditure patterns as well as to develop, target, and implement quality improvement programs and initiatives. For example, if the data provided by CMS to a particular hospital participant reflects that a certain post-acute care (PAC) provider admits beneficiaries who then

have significantly higher rates of inpatient readmissions than the rates experienced by other beneficiaries with similar care needs at similarly situated PAC providers, that may be evidence that the hospital could consider, among other things, the appropriateness of discharges to that provider, whether other alternatives might be more appropriate, and whether there exist certain care interventions that could be incorporated post-discharge to lower readmission rates.

Therefore, for both the baseline period and on a quarterly basis during a participant hospital's performance period, we are proposing to provide participant hospitals with an opportunity to request summary claims data that would encompass the total expenditures and claims for an LEJR episode, including the procedure, inpatient stay, and all related care covered under Medicare Parts A and B within the 90 days after discharge, including hospital care, post-acute care, and physician services for the hospital's beneficiaries whose anchor diagnosis at discharge was either MS DRG 469 or 470. We propose that these summary claims aggregate data reports would also contain payment information, utilizing the categories listed for each episode triggered by a beneficiary as follows:

- Inpatient Hospital.
- Outpatient Hospital.
- Physician.
- Long-Term Care Hospitals (LTCH).
- Inpatient Rehabilitation Facilities (IRF).
- Skilled Nursing Facilities (SNF).
- Home Health Agencies (HHA).
- Hospice.
- Ambulatory Surgical Center.
- Part-B Drugs.
- Durable Medical Equipment (DME).
- Clinical Laboratories.
- Ambulance.

These reports would likely include the following:

- Information such as admission and discharge date from the anchor hospitalization.
- The physician for the primary procedure, Medicare payments during the anchor hospitalization.
- Medicare payments during the post-acute care phase.
- Medicare payments for physician services would likely be included in these reports.

These summary claims data would reflect all Medicare Part A and Part B expenditures during the 90-day episodes, except for those claim types noted later in this section, as well as excluding expenditures related to those MS–DRGs that we are proposing to be specifically excluded from the episode of care, as set forth in section III.B.2. of this proposed rule.

Alternatively, for hospitals with a capacity to analyze raw claims data, we would make- more detailed beneficiary-level information available in accordance with established privacy and security protections. These data would enable hospitals to better coordinate and target care strategies for beneficiaries included in CCJR episodes. For example, in the BPCI initiative, we provide participants with beneficiary-level claims data for all Part A and Part B services furnished to a beneficiary treated by that BPCI participant for all MS–DRGs included in an episode that the participant has selected for participation (See ''Bundled Payments for Care Improvement Initiative (BPCI): Background on Model 2 for Prospective Participants, page 3 at *http://innovation.cms.gov/Files/x/BPCI_Model2Background.pdf.*)

These data include services furnished by the participant, as well as services furnished by other entities during the 30, 60, or 90-day episode. For example, where the entity participating in BPCI is an acute care hospital, we provide beneficiary-level claims data for all Medicare Part A and B services and supplies furnished by the hospital during the inpatient admission, as well as all post-acute services furnished to the beneficiary by the hospital or any other providers or suppliers.

The response from entities participating in BPCI has indicated that the availability of these data is necessary to monitor trends and pinpoint areas where care practice changes are appropriate, as well as assess the cost drivers during the acute and post-acute periods of the episode. Thus, for the baseline period and on a quarterly basis during a hospital's performance period, we propose to provide participant hospitals with an opportunity to request line-level claims data for each episode that is included in the relevant performance year, as described in section III.C. of this proposed rule.

For both the proposed summary claims data and the more detailed claims data formats, we propose that the sets of these files would be packaged and sent to a portal in a ''flat'' or binary format for the individual participant hospitals to retrieve. Furthermore, the files would contain information on all claims triggered by a beneficiary in a participating CCJR hospital. Finally, we note that beneficiary information that is subject to the regulations governing the confidentiality of alcohol and drug abuse patient records (42 CFR part 2) would not be included in any beneficiary identifiable claims data shared with a hospital under our proposal.

We request comments on these proposals as well as the kinds of data and frequency of reports that would be most helpful to the hospitals' efforts in coordinating care, improving health, and producing efficiencies.

3. Aggregate Regional Data

Additionally, because we are proposing to incorporate regional pricing data in the creation of prices for CCJR, as set forth in section III.C.4 of this proposed rule, we believe it will also be necessary to provide comparable aggregate expenditure data available for all claims associated with MS–DRGs 469 and 470 for the census region in which the participant hospital is located. As noted in section III.C, we are proposing that a hospital's target price will be determined based on a blend of its own historical expenditures as well regional pricing data of all other hospitals in its region. Thus, we are also proposing to provide CCJR hospitals with aggregate data on the total expenditures during an acute inpatient stay and 90-day post-discharge period for all Medicare FFS beneficiaries whose anchor diagnosis at discharge was either MS–DRG 469 or 470 (and would have initiated a CCJR episode if discharged from a CCJR hospital) in their census region. These data would not include beneficiary-identifiable claims data, but would provide high-level information on the average episode spending for MS–DRGs 469 and 470 in the region in which the participant hospital is located. We request comments on these proposals as well as the kinds of aggregate data and frequency of data reports that would be most helpful to the hospitals' efforts in coordinating care, improving health, and producing efficiencies.

4. Timing and Period of Baseline Data

We considered various options for the timing of providing baseline data, as described previously, to CCJR participant hospitals. We considered provision of data prior to the effective date of the model, January 1, 2016, as well as providing data to participants at the point of the first payment reconciliation (described in section III.C.6. of this proposed rule). We propose to make baseline data available to hospitals participating in CCJR no sooner than 60 days after January 1, 2016, the effective date of the model. We recognize that these data are important to the abilities of CCJR participant hospitals to estimate costs,

coordinate care, and identify areas for practice transformation, and that early release of this data can facilitate their efforts to do so. We also anticipate that hospitals will view the CCJR effort as one involving continuous improvement. As a result, changes initially contemplated by a hospital could be subsequently revised based on updated information and experiences. While we would like to be able to make data available as soon as possible once the program begins, we do not believe that these baseline data must be immediately available upon its effective date as hospitals can begin considering improvements that would enhance their ability to better coordinate care and increase efficiencies in the absence of these data. Therefore, we propose to begin making baseline data available to CCJR hospitals within 60 days of CMS' receipt of the request by the participant hospital for such data, in a form, time, and manner of such requests to be determined by CMS and announced at a later date. Requests would not be accepted until the model has begun. We seek comments on this proposal.

We have also considered which period of baseline data should be shared with hospitals, for example, whether the data should represent a single year, or some longer period such as a 3-year period or more. To be most useful, we believe the baseline information should be recent enough to reflect current practices yet of a sufficient duration to reflect trends in those recent practices. For example, 1 year of data would likely reflect a hospital's most current practices, but would not be helpful for purposes of identifying trends. In contrast, 3 years of data could both reflect a hospital's most recent performance and recent performance trends. Moreover, making data available for a 3-year period aligns with our proposal to set a target price based on a 3-year period of baseline data, which is a factor in assessing CCJR hospitals' performance (see section III.C). If a hospital has access to baseline data for the 3-year period used to set its target price, then it would be able to assess its practice patterns, identify cost drivers, and ultimately redesign its care practices to improve efficiency and quality.

We alternatively considered making data available for an even longer historical period—for example, 4 or 5 years. However, we question the usefulness of information that is older than 3 years for purposes of changes contemplated for current operations. Accordingly, we are proposing to make available baseline data for up to a 3-year period. We will limit the content of this data set to the minimum data necessary for the participant hospital to conduct quality assessment and improvement activities and effectively coordinate care of its patient population. This period would encompass up to the 3 most recent years for which claims data are available for the hospital and would align with the baseline period we propose to utilize to establish target prices, as noted previously. We seek comments on our proposal and invite comments on alternative time periods that could better help hospitals evaluate their practice patterns and actively manage care delivery so that care is better coordinated, quality and efficiency are improved, and costs are better controlled.

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

The availability of periodically updated beneficiary-identifiable claims data would assist hospitals participating in CCJR to identify areas where they might wish to change their care practice patterns, as well as monitor the effects of any such changes. With respect to these purposes, we have considered what would be the most appropriate period for making updated claims information available to hospitals, while complying with the HIPAA Privacy Rule's ''minimum necessary'' provisions standard. We believe that quarterly claims data updates align with a 90-day episode window. Moreover, as a larger episode window would be included, the claims data would be more representative of total costs and hence more useful to hospitals as they consider long-term practice changes. Accordingly, we are proposing to make updated claims data available to hospitals upon receipt of a request for such information that meets CMS's requirements to ensure the applicable HIPAA conditions for disclosure have been met, as frequently as on a quarterly basis. We seek comments on this proposal.

Related to this is the period of claims that would be represented in each update. For example, we considered limiting this period to 3 months of data, which aligns with the frequency with which we would make updated claims data available. However, other than this alignment, we do not see additional reasons for artificially limiting the period to this extent. Alternatively, we considered providing an updated dataset as frequently as each quarter that would include data from up to the previous 6 quarters. We believe that this level of cumulative data would offer more complete information and allow better trend comparisons.

Accordingly, we propose to make beneficiary-identifiable and aggregate claims data available that would represent up to 6 quarters of information upon receipt of a request for such information that meets the requirements of the HIPAA Privacy Rule. We would note that we intend for the data for this model to be consistent with the performance year (January 1 through December 31). To accomplish this for the first year of CCJR (2016), we would provide, upon request and in accordance with the HIPAA Privacy Rule, claims data from January 1, 2016 to June 30, 2017 on as frequently as a running quarterly basis, as claims are available. For each quarter and extending through June 30, 2017, participants would receive data for up to the current quarter and all of the previous quarters going back to January 1, 2016. These datasets would contain all claims for all potential episodes that were initiated in 2016 and capture a sufficient amount of time for relevant claims to have been processed. We will limit the content of this data set to the minimum data necessary for the participating hospital to conduct quality assessment and improvement activities and effectively coordinate care of its patient population. We seek comment on our proposal.

6. Legal Permission To Share Beneficiary-Identifiable Data

We recognize that there are a number of issues and sensitivities surrounding the disclosure of beneficiary-identifiable health information, and note that a number of laws place constraints on sharing individually identifiable health information. For example, section 1106 of the Act bars the disclosure of information collected under the Act without consent unless a law (statute or regulation) permits for the disclosure. In this instance, the HIPAA Privacy Rule permits this proposed disclosure of individually identifiable health information by us.

In this proposed rule, we are proposing to make participant hospitals financially responsible for services that may have occurred outside of the hospital during the 90-day post-discharge period. Although we expect hospitals to be actively engaged in post-discharge planning and other care during the 90-day post-discharge period for beneficiaries receiving LEJRs, as discussed in section III.A. of this proposed rule, we believe it is necessary for the purposes of the CCJR—JR model to provide participant hospitals with beneficiary-level claims data, either in

summary or line-level claim formats for a 3-year historical period as well as on a quarterly basis during the performance period. We believe that these data constitute the minimum information necessary to enable the participant hospital to understand spending patterns during the episode, appropriately coordinate care, and target care strategies toward individual beneficiaries furnished care by the participant hospital and other providers and suppliers.

Under the HIPAA Privacy Rule, covered entities (defined as health care plans, providers that conduct covered transactions, including hospitals, and health care clearinghouses) are barred from using or disclosing individually identifiable health information (called ''protected health information'' or PHI) in a manner that is not explicitly permitted or required under the HIPAA Privacy Rule.

The Medicare FFS program, a ''health plan'' function of the Department, is subject to the HIPAA Privacy Rule limitations on the disclosure of PHI. The hospitals and other Medicare providers and suppliers are also covered entities, provided they are health care providers as defined by 45 CFR 160.103 and they conduct (or someone on their behalf conducts) one or more HIPAA standard transactions electronically, such as for claims transactions. In light of these relationships, we believe that the proposed disclosure of the beneficiary claims data for an acute inpatient stay plus 90-day post-discharge episode where the anchor diagnosis at discharge was MS–DRG 469 or 470 would be permitted by the HIPAA Privacy Rule under the provisions that permit disclosures of PHI for ''health care operations'' purposes. Under those provisions, a covered entity is permitted to disclose PHI to another covered entity for the recipient's health care operations purposes if both covered entities have or had a relationship with the subject of the PHI to be disclosed, the PHI pertains to that relationship, and the recipient will use the PHI for a ''health care operations'' function that falls within the first two paragraphs of the definition of ''health care operations'' in the HIPAA Privacy Rule (45 CFR 164.506(c)(4)).

The first paragraph of the definition of health care operations includes ''conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines,'' and ''population-based activities relating to improving health or reducing health costs, protocol development, case management and care coordination'' (45 CFR 164.501). Under our proposal, hospitals would be using the data on their patients to evaluate the performance of the hospital and other providers and suppliers that furnished services to the patient, conduct quality assessment and improvement activities, and conduct population-based activities relating to improved health for their patients. When done by or on behalf of a covered entity, these are covered functions and activities that would qualify as ''health care operations'' under the first and second paragraphs of the definition of health care operations at 45 CFR 164.501. Hence, as previously discussed, we believe that this provision is extensive enough to cover the uses we would expect a participant hospital to make of the beneficiary-identifiable data and would be permissible under the HIPAA Privacy Rule. Moreover, our proposed disclosures would be made only to HIPAA covered entities that have (or had) a relationship with the subject of the information, the information we would disclose would pertain to such relationship, and those disclosures would be for purposes listed in the first two paragraphs of the definition of ''health care operations.''

When using or disclosing PHI, or when requesting this information from another covered entity, covered entities must make ''reasonable efforts to limit'' the information that is used, disclosed or requested the ''minimum necessary'' to accomplish the intended purpose of the use, disclosure or request (45 CFR 164.502(b)). We believe that the provision of the proposed data elements listed previously would constitute the minimum data necessary to accomplish the CCJR model goals of the participant hospital.

The Privacy Act of 1974 also places limits on agency data disclosures. The Privacy Act applies when the federal government maintains a system of records by which information about individuals is retrieved by use of the individual's personal identifiers (names, Social Security numbers, or any other codes or identifiers that are assigned to the individual). The Privacy Act prohibits disclosure of information from a system of records to any third party without the prior written consent of the individual to whom the records apply (5 U.S.C. 552a(b)).

''Routine uses'' are an exception to this general principle. A routine use is a disclosure outside of the agency that is compatible with the purpose for which the data was collected. Routine uses are established by means of a publication in the **Federal Register** about the applicable system of records describing to whom the disclosure will be made and the purpose for the disclosure. We believe that the proposed data disclosures are consistent with the purpose for which the data discussed in this proposed rule was collected and may be disclosed in accordance with the routine uses applicable to those records.

Notwithstanding these exceptions, we believe it would be appropriate to provide some form of notice to Medicare beneficiaries about sharing these data. Based on our experiences with data sharing in other CMS programs and models, we propose a strategy for notifying beneficiaries of claims data sharing in this proposed rule, and in order to provide meaningful beneficiary choice over claims data sharing with the participant hospitals in CCJR. We considered both ''opt-in'' and ''opt-out'' options for beneficiaries with respect to data sharing in CCJR. An opt-in method has some advantages, particularly with regard to the fact that consumers have consistently expressed a desire that their consent should be sought before their health information may be shared (Schneider, S. et al. ''Consumer Engagement in Developing Electronic Health Information System.'' Prepared for: Agency for Healthcare Research and Quality, July 2009, at 16. Available at: *http://healthit.ahrq.gov/ahrq-funded-projects/consumer-engagement-developing-electronic-health-information-systems)*.

An opt-out method is used successfully in most systems of electronic exchange of information because it is significantly less burdensome on patients and providers while still providing an opportunity for patients to exercise control over their data. Thus, we propose to use an ''opt-out'' approach to provide beneficiaries with the opportunity to decline claims data sharing directly through 1–800–Medicare, rather than through the participant hospital. We also propose to provide advance notification to all Medicare beneficiaries about the opportunity to decline claims data sharing with entities participating in CMS programs and models through CMS materials such as the Medicare & You Handbook. The Handbook would include information about the purpose of the model, describe the opportunity for participants to request beneficiary identifiable claims data for health care operations purposes, and provide instructions on how beneficiaries may decline claims data sharing by contacting CMS directly through 1–800–Medicare. The Handbook would also contain instructions on how a beneficiary may reverse his or her preference to decline claims data sharing by contacting 1–800–Medicare.

There are several advantages to these strategies. First, we note that 1–800–Medicare is a communication method to which beneficiaries have familiarity and broad exposure. It also has the capability for beneficiaries to use accessible alternative or appropriate assistive technology, if needed. While many procedures in MS–DRGs 469 and 470 are planned in advance, some are emergent or unplanned procedures. Thus, asking the participant hospital to provide advance notification to the beneficiary, prior to the provision of services, may be inappropriate or impossible in certain circumstances. We would continue to maintain a list of beneficiaries who have declined data sharing and ensure that their claims information is not included in the claims files shared with participants. Hospitals with patient portals or Blue Button® may have capability to garner patient input prior to discharge through a hospital intervention specific to patient and care-giver education, while also aiding the hospital to meet reporting requirements for other CMS programs, such as Meaningful Use under the EHR Incentive Program for Medicare Hospitals.

Finally, participant hospitals in CCJR will only be allowed to request beneficiary-identifiable claims data for beneficiaries who: (1) Have been furnished a billable service by the participant hospital corresponding to the episode definitions for CCJR; and (2) have not chosen to opt-out of claims data sharing. A beneficiary that chooses to opt-out of claims data sharing is only opting out of the data sharing portion of the model. The decision to opt-out does not otherwise limit CMS' use of the beneficiaries' data, whether the beneficiary can initiate an episode, inclusion in quality measures, or inclusion in reconciliation calculations. Where a beneficiary chooses to opt-out of claims data sharing, our data contractor would maintain a list of all HICNs that choose to opt-out of data sharing. We would monitor whether participant hospitals continue to request data on beneficiaries who have opted out of having their data shared and do not intend to make such data available in response to a CCJR such hospitals' requests.

We request comments on our proposals related to the provision of both aggregate and beneficiary-identifiable data to participant hospitals in CCJR. We are particularly interested in comments on the kinds and frequency of data that would be useful to hospitals, potential privacy and security issues, the implications for sharing protected health information with hospitals, and the use of a beneficiary opt-out, as opposed to an opt-in, to obtain beneficiary consent to the sharing of their information. We also request comment on whether it would be helpful to provide any such system of notices, since Medicare claims information and other electronic information is already routinely shared for many other purposes among health care providers and insurers, and generally is subject to HIPAA protections. We also propose where available, the exchange of CMS beneficiary data with the local electronic health information exchange, a system that allows doctors, nurses, pharmacists, other health care providers and patients to appropriately access and securely share a patient's vital medical information electronically in order to facilitate the hospitals ability to share timely patient data supporting improved patient referral, access, and care coordination across varied service settings.

F. Monitoring and Beneficiary Protection

1. Introduction and Summary

We are proposing the CCJR model as we believe it is an opportunity to improve the quality of care and that the policies of the model support making care more easily accessible to consumers when and where they need it, increasing consumer engagement and thereby informing consumer choices. For example, under this model we are proposing certain waivers which would offer participant hospitals additional flexibilities with respect to furnishing telehealth services, post-discharge home visits, and care in skilled nursing facilities, as discussed in section III.C.11 of this proposed rule. We believe that this model will improve beneficiary access and outcomes. Conversely, we do note that these same opportunities could be used to try to steer beneficiaries into lower cost services without an appropriate emphasis on maintaining or increasing quality. We direct readers to sections III.C.5 and III.D. of this proposed rule for discussion of the methodology for incorporating quality into the payment structure and the measures utilized for this model.

We believe that existing Medicare provisions can be effective in protecting beneficiary freedom of choice and access to appropriate care under the CCJR model. However, because the CCJR model is designed to promote efficiencies in the delivery of all care associated with lower extremity joint replacement procedures, providers may seek greater control over the continuum of care and, in some cases, could attempt to direct beneficiaries into care pathways that save money at the expense of beneficiary choice or even beneficiary outcomes. As such, we acknowledge that some additional safeguards may be necessary under the CCJR model as providers are simultaneously seeking opportunities to decrease costs and utilization. We believe that it is important to consider any possibility of adverse consequences to patients and to ensure that sufficient controls are in place to protect Medicare beneficiaries receiving lower extremity joint replacement related services under the CCJR model.

2. Beneficiary Choice and Beneficiary Notification

Because we have proposed that hospitals in selected geographic areas will be required to participate in the model, individual beneficiaries will not be able to opt out of the CCJR model when they receive care from a participant hospital in the model. We do not believe that it is appropriate or consistent with other Medicare programs to allow patients to opt out of a payment system that is unique to a particular geographic area. For example, the state of Maryland has a unique payment system under Medicare, but that payment system does not create an alternative care delivery system, nor does it in any way impact beneficiary decisions. Moreover, we do not believe that an ability to opt out of a payment system is a factor in upholding beneficiary choice or is otherwise advantageous to beneficiaries or even germane to beneficiary decisions given that this model does not increase beneficiary cost-sharing. We also believe that full notification and disclosure of the payment model and its possible implications is critical for beneficiary understanding and protection. However, it is important to create safeguards for beneficiaries to ensure that care recommendations are based on clinical needs and not inappropriate cost savings. It is also important for beneficiaries to know that they can raise any concerns with their physicians, with 1–800–Medicare, or with their local Quality Improvement Organizations.

This proposed payment model does not limit the ability to choose among Medicare providers or the range of services available to the beneficiary. Beneficiaries may continue to choose any Medicare participating provider, or any provider who has opted out of Medicare, with the same costs, copayments and responsibilities as they

have with other Medicare services. Although the proposed model would allow participant hospitals to enter into CCJR Sharing Arrangements with certain providers and these preferred providers may be recommended to beneficiaries as long as those recommendations are made within the constraints of current law, hospitals may not restrict beneficiaries to any list of preferred or recommended providers that surpass any restrictions that already exist under current statutes and regulations. Moreover, hospitals may not charge any CCJR collaborator a fee to be included on any list of preferred providers or suppliers, nor may the hospital accept such payments, which would be considered to be outside the realm of risk-sharing agreements. Thus, this proposed payment model does not create any restriction of beneficiary freedom to choose providers, including surgeons, hospitals, post-acute care or any other providers or suppliers.

Moreover, as participant hospitals redesign care pathways, it may be difficult for providers to sort individuals based on health care insurance and to treat them differently. We anticipate that care pathway redesign occurring in response to the model will increase coordination of care, improve the quality of care, and decrease cost for all patients, not just for Medicare beneficiaries. This anticipated change in the delivery of care to all patients may further promote consistent treatment of all beneficiaries.

We believe that beneficiary notification and engagement is essential because there will be a change in the way participating hospitals are paid. We believe that appropriate beneficiary notification should explain the model, advise patients of both their clinical needs and their care delivery choices, and should clearly specify that any non-hospital provider holding a risk-sharing agreement with the hospital should be identified to the beneficiary as a ''financial partner of the hospital for the purposes of LEJR services.'' These policies seek to enhance beneficiaries' understanding of their care, improve their ability to share in the decision-making, and ensure that they have the opportunity to consider competing benefits even as they are presented with cost-saving recommendations. We believe that appropriate beneficiary notification should do all of the following:

- Explain the model and how it will or will not impact their care.
- Inform patients that they retain freedom of choice to choose providers and services.
- Explain how patients can access care records and claims data through an available patient portal and through sharing access to care-givers to their Blue Button® electronic health information.
- Advise patients that all standard Medicare beneficiary protections remain in place.

These include the ability to report concerns of substandard care to Quality Improvement Organizations (QIO) and 1–800–MEDICARE.

After carefully considering the appropriate timing and circumstances for the necessary beneficiary notification, we are proposing that participating hospitals must require all providers and suppliers who execute a CCJR Sharing Arrangement with a participant hospital to share certain notification materials, to be developed or approved by CMS, that detail this proposed payment model before they order an admission for joint replacement for a Medicare FFS patient who would be included under the model. Participant hospitals must require this notification as a condition of any CCJR Sharing Arrangement. Where a participant hospital does not have CCJR Sharing Arrangements with providers or suppliers that furnish services to beneficiaries during a CCJR episode of care, or where the admission for joint replacement for a Medicare FFS patient who would be included under the model was ordered by a physician who does not have a CCJR Sharing Arrangement, the beneficiary notification materials must be provided to the beneficiary by the participant hospital. The purpose of this proposed policy is to ensure that all beneficiaries that initiate a CCJR episode receive the beneficiary notification materials, and that they receive such materials as early as possible. We believe that this proposal targets beneficiaries for whom information is relevant, and increases the likelihood that patients will become engaged and seek to understand the model and its potential impact on their care.

We note that beneficiaries are accustomed to receiving similar notices of rights and obligations from healthcare providers prior to the start of inpatient care. However, we also considered that this information might be best provided by hospitals at the point of admission for all beneficiaries, as hospitals provide other information concerning patient rights and responsibilities at that time. We invite comment on ways in which the timing and source of beneficiary notification could best serve the needs of beneficiaries without creating unnecessary administrative work for providers. We believe that this notification is an important safeguard to help ensure that beneficiaries in the model receive all medically necessary services, but it is also an important clinical opportunity to better engage beneficiaries in defining their goals and preferences as they share in the planning of their care.

3. Monitoring for Access to Care

Given that participant hospitals would receive a reconciliation payment when they are able to reduce average costs per case and meet quality thresholds, they could have an incentive to avoid complex, high cost cases by referring them to nearby facilities or specialty referral centers. We intend to monitor the claims data from participant hospitals—for example, to compare a hospital's case mix relative to a pre-model historical baseline to determine whether complex patients are being systematically excluded. We will publish these data as part of the model evaluation to promote transparency and an understanding of the model's effects. We also propose to continue to review and audit hospitals if we have reason to believe that they are compromising beneficiary access to care. For example, where claims analysis indicates an unusual pattern of referral to regional hospitals located outside of the model catchment area or a clinically unexplained increase or decrease in joint replacement surgery rates.

4. Monitoring for Quality of Care

As we noted previously, in any payment system that promotes efficiencies of care delivery, there may be opportunities to direct patients away from more expensive services at the expense of outcomes and quality. We believe that professionalism, the quality measures in the model, and clinical standards can be effective in preventing beneficiaries from being denied medically necessary care in the inpatient setting and in post-acute care settings during the 90 days post-discharge. Accordingly, the potential for the denial of medically necessary care within the CCJR model will not be greater than that which currently exists under IPPS. However, we also believe that we have the authority and responsibility to audit the medical records and claims of participating hospitals and their CCJR collaborators in order to ensure that beneficiaries receive medically necessary services. We may also monitor arrangements between participant hospitals and their CCJR collaborators to ensure that such arrangements do not result in the denial

of medically necessary care or other program or patient abuse. We invite public comment on whether there are elements of the CCJR model that would require additional beneficiary protection for the appropriate delivery of inpatient care, and if so, what types of monitoring or safeguards would be most appropriate.

With respect to post-acute care, we believe that requiring participating hospitals to engage patients in shared decision making is the most important safeguard to prevent inappropriate recommendations of lower cost care, and that such a requirement can be best effected by requiring hospitals to make this a condition of any CCJR Sharing Arrangements with practitioners who perform these procedures. Additional deterrents are created by the financial accountability of the 90-day bundle, which is sufficiently long that it encourages the provision of high-quality care to avoid the risk of complications and readmissions, which would typically occur within that time period. Physician patterns of practice are also constrained by clinical standards of care, and we believe that the risk associated with deviations from those standards provides further deterrence to compromising care.

We believe that these safeguards are all enhanced by beneficiary knowledge and engagement. Therefore, we are proposing to require that participant hospitals must, as part of discharge planning, account for potential financial bias by providing patients with a complete list of all available post-acute care options in the service area consistent with medical need, including beneficiary cost-sharing and quality information (where available and when applicable). We expect that the treating surgeons or other treating practitioners, such as physiatrists, will continue to identify and discuss all medically appropriate options with the beneficiary, and that hospitals will discuss the various facilities and providers who are available to meet the clinically identified needs. These proposed requirements for CCJR participant hospitals would supplement the existing discharge planning requirements under the hospital Conditions of Participation. We also specifically note that neither the Conditions of Participation nor this proposed transparency requirement preclude hospitals from recommending preferred providers within the constraints created by current law, as coordination of care and optimization of care are important factors for successful participation in this model. We invite comment on this proposal, including additional opportunities to ensure high quality care.

5. Monitoring for Delayed Care

This model is based in part on an incentive for hospitals to create efficiencies in the delivery of care within a 90-day episode following the joint replacement surgery. Theoretically this basis could create incentives for hospitals and other CCJR collaborators involved in any CCJR Sharing Arrangements to delay services until after that window has closed.

We believe that existing Medicare safeguards are sufficient to protect beneficiaries. First, our experience with other bundled payments such as the BPCI initiative has shown that providers focus on appropriate care first and efficiencies only when those efficiencies can be obtained in the setting of appropriate care. We believe that a 90-day post-discharge episode will sufficiently minimize the risk that services furnished in relation to the beneficiary's lower extremity joint replacement procedure will be necessary beyond the end of the episode duration. To ensure that the length of the episode duration sufficiently minimizes the risk that any lower extremity joint replacement related care will not exceed the time established for the episode, we proposed to establish a 90-day post-discharge duration. We believe that participant hospitals would be unlikely to postpone services beyond a 90-day period because the consequences of delaying care beyond this long episode duration would be contrary to usual standards of care.

However, we also note that additional monitoring would occur as a function of the payment model. We have proposed as part of the payment definition (see section III.C of this proposed rule) that certain post-episode payments occurring in the 30-day window subsequent to the end of the 90-day episode would be counted as an adjustment against savings. We believe that the inclusion of this payment adjustment would create an additional deterrent to delaying care beyond the episode duration. In addition, the data collection and calculations used to determine this adjustment provide a mechanism to check if providers are inappropriately delaying care. Finally, we note that the proposed quality measures create additional safeguards as they are used to monitor and influence hospital clinical care at the institutional level.

In accordance with section 1115A of the Act, we are proposing to codify these proposals in regulation in the new proposed Part 510. We invite public comment on our proposed requirements for notification of beneficiaries and our proposed methods for monitoring participants' actions and ensuring compliance as well as on other methods to ensure that beneficiaries receive high quality, clinically appropriate care.

G. Coordination With Other Agencies

Impacts created by payment changes under this model are entirely internal to HHS operations; coordination with other agencies is not required outside of the usual coordination involved in the publication of all HHS regulatory changes.

IV. Evaluation Approach

A. Background

The proposed CCJR model is intended to enable CMS to better understand the effects of bundled payments models on a broader range of Medicare providers than what is currently being tested under BPCI. Obtaining information that is representative of a wide and diverse group of hospitals will best inform us on how such a payment model might function were it to be more fully integrated within the Medicare program. All CMS models, which would include the proposed CCJR model, are rigorously evaluated on their ability to improve quality and reduce costs. In addition, we routinely monitor CMS models for potential unintended consequences of the model that run counter to the stated objective of lowering costs without adversely affecting quality of care. Outlined in this proposed rule are the proposed design and evaluation methods, the data collection methods, key evaluation research questions, and the evaluation period and anticipated reports for the proposed CCJR model.

B. Design and Evaluation Methods

Our evaluation approach for the CCJR model will have elements in common with the standard Innovation Center evaluation approaches we have taken in other projects such as the BPCI initiative, Acute Care Episode (ACE) Demonstration, Pioneer ACO model, and other Innovation Center models. Specifically, the evaluation design and methodology for the proposed CCJR model would be designed to allow for a comparison of historic patterns of care among the CCJR providers to any changes made in these patterns in response to the CCJR model.

Our evaluation methodology for this model builds upon the fact that MSAs will be selected for participation in the model by stratified random assignment. Due to the random assignment, we can evaluate the effects of the model on outcomes of interest by directly

comparing MSAs that are randomly selected to participate in the model to a comparison group of MSAs that were not randomly selected for the model (but could have been). Randomized evaluation designs of this kind are widely considered the ''gold standard'' for social science and medical research because they ensure that the systematic differences are reduced between units that do and do not experience an intervention, which ensures that (on average) differences in outcomes between participating and non-participating units reflect the effect of the intervention. In constructing the comparison group, we are considering whether to use a simple comparison group that consists of all non-selected MSAs or to instead select a comparison group from among the non-selected providers based on how well they match the providers along a variety of measurable dimensions, such as hospital size, LEJR expenditures, provider characteristics and market characteristics. The latter approach is sometimes referred to as ''post-stratification'' in the literature on the analysis of randomized experiments.

We plan to use a range of analytic methods, including regression and other multivariate methods appropriate to the analysis of stratified randomized experiments to examine each of our measures of interest. Measures of interest could include, for example, quality of and access to care, utilization patterns, expenditures, and beneficiary experience. The evaluation would also include rigorous qualitative analyses in order to capture the evolving nature of the care model interventions.

In our design, we plan to take into account the impact of the CCJR model at the geographic unit level, the hospital level, and at the patient level. We are also considering various statistical methods to address factors that could confound or bias our results. For example, we would use statistical techniques to account for clustering of patients within hospitals and markets. Clustering allows our evaluation to compensate for commonalities in beneficiary outcomes by hospitals and by markets. Thus, in our analysis, if a large hospital consistently has poor performance, clustering would allow us to still be able to detect improved performance in the other, smaller hospitals in a market rather than place too much weight on the results of one hospital and potentially lead to biased estimates and mistaken inferences. Finally, we plan to use various statistical techniques to examine the effects of the CCJR model while also taking into account the effects of other ongoing interventions such as BPCI, Pioneer ACOs, and Medicare Shared Savings Program. For example, we are considering additional regression techniques to help identify and evaluate the incremental effects of adding the CCJR model in areas where patients and market areas are already subject to these other interventions as well as potential interactions among these efforts.

C. Data Collection Methods

We are considering multiple sources of data to evaluate the effects of the CCJR model. We expect to base much of our analysis on secondary data sources such as Medicare FFS claims and required patient assessment instruments such as the Minimum Data Set (MDS) collected for skilled nursing facility stays, the Patient Assessment Instrument for Inpatient Rehabilitation Facility (IRF–PAI) collected for IRF stays and the Outcome and Assessment Information Set (OASIS) collected for home health episodes of care. The beneficiary claims data would provide information such as expenditures in total and by type of provider and service as well as whether or not there was an inpatient hospital readmission. The assessment tools would provide information on a beneficiary's functioning (for example, physical, psychological and psychosocial functioning).

In conjunction with the previously stated secondary data sources, we are considering a CMS-administered survey of beneficiaries who received an LEJR during the performance period. This survey would be administered to beneficiaries who either had received an LEJR under the CCJR model or were selected as part of a control group. The primary focus of this survey would be to obtain information on the beneficiary's perception of their functional status before and after the LEJR as well as information on their pain and LE joint symptoms, and perceptions on access to care. The administration of this beneficiary survey would be coordinated with administration of the HCAHPS survey so as to not conflict with or compromise the HCAHPS efforts. Likewise, we are considering a survey administered by CMS and guided interviews conducted by CMS with providers including, but not limited to, the orthopedic surgeons, initiating hospitals, and PAC providers participating furnishing services to beneficiaries included in the CCJR model. These surveys would provide insight on beneficiaries' experience under the model and additional information on the care redesign strategies undertaken by health care providers.

In addition, we are considering CMS evaluation contractor administered site visits with selected hospitals and PAC providers as well as focus groups with a range of populations such as PAC providers and orthopedic surgeons. We believe that these qualitative methods would provide contextual information that would help us better understand the dynamics and interactions occurring among CCJR providers furnishing services included within a CCJR episode. For example, these data could help us better understand hospitals' intervention plans as well as how they were implemented and what they achieved. Moreover, in contrast to relying on quantitative methods alone, qualitative approaches would enable us to view program nuances as well as identify factors that are associated with successful interventions and distinguish the effects of multiple interventions that may be occurring within participating providers, such as simultaneous ACO and bundled payment participation.

D. Key Evaluation Research Questions

Our evaluation would assess the impact of the CCJR model on the aims of improved care quality and efficiency as well as reduced health care costs. This would include assessments of patient experience of care, utilization, outcomes, Medicare expenditures, provider costs, quality, and access. Our key evaluation questions would include, but are not limited to, the following:

- PAYMENT. Is there a reduction in total Medicare expenditures in absolute terms or for subcategories of providers (for example, acute vs post-acute providers, providers in certain geographic areas, providers within concentrated vs non-concentrated market areas or in urban vs rural areas)? Do the participants reduce or eliminate variations in utilization and expenditures or both that are not attributable to differences in health status? If so, how have they accomplished these changes?
- UTILIZATION. Are there changes in Medicare utilization patterns overall or for specific types of providers or services? How do these patterns compare to historic patterns, regional variations, and national patterns of care? How are these patterns of changing utilization associated with Medicare payments, patient outcomes and general clinical judgment of appropriate care?
- OUTCOMES/QUALITY. Is there either a negative or positive impact on quality of care and patient experiences of care or both? Did the incidence of complications remain constant or

decrease? Was there a change in beneficiaries' level of pain reduction, functional outcomes or return to independence under the model than relative to appropriate comparison groups? If so, how and for which beneficiaries?

• REFERRAL PATTERNS AND MARKET IMPACT. How, if at all, has the behavior in the selected geographic areas changed under the model? How have the referral patterns changed and for which type(s) of providers? Similarly, does the model have an impact on the number of patients with LEJR procedures and what types of patients are undergoing the procedure? To what extent, if any, is this related to gainsharing activities?

• UNINTENDED CONSEQUENCES. Did the CCJR model result in any unintended consequences, including adverse selection of patients, access problems, cost shifting beyond the agreed upon episode, evidence of stinting on appropriate care, anti-competitive effects on local health care markets, evidence of inappropriate referrals practices? Is so, how, to what extent, and for which beneficiaries or providers?

• POTENTIAL FOR EXTRAPOLATION OF RESULTS. What was the typical patient case mix in the participating practices and how did this compare to regional and national patient populations? What were the characteristics of participating practices and to what extent were they representative of practices treating Medicare FFS beneficiaries? Was the model more successful in certain types of markets? To what extent would the results be able to be extrapolated to similar markets and nationally or both?

• EXPLANATIONS FOR VARIATIONS IN IMPACT. What factors are associated with the patterns of results? Specifically, are the results related to the following?

++ Characteristics of the models including variations by year and factors such as presence of downside risk?

++ The participating hospital's specific features and ability to carry out their proposed intervention?

++ Characteristics and nature of interaction with partner providers including orthopedic surgeons and PAC provider community?

++ Characteristics of the geographic area, such as market concentration or size of city and availability of PAC providers?

++ Characteristics associated with the patient populations served?

E. Evaluation Period and Anticipated Reports

As discussed in section III.A. of this proposed rule, each of the selected participants in the CCJR model would have a 5-year performance period. The evaluation period would encompass this entire 5-year period and up to two years after. We plan to evaluate the CCJR model on an annual basis. We recognize, however, that interim results are subject to issues such as sample size and random fluctuations in practice patterns. Hence, while CMS intends to have internal periodic summaries to offer useful insight during the course of the effort, a final analysis after the end of the 5-year performance period will be important for ultimately synthesizing and validating results.

We seek comments on our design, evaluation, data collection methods, and research questions.

V. Collection of Information Requirements

As stated in section1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the the testing and evaluation of models under section 1115A. As a result, the information collection requirements contained in this proposed rule need not be reviewed by the Office of Management and Budget.

VI. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this proposed rule, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

VII. Regulatory Impact Analysis

We have examined the impact of this rule as required by Executive Order 12866 and other laws and Executive Orders requiring economic analysis of the effects of proposed rules.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, to the best of our ability, presents the costs and benefits of the rulemaking.

A. Statement of Need

This proposed rule is necessary in order to create and test a new payment model under the authority of section 1115A of the Act that allows the Innovation Center to test innovative payment and service delivery models in order to ''reduce program expenditures while preserving or enhancing the quality of care furnished to individuals.'' The underlying issue addressed by the proposed model is that under FFS, Medicare makes separate payments to providers and suppliers for items and services furnished to a beneficiary over the course of a treatment (an episode of care). Because the amount of payment is dependent on the volume of services delivered, this creates incentives for care that are fragmented, unnecessary or duplicative, while impeding the investment in quality improvement or care coordination that would maximize patient benefit. We anticipate the proposed model may reduce costs while maintaining or improving quality where the provision of ''bundled services'' in which all the services needed for a given episode of care are included in a single payment arrangement that provides incentives to promote high quality and efficient care.

This proposed rule would create and test the first bundled care model under the Innovation Center authority in which providers would be required to participate, building on the experience of the current voluntary BPCI and ACE efforts. Testing the model in this manner would also allow us to learn more about patterns of inefficient utilization of health care services and how to incentivize the improvement quality for common LEJR procedure episodes. This learning could inform future Medicare payment policy.

Under the proposed CCJR model, acute care hospitals in certain selected counties will receive retrospective bundled payments for episodes of care for lower extremity joint replacement or reattachment of a lower extremity. This proposed rule was developed based on the experiences we gained from the implementation of the Bundled Payments and Care Improvement Initiative and the Medicare Acute Care Episode (ACE) Demonstration to test bundled payments. We believe the model may benefit Medicare beneficiaries through improving the coordination and transition of care, improving the coordination of items and services paid for through Medicare FFS payments, encouraging provider investment in infrastructure and redesigned care processes for high

quality and efficient service delivery, and incentivizing higher value care across the inpatient and post-acute care spectrum spanning the episode of care. It will also provide an opportunity to evaluate the nature and extent of reductions in the cost of treatment by providing financial incentives for providers to coordinate their efforts to provide services to meet patient needs and prevent future costs.

As detailed in Table 18, we estimate a total aggregate impact of $153 million in net Medicare savings over the proposed duration of the model, CYs 2016 through 2020, from the proposed implementation of the CCJR model. These estimated impacts represent the net effect of federal transfers that reward or penalize hospitals for improving care while making it more efficient. Furthermore, the proposed CCJR model may benefit beneficiaries since the model requires participant hospitals to be accountable for 90-day episodes of care for Medicare beneficiaries with a lower extremity joint replacement, improve the coordination of FFS items and services, and encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery that demonstrate a dedication and focus toward patient-centered care.

Our analysis of the model's effects shows that this proposed rule would trigger the threshold of ''an annual effect on the economy of $100 million or more'' or any of the other criteria for significant economic effects under E.O. 12866. Accordingly it would also be a major rule under the Congressional Review Act, and we are required to prepare an analysis that presents the costs and benefits of this proposed rule. We have prepared an analysis that address benefits and costs that applies to ''economically significant'' or ''major'' rules. We solicit comment on the assumptions and analysis presented throughout this regulatory impact section.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. As previously stated, this proposed rule triggers these criteria.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, pre-empts state law, or otherwise has federalism implications. We do not believe that there is anything in this proposed rule that either explicitly or implicitly pre-empts any state law, and furthermore we do not believe that this proposed rule will have a substantial direct effect on state or local governments, preempt states law, or otherwise have a federalism implication.

C. Anticipated Effects

1. Overall Magnitude of the Model and Its Effects on the Market

According to Medicare FFS claims data in FY 2014 (October 1, 2013 through September 30, 2014), there were approximately 21,000 discharges for MS–DRG 469 and 406,000 discharges for MS–DRG 470 (these DRG's cover knee and hip replacements, respectively with and without complications) nationally. Based on the same data, we estimate that the participant hospitals cover approximately 111,000 LEJR episodes in this model or about 25 percent of LEJR discharges nationally. The number of such procedures has grown in recent years, due both to the aging of the American population and to advances in medical technology and care that have made these operations less physically burdensome on patients and led to faster recovery times.

More uncertain are the total costs of these procedures. The mean estimated 90-day episode payment for lower extremity joint replacement procedures (defined as discharges for MS–DRG 469 and MS–DRG 470) is about $26,000 based on Medicare claims data for FY 2014 where approximately 55 percent of the spending is attributed to hospital inpatient services, 25 percent of spending is attributed to post-acute services such as physical therapy (either ambulatory and in a facility) and 20 percent to physician, outpatient hospital and other spending.

We have proposed to apply the model in 75 MSAs out of 196 MSAs eligible for selection, as described previously in this proposed rule. Based on this proposed selection methodology, we estimate that the model will cover about 25 percent of all lower extremity joint replacement procedures nationally. We estimate the model will cover about $2.261 billion in episode spending in 2016 and $2.713 billion in episode spending in 2020 as displayed in Table 18 later in this section. As discussed subsequently in this analysis, this is likely to generate approximately a net amount of $153 million in savings to Medicare over the entire duration of the model. Annual reconciliation payments for each performance year may be greater than or less than the net change as detailed in Table 18 later in this section. In years 2019 and 2020 of the proposed model, we estimate a net change that is less than $100 million, but with repayments that may be greater than $100 million, which exceed the $100 million dollar threshold for economic significance.

There may also be spillover effects in the non-Medicare market, or even in the Medicare market in other areas as a result of this model. We believe these are likely to be small, but cannot be certain. These issues are discussed later in the analysis. We welcome comments on our assumptions and calculations.

2. Effects on the Medicare Program

The proposed CCJR model is a model involving an innovative mix of financial incentives for quality of care and efficiency gains within FFS Medicare for lower extremity joint replacement episodes. This model represents a new approach for the Medicare FFS program because it applies bundled payments to hospitals that might not otherwise

participate in Innovation Center models or Medicare demonstrations and tests bundled payment models for episodes of care for LEJR procedures in multiple geographic areas. As such, we are interested in testing and evaluating the impact of a bundled payment approach for LEJR procedures in a variety of circumstances, especially among those providers that may not have decided to engage in programs or models in which Medicare makes payments differently than Medicare FFS.

As described earlier in this proposed rule, episodes would begin with admission to an acute care hospital for an LEJR procedure that is paid under the IPPS through MS–DRG 469 or 470 and extend 90 days following discharge from the acute care hospital. The episode would include the LEJR procedure, inpatient stay, and all related care covered under Medicare Parts A and B within the 90 days after discharge, including hospital care, post-acute care, and physician services. Furthermore, we have proposed to designate participant hospitals as the episode initiators and to be financially responsible for episode cost under the proposed CCJR model. We propose to require all hospitals paid under the IPPS and physically located in selected geographic areas to participate in the CCJR model, with limited exceptions. Eligible beneficiaries who receive care at these hospitals will automatically be included in the model. Geographic areas, based on MSAs, are proposed to be selected through a stratified random sampling methodology based on the following criteria: Historical episode wage-adjusted payment quartiles and population size halves. We anticipate the proposed model may have financial and quality of care effects on non-hospital providers that are involved in the care of Medicare beneficiaries with an LEJR episode, improving the coordination of items and services paid for through Medicare FFS, encouraging more provider investment in infrastructure and redesigned care processes for higher quality and more efficient service delivery, and incentivizing higher value care across the inpatient and post-acute care spectrum spanning the episode of care. However, the proposed model attributes episode spending and makes the retrospective reconciliation payment to or repayment from the participant hospital. Accordingly, our analysis examines the proposed effects on participant hospitals, as they are the providers accountable for the episode payment under this model. Additionally, we have proposed to test CCJR for a 5-year period, beginning January 1, 2016, and ending December 31, 2020 and our estimates cover the 5 years of the model.

As described earlier in this proposed rule, we propose to continue paying hospitals and other providers according to the usual Medicare FFS payment systems during all performance years. After the completion of a performance year, the Medicare claims payments for services furnished to the beneficiary during the episode, based on claims data, would be combined to calculate an actual episode payment. The actual episode payment is the sum of Medicare claims payments furnished to a beneficiary during a CCJR episode. The actual episode payment would then be reconciled against an established CCJR target price, with consideration of additional payment adjustments based on quality performance and post episode spending. The amount of this calculation, if positive, would be paid to the participant hospital if the hospital has met the quality thresholds proposed in this rule. This payment is the reconciliation payment. If negative, the participant hospital would be required to make repayment to Medicare. We also proposed to phase in the requirement that hospitals whose actual episode payments exceed their CCJR target price to pay the difference back to Medicare beginning in performance year 2. Under this proposal, Medicare will not require repayment from hospitals for CCJR episode cost performance above their target price in performance year 1. Lastly, we propose to limit how much a hospital can gain or lose based on its reconciliation calculation with additional policies to further limit the risk of high payment cases for all participant hospitals and for special categories of hospitals.

Based on the mix of financial and quality incentives, the proposed CCJR model could result in a range of possible outcomes for participant hospitals. The effects on hospitals of potential savings and liabilities will have varying degrees.

Table 18 summarizes the estimated impact for the CCJR model. Our model estimates that the Medicare program will save $153 million dollars over the 5 performance years (2016 through 2020). Savings to the Medicare program may be greater if providers are able to improve the coordination of care, invest in infrastructure, and redesign care processes to promote high quality and efficient service delivery. Costs to the Medicare program may increase if providers are able to use waivers provided under the model to increase episode volume among beneficiaries that are expected to be less costly than the hospitals target price without the need for improving the coordination of care. Our analysis to the best of our ability presents the cost and transfer payment effects of this proposed rule. We solicit comment on the assumptions and analysis presented.

a. Assumptions and Uncertainties

We used final action Medicare claims data from January 1, 2012 through December 31, 2014 to simulate the impact that this model would have on Medicare spending for joint replacement episodes. This time period is consistent with the historical period that are proposing to use to calculate target prices for performance years 1 and 2 of the model as described in section III.C of this proposed rule (we note that for performance year 3 through 5, target prices would be calculated based on episodes that start between in the proposed period of January 1, 2014 to December 31, 2016). Specifically we applied the methodology provided in this proposed rule for calculating target prices for all hospitals that would be required to participate in the model, as discussed in section III.A. of this proposed rule, based on their performance from calendar years 2012 through 2014. Specifically, all IPPS hospitals in the selected MSAs not currently participating in Model 1 or Phase II of BPCI Models 2 or 4 for the LEJR clinical episode were included in this analysis. We identified the anchor hospitalizations based on claims with MS–DRG 469 and MS–DRG 470 and included the related spending that occurred 90 days after discharge. We removed payments excluded from the episode as not being associated with joint replacement care, as well as removing the IPPS add-on payments including disproportionate share hospital and indirect medical educational payments, and new technology payments associated with the anchor hospitalization. We note that we have proposed other payment exclusions in the calculation of the episode target price, in comparing actual episode payments with target prices, and in determining whether a reconciliation payment should be made to the hospital or repayment from the hospital should be made as described in section III.C of this proposed rule. For the purpose of this impact analysis, we have only limited our calculations to remove the IPPS add-on payments for disproportionate share hospital and indirect medical educational payments, and new technology payments in calculating estimated target prices and in comparing the target price to actual episode payments. We then excluded

episodes where the anchor hospitalization occurred in hospitals that are not paid under the IPPS. With the remaining episodes, we standardized episode payments to remove the variation in spending due to differences in the hospital's wage index. We trended utilization and prices in 2012 and 2013 to match 2014 national performance, and we incorporated the proposed outlier policy to cap spending for high cost outlier episodes such that payments are capped at the MS–DRG anchor value that is two standard deviations above the mean as described in section III.C of this proposed rule. After we pooled episodes for MS–DRGs 469 and 470, we calculated average episode prices for each hospital and census region, as well as a hospital-specific weight representing a case mix value for each hospital that is dependent only on episode volume for MS–DRGs 469 and 470, and the national anchor factor. We then calculated blended prices for each hospital, with prices set at two-thirds of the hospital's experience and one-third of the region's average experience for performance years 1 and 2 of the model, as one-third of the hospital's experience and two-thirds of the region's experience as used for performance year 3 of the model, and as the region's average experience for performance years 4 and 5 of the model. We made an exception for hospitals with low historical CCJR episode volume defined in this proposed rule as those with fewer than 20 CCJR episodes in total across the 3 historical years, by setting their target price as the region's experience. These average prices were then disaggregated based on the national anchor factor of average episode spending for MS–DRG 470 relative to MS–DRG 469, the computed hospital-specific weight, the hospital's wage index was then applied back to the price, and a 2 percent discount was applied.

After calculating target prices for MS–DRG 469 and 470 for each hospital appropriate for each performance year, we compared these target prices against actual performance in the 2014 calendar year. We capped actual spending for individual episodes based on the methodology in this proposed rule for high cost outlier spending episodes. After incorporating the proposed outlier policy, total Medicare FFS spending in the 2014 calendar year for each hospital was reconciled against the target price and total number of episodes for the hospital. The aggregate impacts were then determined by multiplying by the total episodes for each MS–DRG.

We have proposed that the difference between each CCJR episode's actual payment and the relevant target price (calculated as target price subtracted by CCJR episode actual episode payment) would be aggregated for all episodes for a participant hospital within the performance year, creating the NPRA. Any positive NPRA amount greater than the proposed stop-gain limit would be capped at the stop-gain limit of 20 percent for each performance year of the model, and any negative NPRA amount exceeding the proposed stop-loss limit would be capped at the stop-loss limit as described in section III.C.8.b of this proposed rule. To limit a hospital's overall repayment responsibility under this model, we have proposed a 10 percent repayment limit in performance year 2 and a 20 percent repayment limit in performance year 3 and subsequent years. For rural hospitals, MDHS, SCHs and RRCs, we have proposed a 3 percent repayment limit in performance year 2 and a 5 percent repayment limit in performance year 3 and subsequent years. Furthermore, as described earlier in this proposed rule, in order for a participant hospital to qualify for a reconciliation payment, a hospital must meet or exceed the 30th percentile benchmark for each of the three proposed quality measures in performance years 1 through 3:

- Hospital-level risk-standardized complication rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1550)
- Hospital-level 30-day, all-cause risk-standardized readmission rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1551)
- HCAHPS Survey (NQF #0166).

In performance years 4 through 5, a hospital must meet or exceed the 40th percentile benchmark for those proposed quality measures.

To simulate the impact for performance year 1 or 2016, we calculated the NPRA assuming no downside risk to hospitals as proposed, and using the target price calculated for performance year 1, that is two-thirds hospital experience and one-third region experience. If the estimated NPRA is negative (that is, in the aggregate, the actual episode payments for all episodes is greater than the target price multiplied by the number of episodes) for performance year 1, Medicare would not require repayment of the NRPA from the hospital because we have proposed no hospital responsibility for repayment for the first performance year. Additionally, as part of this estimate, we accounted for whether a hospital met the quality benchmarks to be eligible for a reconciliation payment. Lastly, we have applied the proposed 20 percent stop-gain limit on the estimated reconciliation payments made to participant hospitals total reconciliation payments reflect what we would expect Medicare to pay hospitals due to normal claims variation, and due to a blended target price which rewards hospitals that already perform better than their regional average.

To simulate the impact in performance year 2, we calculated the NPRA assuming full risk as proposed for this model, rewarding hospitals that perform better than their 2 percent discount that met the 30th percentile threshold for the complications, readmissions and HCAHPs quality metrics, but only requiring repayments from hospitals for total spending that is above a 1 percent discount. For the simulation in performance year 2, we used the target price calculated for performance year 2 that is two-thirds hospital experience and one-third regional experience. A 10 percent stop-loss limit was applied to repayments, and 3 percent stop-loss limit was applied for rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral centers, as proposed, and a 20 percent stop-gain limit was applied.

To simulate the impact in performance year 3, we calculated the NPRA assuming full risk as proposed in the model and rewarding hospitals that perform better than their 2 percent discount and met the 30th percentile thresholds for all three of the quality metrics, and requiring repayments from hospitals for total spending that is above the 2 percent discount. For the simulation in year 3, we used the target price calculated as one-third of the hospital's experience and two-thirds of the regional experience. We included a 20 percent stop-gain limit for all hospitals, a 20 percent stop-loss limit on repayments from acute care hospitals included in this analysis, but used a 5 percent stop-loss limit on reconciliation repayments from rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral centers, as proposed.

For performance years 4 and 5, the impact estimates were calculated in the same way except that the episode target prices are based on 100 percent of the regional experience, as proposed. Additionally, the impact estimates accounted for the proposal that a hospital must meet or exceed the 40th percentile benchmark for those proposed quality measures in order to be eligible for a reconciliation payment.

In this proposed model, we are selecting a total of 75 MSAs from 8 MSA groupings. IPPS hospitals located within the selected MSAs will be required to participate in this model unless they participate in BPCI as discussed earlier in this proposed rule in section III.A.

Additionally, as described earlier in this proposed rule in section III.C.5, hospitals can qualify for a lower discount applied to their target episode price if they voluntarily submit patient-reported outcome measures data. More specifically, for hospitals that successfully submit patient-reported outcome measures data for episodes beginning in performance year 2, the discount percentage is reduced from 2 percent to 1.7 percent for purposes of determining the hospital's opportunity to receive reconciliation payment for actual episode spending below the target price, and reduce the discount percentage from 1 percent to 0.7 percent for purposes of determining the amount Medicare would require the hospital to repay. We modeled the effects of this proposal by re-running the simulation using a 1.7 percent discount for all hospitals in performance years 2 through 5, and in performance year 2 only requiring repayments that are beyond a 0.7 percent discount. We combined the simulations with a 2 percent discount and 1.7 percent discount by assuming that 33 percent of hospitals would submit the patient-reported outcome measures data.

Additionally, we note for these estimates, we did not make assumptions for changes in efficiency or utilization over the course of the model. Over the 5 years of the model, we estimate $153 million dollars in savings to the Medicare program, out of $12.321 billion in total episode spending.

TABLE 18: PROPOSED ESTIMATES OF RECONCILIATION PAYMENTS *

	Year of proposed model					Across all 5 years of the proposed model
	2016	2017	2018	2019	2020	
Total episode spending	$2,261	$2,332	$2,447	$2,568	$2,713	$12,321
Net reconciliation payments**	23	(29)	(43)	(50)	(53)	(153)
Reconciliation amounts	23	24	47	63	66	223
Repayment amounts	0	(53)	(90)	(113)	(120)	(376)
Net reconciliation as a percentage of total episode spend	1.0%	(1.3%)	(1.7%)	(2.0%)	(2.0%)	(1.2%)

* Impact for 75 selected MSAs. All numbers rounded to closest million.
** Sum of reconciliation amount and repayment amount may not add to net reconciliation payment due to rounding.

These estimates contain a significant amount of uncertainty. As a result, this proposed model could produce more significant Medicare savings or could result in additional costs to the Medicare program. The primary source of uncertainty stems from the normal variation in claim cost trends each year coupled with the proposed cap on the repayment made at reconciliation. In addition, this analysis assumes no change in utilization both for the use of services within the bundled episode, as well as no change in total episodes among hospitals. The prospective prices for the proposed CCJR model incorporate price updates from the FFS payment systems, but assume no change in utilization for the performance years. If there is a national increase in utilization within each bundle that is independent of this model, then savings to the Medicare program may increase due to greater repayments paid back to Medicare. If there is a national decrease in utilization within each bundle that is independent of this model then costs to the Medicare program may increase due to greater reconciliation payments paid by Medicare to hospitals. The results will also depend on the cumulative effects over time and across providers on whether and how to change either actual medical procedures or the allocations of payments among service providers. We would expect significant variation among hospitals and among metropolitan areas, but are unable to predict these.

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

b. Analyses

The first performance year of the model is expected to cost the Medicare program $23 million in reconciliation payments made by CMS to hospitals. We have proposed that no repayments from hospitals will be assessed because hospitals are not subject to downside risk in performance year 1. Hospitals that would receive reconciliation payments are the hospitals that provide lower cost care relative to their regional average.

In the second performance year of the model, participant hospitals on net are expected to pay $29 million to CMS. We have proposed a 10 percent stop-loss limit for acute care hospitals, with exception for rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral center hospitals which would be subject to a 3 percent stop-loss limit. These limits would cap the total amount of repayments paid by hospitals to CMS.

In the third performance year of the model, net reconciliation payments are expected to be $43 million in savings to the Medicare program. The additional savings in performance year 3 compared to performance year 2 can be attributed to receiving repayments from hospitals for total spending that is above a 1 percent discount in performance year 2, while in performance year 3, we would require repayments from hospitals for total spending that is above a 2 percent discount.

For performance years 4 and 5 of the model, the proposed episode target price will be based on full regional pricing. This creates great variation between the target price and hospital's own experience. Therefore, the stop-gain and stop-loss limits on reconciliation payments are estimated to have a larger impact. As a result, net payments are expected to be $50 million dollars from hospitals to the Medicare program in the fourth year and $53 million in the fifth year. Savings to the Medicare program increases as a higher proportion of hospitals that provide care more efficiently than their regional average will forego reconciliation

payments due to failure to meet the proposed thresholds on all three of the quality of care measures. These estimated savings in years 4 and 5 represent 2.0 percent of total episode spending in those years. The proposed total savings to the Medicare program after 5 years of the model are expected to be $153 million dollars out of $12.321 billion dollars or 1.2 percent in total episode spending. Due to the uncertainty of estimating this model, actual results could be significantly higher or lower than this estimate.

c. Further Consideration

We can use our experience in previous implementation of bundled payment models to help inform our impact analyses. We have previously used our statutory authority to create payment models such as the BPCI initiative and the ACE Demonstration to test bundled payments. Under the authority of section 1866C of the Act, CMS funded a 3-year demonstration, the ACE Demonstration. The demonstration used a prospective global payment for a single episode of care as an alternative approach to payment for service delivery under traditional Medicare FFS. The episode of care was defined as a combination of Parts A and B services furnished to Medicare FFS beneficiaries during an inpatient hospital stay for any one of a specified set of cardiac and orthopedic MS DRGs. The MS DRGs tested included 469 and 470, those proposed for inclusion in the CCJR model. The discounted bundled payments generated an average gross savings to Medicare of $585 per episode for a total of $7.3 million across all episodes (12,501 episodes) or 3.1 percent of the total expected costs for these episodes. After netting out the savings produced by the Medicare Parts A and B discounted payments and some increased post-acute care costs that were observed at two sites, Medicare saved approximately $4 million, or 1.72 percent of the total expected Medicare spending. Additionally, we are currently testing the BPCI initiative. Under the initiative, entities enter into payment arrangements with CMS that include financial and performance accountability for episodes of care. Episodes of care under the BPCI initiative begin with either an—(1) inpatient hospital stay; or (2) post-acute care services following a qualifying inpatient hospital stay and include tests of LEJR episodes. The BPCI initiative is evaluating the effects of episode based payment approaches on patient experience of care, outcomes, and cost of care for Medicare FFS beneficiaries. Although there is limited evidence from BPCI and ACE suggesting that providers may improve their performance, both of these demonstrations were voluntary, and the participants that volunteered for these demonstrations may be in a better position to reduce episode spending relative to the average provider. We believe that our experiences with BPCI support the proposed design of the CCJR Model.

3. Effects on Beneficiaries

In 2014, approximately 430,000 Medicare beneficiaries had discharges for lower extremity joint replacements (MS–DRG 469 and MS–DRG 470) nationally. We anticipate that the CCJR model may benefit beneficiaries receiving lower extremity joint replacements because the intent of the model is to test whether providers under this bundled payment system are able to improve the coordination and transition of care, invest in infrastructure and redesigned care processes for high quality and efficient service delivery, and incentivize higher value care across the inpatient and post-acute care spectrum spanning the episode of care. We believe the model has a patient-centered focus such that healthcare delivery and communication on the patient and those who are close to the patient and bases the care and communication delivered around the needs of the beneficiary, thus benefitting the beneficiary community.

We have proposed several quality of care and patient experience measures to evaluate participant hospitals in the CCJR model with the intent that it will encourage the provider community to focus on and deliver improved quality care for the Medicare beneficiary. We are proposing to adopt and publicly report three hospital level quality of care measures for the CCJR model. Those measures include a complication measure, readmission measure, and a patient experience survey measure. In addition, we are proposing to voluntarily collect data to develop a hospital-level measure of patient reported outcomes following an elective primary total hip or total knee arthroplasty. We propose to use these measures to test the success of the model and to monitor for beneficiary safety. Additionally, participant hospitals must meet the proposed quality performance standards in order to qualify to receive a reconciliation payment. The accountability of participant hospitals for both quality and cost of care provided for Medicare beneficiaries with an LEJR episode provides the hospitals with new incentives to improve the health and well-being of the Medicare beneficiaries they treat.

Additionally, the model does not affect the beneficiary's freedom of choice to obtain health services from any individual or organization qualified to participate in the Medicare program guaranteed under section 1802 of the Act. Under the CCJR model, eligible beneficiaries who choose to receive services from a participant hospital would not have the option to opt out of inclusion in the model. Although the proposed model allows hospitals to enter into risk-sharing arrangements with certain other providers and these hospitals may recommended those providers to the beneficiary, hospitals may not prevent or restrict beneficiaries to any list of preferred or recommended providers.

Many controls exist under Medicare to ensure beneficiary access and quality and we have proposed to use our existing authority, if necessary, to audit participant hospitals if claims analysis indicates an inappropriate change in delivered services. As described earlier in this proposed rule, given that participant hospitals would receive a reconciliation payment when they are able to reduce average costs per case and meet quality thresholds, they could have an incentive to avoid complex, high cost cases by referring them to nearby facilities or specialty referral centers. We intend to monitor the claims data from participant hospitals—for example, to compare a hospital's case mix relative to a pre-model historical baseline to determine whether complex patients are being systematically excluded. Furthermore, we also proposed to require providers to supply beneficiaries with written information regarding the design and implications of this model as well as their rights under Medicare, including their right to use their provider of choice.

We have proposed to implement several safeguards to ensure that Medicare beneficiaries do not experience a delay in services. We believe that the longer the episode duration, the lower the risk of delaying care beyond the episode duration, and we believe that a 90 day episode is sufficiently long to minimize the risk that any lower extremity joint replacement related care will be delayed beyond the end of the episode. Moreover, we have proposed as part of the payment definition (see section III.C of this proposed rule) that certain outlier costs post-episode payments occurring in the 30 day window subsequent to the end of the 90-day episode will be counted as an

adjustment against savings. Importantly, approaches to saving costs will include taking steps that facilitate patient recovery, that shorten recovery duration, and that minimize post-operative problems that might lead to readmissions. Thus, the model itself rewards better patient care.

Lastly, we note that Medicare payments for services will continue to be made for each Medicare FFS payment system under this model, and will include normal beneficiary copayments, deductibles, and coinsurance. We expect and assume that beneficiary payments will not be affected, as only the hospital will be subject to the reconciliation process. Beneficiaries may benefit if providers are able to systematically improve the quality of care while reducing costs. We welcome public comments on our estimates of the impact of our proposals on Medicare beneficiaries.

4. Effects on Small Entities

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities, either by virtue of their nonprofit status or by qualifying as small businesses under the Small Business Administration's size standards (revenues of less than $7.5 to $38.5 million in any 1 year; NAIC Sector–62 series). States and individuals are not included in the definition of a small entity. For details, see the Small Business Administration's Web site at *http://www.sba.gov/content/small-business-size-standards.*

For purposes of the RFA, we generally consider all hospitals and other providers and suppliers to be small entities. We believe that the provisions of this proposed rule relating to acute care hospitals would have some effects on a substantial number of other providers involved in these episodes of care including surgeons and other physicians, skilled nursing facilities, physical therapists, and other providers.

Although we acknowledge that many of the affected entities are small entities, and the analysis discussed throughout this proposed rule discusses aspects of the model that may or will affect them, we have no reason to assume that these effects will reach the threshold level of 5 percent of revenues used by HHS to identify what are likely to be ''significant'' impacts. Although lower extremity joint replacement procedures (MS–DRGs 469 and 470) are among the most common surgical procedures undergone by Medicare beneficiaries, they are only about 5 percent of all acute hospital discharges.[81] We assume that all or almost all of these entities will continue to serve these patients, and to receive payments commensurate with their cost of care. Such changes occur frequently already (for example, as both hospital affiliations and preferred provider networks change), and we have no reason to assume that this will change significantly under the model.

Accordingly, we have determined that this proposed rule will not have a significant impact on a substantial number of small entities. We solicit public comments on our estimates and analysis of the impact of our proposals on those small entities.

5. Effects on Small Rural Hospitals

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a proposed rule or final rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, a small rural hospital is defined as a hospital that is located outside of an MSA and has fewer than 100 beds. We note that, according to this definition, the CCJR model would not include any rural hospitals given that the CCJR model would only include hospitals located in MSAs, as proposed in section III.A. However, we also note that as discussed in section III.C.8., for purposes of our proposal to include a more protective stop-loss policy for certain hospitals, we are proposing to define a rural hospital as an IPPS hospital that is either located in a rural area in accordance with § 412.64(b) or in a rural census tract within an MSA defined at § 412.103(a)(1) or has reclassified to rural in accordance with § 412.103. Thus, the proposed model will affect some rural hospitals, as discussed previously in section III.C.8 of this proposed rule.

Because of our concerns that rural hospitals may have lower risk tolerance and less infrastructure and support to achieve efficiencies for high payment episodes, we have proposed additional financial protections for certain categories of hospitals, including rural hospitals. In performance year 2, a hospital could owe Medicare no more than 10 percent of the target price multiplied by the number of the hospital's LEJR episodes in CCJR as we phase in repayment responsibility under the model. In performance year 3 and beyond when full repayment responsibility is in place, no more than 20 percent of the target price multiplied by the number of the hospital's LEJR episodes in CCJR could be owed by a hospital to Medicare. However, for rural hospitals, Medicare Dependent Hospitals, Rural Referral Centers and Sole Community, we proposed a stop loss limit policy of 3 percent of episode payments for these categories of hospitals. More specifically, in performance year 2, a hospital could owe Medicare no more than 3 percent of the target price multiplied by the number of the hospital's episodes in CCJR. In performance years 3 through 5, a hospital could owe Medicare no more than 5 percent of the target price multiplied by the number of the hospital's episodes. Although we propose these additional protections, we believe that few rural hospitals will be included in the model, and therefore that few will need those protections.

Because lower extremity joint replacement procedures (MS–DRGs 469 and 470) account for only about 5 percent of all discharges, because relatively few of these procedures are performed at small rural hospitals, and because our model is designed to minimize adverse effects on rural hospitals, we do not believe that rural hospitals will experience significant adverse economic impacts. Accordingly, we conclude that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

We are soliciting public comments on our estimates and analysis of the impact of our proposals on those small rural hospitals.

6. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2015, that is approximately $144 million. This proposed rule does not include any mandate that would result in spending by state, local or tribal governments, in the aggregate, or by the private sector in the amount of $144 million in any 1 year.

[81] Medicare Inpatient Claims data from January–December 2014, Chronic Conditions Warehouse.

D. Alternatives

Throughout this proposed rule, we have identified our proposed policies and alternatives that we have considered, and provided information as to the effects of these alternatives and the rationale for each of the proposed policies. We solicit and welcome comments on our proposals, on the alternatives we have identified, and on other alternatives that we should consider, as well as on the costs, benefits, or other effects of these. We note that our estimates are limited to the IPPS hospitals that would be selected to participate in this proposed model. This proposed rule will not impinge directly on hospitals that are not participating in the model. However, it may encourage innovations in health care delivery in other areas or in care reimbursed through other payers. For example, a hospital and affiliated providers may choose to extend their arrangements to all joint replacement procedures they provide, not just those reimbursed by Medicare. Alternatively, a hospital and affiliated providers in one city may decide to hold themselves forth as ''centers of excellence'' for patients from other cities, both those included and not included in the model. We welcome comments that address these or other possibilities.

E. Accounting Statement

As required by OMB Circular A–4 under Executive Order 12866 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*) in Table 19, we have prepared an accounting statement showing the classification of transfers, benefits, and costs associated with the provisions in this proposed rule. The accounting statement is based on estimates provided in this regulatory impact analysis. Because of the uncertainties identified in establishing the economic impact estimates, we intend to update the estimates in the final rule. As described in Table 18, we estimate this proposed model will result in savings to the federal government of $153 million over the 5years of the model from 2016 to 2020. The following Table 19 shows the annualized change in (A) net federal monetary transfers, and (B) potential reconciliation payments to participating hospitals net of repayments from participant hospitals that is associated with the provisions of this proposed rule as compared to baseline. In Table 19, the annualized change in payments based on a 7 percent and 3 percent discount rate, results in net federal monetary transfer from the participant IPPS hospitals to the federal government of $28 million and $30 million respectively.

TABLE 19—ACCOUNTING STATEMENT ESTIMATED IMPACTS

Category	Primary estimate	Source citation (RIA, preamble, etc.)
BENEFITS:		
Annualized monetized transfers: Discount rate: 7%	$28 million	Change from baseline to proposed changes (Table 18).
Annualized monetized transfers: Discount rate: 3%	$30 million.	
From whom to whom?	From Participant IPPS Hospitals to Federal Government.	

F. Conclusion

The preceding analysis, together with the remainder of this preamble, provides the Regulatory Impact Analysis of a rule with a significant economic effect. As a result of this proposed rule, we estimate of the financial impact of the CCJR model for CYs 2016 through 2020 would be net federal savings of $153 million over a 5 year period. The annualized change in payments based on a 7 percent and 3 percent discount rate, results in net federal monetary transfer from the participant IPPS hospitals to the federal government of $28 million and $30 million respectively.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

List of Subjects for 42 CFR Part 510

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, under the authority at section 1115A of the Social Security Act, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR Chapter IV as follows:

■ 1. Revise the heading of Subchapter H to read as follows:

SUBCHAPTER H—HEALTH CARE INFRASTRUCTURE AND MODEL PROGRAMS

■ 2. Part 510 is added to Subchapter H to read as follows:

PART 510—COMPREHENSIVE CARE FOR JOINT REPLACEMENT MODEL

Secs.

Subpart A—General Provisions

510.1 Basis and scope.
510.2 Definitions.

Subpart B—Comprehensive Care for Joint Replacement Model Participants

510.100 Episodes being tested.
510.105 Geographic areas.

Subpart C—Scope of Episodes

510.200 Time periods, included services, and attribution.
510.205 Beneficiary inclusion criteria.
510.210 Determination of the episode.

Subpart D—Pricing and Payment

510.300 Determination of episode target prices.
510.305 Determination of the NPRA and reconciliation process.
510.310 Appeals process.
510.315 Quality thresholds for reconciliation payment eligibility.
510.320 Treatment of incentive programs or add-on payments under existing Medicare payment systems.
510.325 Allocation of payments for services that straddle the episode.

Subpart E—Quality Measures, Beneficiary Protections, and Compliance Enforcement

510.400 Quality measures and reporting.
510.405 Beneficiary choice and beneficiary notification.
510.410 Compliance enforcement.

Subpart F—Financial Arrangements and Beneficiary Incentives

510.500 Financial arrangements under the CCJR model.
510.505 Beneficiary incentives under the CCJR model.

Subpart G—Waivers

510.600 Waiver of direct supervision requirement for certain post-discharge home visits.
510.605 Waiver of certain telehealth requirements.
510.610 Waiver of SNF 3-day rule.
510.615 Waiver of certain post-operative billing restrictions.

Authority: Secs. 1102, 1115A, and 1871 of the Social Security Act (42 U.S.C. 1302, 1315(a), and 1395hh).

Subpart A—General Provisions

§ 510.1 Basis and scope.

(a) *Basis.* This part implements the test of the Comprehensive Care for Joint Replacement model under section 1115A of the Act. Except as specifically noted in this part, the regulations under this part must not be construed to affect the payment, coverage, program integrity, and other requirements (such as those in parts 412 and 482 of this chapter) that apply to providers and suppliers under this chapter.

(b) *Scope.* This part sets forth the following:

(1) The participants in the Comprehensive Care for Joint Replacement model.

(2) The episodes being tested in the model.

(3) The methodology for pricing and payment under the model.

(4) Quality performance standards and quality reporting requirements.

(5) Safeguards to ensure preservation of beneficiary choice and beneficiary notification.

§ 510.2 Definitions.

For the purposes of this part, the following definitions are applicable:

ACO stands for Accountable Care Organization.

Actual episode payment means the sum of Medicare claims payments for items and services that are included in the episode in accordance with § 510.200(b), excluding the items and services described in § 510.200(d) and the incentive programs and add-on payments specified in § 510.320, and subject to the cap described in § 510.300(b)(4).

Alignment payment means a payment from a Comprehensive Care for Joint Replacement collaborator to a participant hospital under a Comprehensive Care for Joint Replacement sharing arrangement.

Anchor hospitalization means the initial hospital stay upon admission for a lower extremity joint replacement.

BPCI stands for the Bundled Payments for Care Improvement initiative.

CCJR stands for Comprehensive Care for Joint Replacement.

CCJR collaborator means one of the following persons or entities that enter into a CCJR sharing arrangement:

(1) Skilled nursing facility.

(2) Home health agency.

(3) Long-term care hospital.

(4) Inpatient rehabilitation facility.

(5) Physician.

(6) Nonphysician practitioner.

(7) Outpatient therapy provider.

(8) Physician group practice.

CCJR-eligible hospital means a hospital that is paid under IPPS and not a participant in BPCI Model 1 or in the risk-bearing period of Models 2 or 4 for LEJR episodes, regardless of whether or not the metropolitan statistical area in which the hospital is located is selected for inclusion in the CCJR model.

CCJR reconciliation report means the report prepared after each reconciliation that CMS provides to each participant hospital notifying the participant hospital of the outcome of the reconciliation.

CCJR sharing arrangement means a financial arrangement between a participant hospital and a CCJR collaborator for the sole purpose of sharing the following:

(1) CCJR reconciliation payments.

(2) The participant hospital's internal cost savings.

(3) The participant hospital's responsibility for repayment to Medicare.

Core-based statistical area (CBSA) means a statistical geographic entity consisting of the county or counties associated with at least one core (urbanized area or urban cluster) of at least 10,000 population, plus adjacent counties having a high degree of social and economic integration with the core as measured through commuting ties with the counties containing the core.

Critical access hospital (CAH) means a hospital designated under subpart F of part 485 of this chapter.

Episode of care (Episode) means all Medicare Part A and B items and services described in § 510.200(b) (and excluding the items and services described in § 510.200(d)) that are furnished to a beneficiary described in § 510.205 during the time period that begins with such beneficiary's admission to an anchor hospitalization and ends 90 days after discharge from the anchor hospitalization.

Episode target price means the amount determined in accordance with § 510.300 and applied to an episode in determining a net payment reconciliation amount.

Gainsharing payment means a payment from a participant hospital to a CCJR collaborator, under a CCJR sharing arrangement, composed of only reconciliation payments or internal cost savings or both.

Historical episode payment means the most recent 3 years of expenditures for an episode in a given participant hospital.

Hospital means a hospital subject to the prospective payment system specified in § 412.1(a)(1) of this chapter.

ICD–CM stands for International Classification of Diseases, Clinical Modification.

Inpatient prospective payment systems (IPPS) means the payment systems for subsection (d) hospitals as defined in section 1886(d)(1)(B) of the Act.

Internal cost savings means the measurable, actual, and verifiable cost savings realized by the participant hospital resulting from care redesign undertaken by the participant hospital in connection with providing items and services to beneficiaries within specific CCJR episodes of care. Internal cost savings does not include savings realized by any individual or entity that is not the participant hospital.

Lower-extremity joint replacement (LEJR) means any procedure that is within MS–DRG 469 or 470, including lower-extremity joint replacement procedures or reattachment of a lower extremity.

Medicare severity diagnosis-related group (MS–DRG) means a patient classification system for inpatient discharges and adjusting payments under the IPPS.

Medicare-dependent, small rural hospital (MDH) means a specific type of hospital that meets the classification criteria specified under § 412.108 of this chapter.

Metropolitan Statistical Area (MSA) means a core-based statistical area associated with at least one urbanized area that has a population of at least 50,000.

Net payment reconciliation amount (NPRA) means the amount determined in accordance with § 510.305(e).

NPI stands for National Provider Identifier.

OIG stands for the *Department of Health and Human Services'*, Office of the Inspector General.

Participant hospital means an IPPS hospital (other than those hospitals specifically excepted under § 510.100(b)) that is physically located in one of the geographic areas selected for participation in the CCJR model in accordance with § 510.105, as of the date of selection or any time thereafter during any performance period.

Participation agreement means a written, signed agreement between a CCJR collaborator and a participant hospital that meets the requirements of § 510.500(c).

PBPM stands for per-beneficiary-per-month.

Performance year means one of the calendar years in which the CCJR model will be tested.

Post-episode spending amount means the sum of Medicare Parts A and B payments for items and services that are furnished within 30 days after the end of the episode.

Reconciliation payment means a payment of the NPRA made to a CCJR participant hospital.

Region means one of the nine U.S. census divisions, as defined by the U.S. Census Bureau.

Rural hospital means a hospital that meets one of the following definitions:

(1) Is located in a rural area as defined under § 412.64 of this chapter.

(2) Is located in a rural census tract defined under § 412.103(1) of this chapter.

(3) Has reclassified as a rural hospital under § 412.103 of this chapter.

Rural referral center (RRC) has the same meaning given this term under § 412.96 of this chapter.

Sole community hospital (SCH) means a certain type of hospital that meets the classification criteria specified in § 412.92 of this chapter.

TIN stands for Taxpayer Identification Number.

Total episode payments means the total Medicare FFS Parts A and B claims for an episode.

Subpart B—Comprehensive Care for Joint Replacement Program Participants

§ 510.100 Episodes being tested.

(a) *Initiation of an episode.* An episode is initiated when a participant hospital admits a Medicare beneficiary described in § 510.205 for an anchor hospitalization.

(b) *Exclusions.* A hospital is excluded from being a participant hospital if any of the following conditions apply on or after July 1, 2015:

(1) The hospital is an episode initiator for an LEJR episode in the risk-bearing period of Models 2 or 4 of the BPCI. This exclusion ceases to apply to the hospital upon any termination of its participation as an episode initiator for a lower-extremity joint replacement episode.

(2) The hospital is participating in Model 1 of the BPCI. This exclusion ceases to apply to the hospital upon any termination of its participation in BPCI in Model 1.

§ 510.105 Geographic areas.

(a) *General.* The geographic areas for inclusion in the CCJR model are obtained using a stratified random sampling of certain MSAs in the United States. All counties within each of the selected MSAs are selected for inclusion in the CCJR model.

(b) *Stratification criteria.* Geographic areas in the United States are stratified according to the characteristics that CMS determines are necessary to ensure that the model is tested on a broad range of different types of hospitals that may face different obstacles and incentives for improving quality and controlling costs.

(c) *Exclusions.* CMS excludes from the selection of geographic areas MSAs that met the following criteria between July 1, 2013 and June 30, 2014:

(1) Had fewer than 400 episodes;

(2) Had fewer than 400 non-BPCI episodes;

(3) Had at least 400 non-BPCI episodes, but—

(i) Had more than 50 percent of otherwise qualifying (BPCI or non BPCI) episodes in Phase 2 of BPCI Model 2 or 4 with hospital episode initiators; or

(ii) Had more than 50 percent of otherwise qualifying (BPCI or non-BPCI) episodes treated in a SNF or HHA that were treated in a BPCI Model 3 initiating provider;

(4) Had more than 50 percent of episodes that were paid under the Maryland State Waiver System, if any part of the MSA was located in Maryland.

Subpart C—Scope of Episodes

§ 510.200 Time periods, included services, and attribution.

(a) *Time periods.* All episodes being tested in the CCJR model begin on or after January 1, 2016 and end on or before December 31, 2020.

(b) *Included services.* All Medicare Parts A and B items and services are included in the episode, except as specified in paragraph (d) of this section. These services include, but are not limited to, the following:

(1) Physicians' services.

(2) Inpatient hospital services (including hospital readmissions).

(3) Inpatient hospital readmission services.

(4) Inpatient psychiatric facility (IPF) services.

(5) Long-term hospital care (LTCH) services.

(6) Inpatient rehabilitation facility (IRF) services.

(7) Skilled nursing facility (SNF) services.

(8) Home health agency (HHA) services.

(9) Hospital outpatient services.

(10) Independent outpatient therapy services.

(11) Clinical laboratory services.

(12) Durable medical equipment (DME).

(13) Part B drugs and biologicals.

(14) Hospice services.

(15) PBPM payments under models tested under section 1115A of the Act.

(c) *Episode attribution.* All items and services included in the episode (as described in paragraph (b) of this section) are attributed to the participant hospital at which the anchor hospitalization occurs.

(d) *Excluded services.* The following items, services, and payments are excluded from the episode:

(1) Hemophilia clotting factors provided in accordance with § 412.115 of this chapter.

(2) New technology add-on payments, as defined in part 412, subpart F of this chapter.

(3) Items and services unrelated to the anchor hospitalization, as determined by CMS. Such excluded services include, but are not limited to, the following:

(i) Inpatient hospital admissions for MS–DRGs that group to the following categories of diagnoses:

(A) Oncology.

(B) Trauma medical.

(C) Chronic disease surgical, such as prostatectomy.

(D) Acute disease surgical, such as appendectomy.

(ii) Medicare Part B services as identified by the principal ICD–CM diagnosis code, based on the ICD–CM version in use during the performance year, on the claim that group to the following categories of diagnoses:

(A) Acute disease diagnoses, such as severe head injury.

(B) Certain chronic disease diagnoses, as specified by CMS on a diagnosis-by-diagnosis—basis depending on whether the condition was likely to have been affected by the lower-extremity joint replacement procedure and recovery period or whether substantial services were likely to be provided for the chronic condition during the episode. Such chronic disease diagnoses are posted on the CMS Web site and may be revised in accordance with paragraph (e) of this section.

(C) Certain PBPM payments under models tested under section 1115A of the Act. PBPM model payments are excluded if they are determined to be primarily used for care coordination or care management services for clinical conditions in excluded categories of diagnoses, as described in this paragraph. The list of excluded PBPM payments is posted on the CMS Web site and is updated consistent with the following. Notwithstanding the foregoing, all PBPM model payments

funded from CMMI's appropriation are excluded from the episode.

(*1*) The list of excluded PBPM payments will be posted on the CMS Web site.

(*2*) On an annual basis, or more frequently as needed, CMS updates the list of excluded PBPM payments.

(*3*) Criteria for exclusion of PBPM payments under certain models tested under section 1115A of the Act. Model PBPM payments are excluded from episode target price and actual episode payments if determined to be primarily used for care coordination or care management services for clinical conditions in excluded categories of diagnoses, as described in paragraph (d) of this section.

(*4*) Updating the list of excluded PBPM payments to account for new models.

CMS posts potential new exclusions of PBPM payments to the CMS Web site to allow for public comment and finalize and post to the CMS Web site the updated exclusions list after consideration of public input.

(D) Previous years' reconciliation or repayment amounts are not included in the episode for purposes of calculating episode target prices (§ 510.300) or total episode payments during a performance period.

(e) *Updating the lists of excluded services.* (1) The list of excluded MS–DRGs and ICD–CM diagnosis codes are posted on the CMS Web site.

(2) On an annual basis, or more frequently as needed, CMS updates the list of excluded services to reflect annual coding changes or other issues brought to CMS's attention.

(3) CMS applies the following standards when revising the list of excluded services for reasons other than to reflect annual coding changes:

(i) Items or services that are directly related to the LEJR procedure or the quality or safety of LEJR care would be included in the episode.

(ii) Items or services for chronic conditions that may be affected by the LEJR procedure or post-surgical care would be related and included in the episode.

(iii) Items and services for chronic conditions that are generally not affected by the LEJR procedure or post-surgical care would be excluded from the episode.

(iv) Items and services for acute clinical conditions not arising from existing, episode-related chronic clinical conditions or complications of LEJR surgery would be excluded from the episode.

(4) CMS posts the following to the CMS Web site:

(i) Potential revisions to the exclusion to allow for public comment; and

(ii) An updated exclusions list after consideration of public comment.

§ 510.205 Beneficiary inclusion criteria.

(a) Episodes tested in the CCJR model include only those in which care is furnished to beneficiaries who meet all of the following criteria upon admission to the anchor hospitalization:

(1) The beneficiary is enrolled in Medicare Parts A and Part B.

(2) The beneficiary's eligibility for Medicare is not on the basis of end stage renal disease, as described in § 406.13 of this chapter.

(3) The beneficiary is not enrolled in any managed care plan (for example, Medicare Advantage, health care prepayment plans, or cost-based health maintenance organizations).

(4) The beneficiary is not covered under a United Mine Workers of America health care plan.

(5) Medicare is the primary payer.

(b) If at any time during the episode the beneficiary no longer meets all of the criteria in this section, the episode is canceled in accordance with § 510.210(b).

§ 510.210 Determination of the episode.

(a) *General.* The episode begins with the admission of a Medicare beneficiary described in § 510.205 to a participant hospital for an anchor hospitalization and ends 90 calendar days after discharge from the anchor hospitalization.

(b) *Cancellation of an episode.* The episode is cancelled and is not included in the determination of NPRA as specified in § 510.305 if the beneficiary does any of the following:

(1) Ceases to meet any criterion listed in § 510.205 at any time during the episode.

(2) Is readmitted to any participant hospital during the episode for another anchor hospitalization;

(3) Initiates an LEJR episode under BPCI

(4) Dies during the anchor hospitalization.

Subpart D—Pricing and Payment

§ 510.300 Determination of episode target prices.

(a) *General.* CMS establishes episode target prices for participant hospitals for each performance year the model as specified in this section. Episode target prices are established according to the following:

(1) MS–DRG assigned at discharge for anchor hospitalization—

(i) MS–DRG 469; or

(ii) MS–DRG 470.

(2) Applicable time period for performance period episode target prices. Episode target prices are be updated to account for midyear payment updates no less than twice per year, for updated episode target prices effective October 1 and January 1, and at other intervals if necessary.

(3) Episodes that straddle performance years or midyear payment updates. Episode target prices apply for the time period in which the date of the anchor hospitalization admission occurs.

(4) Adjustments for quality reporting, as discussed in § 510.305(g).

(b) *Episode target price.* (1) CMS calculates episode target prices based on a blend of each participant hospital's most recent 3 years of expenditures for an episode and the most recent 3 years of expenditures for an episode in the region in which the participant hospital is physically located. Specifically, the blend consists of the following:

(i) Two-thirds of the participant hospital's own historical episode payments and one-third of the regional historical episode payments for performance years 1 and 2.

(ii) One-third of the hospital's own historical episode payments and two-thirds of the regional historical episode payments for performance year 3.

(iii) Regional historical episode payments for performance years 4 and 5.

(2) *Exception for low-volume hospitals.* Episode target prices for participant hospitals with fewer than 20 CCJR episodes in total across the 3 historical years of data used to calculate the episode target price are based on 100 percent regional historical episode payments.

(3) *Exception for recently merged or split or altogether new hospitals.* (i) Hospital-specific historical payments for recently merged or split hospitals would incorporate the historical episodes attributed to their previous entities.

(ii) New hospitals (with new CMS provider agreements) would receive target prices using the same blended approach and low-volume policy for existing hospitals as described in in this section.

(4) *Exception for high episode spending in baseline period.* Historical episode payments are capped at 2 standard deviations above the mean episode payment for purposes of calculating the episode target prices.

(5) *Exclusion of incentive programs and add-on payments under existing Medicare payment systems.* Certain incentive programs and add-on payments are excluded, as applicable, from target price and total episode payment calculations by using the CMS

Price Standardization methodology used for the Medicare spending per beneficiary measure in the Hospital Value-Based Purchasing Program.

(6) *Communication of episode target prices.* CMS communicates episode target prices to participant hospitals before the performance period in which they apply for performance years 2 through 5, and before or shortly after the start of performance year 1.

(c) *Discount factor.* A participant hospital's episode target prices incorporate applicable discount factors to reflect Medicare's portion of reduced expenditures from the CCJR model as described in this section.

(1) Except as provided in paragraph (c)(2) of this section, the applicable discount factor is for a participant hospital that—

(i) Does not successfully submit voluntary patient-reported outcome data for that performance year as provided in § 510.400(b) is 2.0 percent.

(ii) Successfully submits voluntary patient-reported outcome data for that performance year as provided in § 510.400(b) is 1.7 percent.

(2) For performance year 2 only, if the participant hospital's NPRA (defined in section § 510.305(e)) would be negative using the applicable discount factor under paragraph (c)(1) of this section, then for purposes of determining the participant hospital's NPRA, the discount factor is applied in lieu of the applicable discount factor under paragraph (c)(1) of this section for a participant hospital that—

(i) Successfully submits the voluntary patient-reported outcomes data for performance year 2 as provided in § 510.400(b) is 0.7 percent.

(ii) Does not successfully submit the voluntary patient-reported outcomes data for performance year 2 as provided in § 510.400(b), is 1 percent.

(d) *Data sharing.* (1) CMS makes available to participant hospitals, through the most appropriate means, data that CMS determines may be useful to participant hospitals to do the following:

(i) Determine appropriate ways to increase the coordination of care.

(ii) Improve quality.

(iii) Enhance efficiencies in the delivery of care.

(iv) Otherwise achieve the goals of the CCJR model described in this section.

(2) *Beneficiary-identifiable data.* (i) CMS makes beneficiary-identifiable data available to a participant hospital in accordance with applicable privacy laws and only in response to the hospital's request for such data for a beneficiary who has been furnished a billable service by the participant hospital corresponding to the episode definitions for CCJR and has not chosen to opt out of claims data sharing.

(ii) The minimum data necessary to achieve the goals of the CCJR model, as determined by CMS, may be provided under this section for a participant hospital's baseline period and as frequently as on a quarterly basis throughout the hospital's participation in the CCJR model.

§ 510.305 Determination of the NPRA and reconciliation process.

(a) *General.* Providers and suppliers furnishing items and services included in the episode bill for such items and services in accordance with existing rules and as if this part were not in effect.

(b) *Reconciliation.* Medicare uses a series of reconciliation processes, which CMS performs as described in paragraphs (d) and (f) of this section after the end of each performance year, to establish final payment amounts to participant hospitals for CCJR episodes for a given performance year. Following the end of each performance year, CMS determines actual episode payments for each episode for the performance year (other than episodes that have been canceled in accordance with § 510.210(b)) and determines the amount of a reconciliation or repayment amount.

(c) *Data used.* CMS uses the most recent claims data available to perform each reconciliation calculation.

(d) *Annual reconciliation.* (1) Two months after the end of each performance year, CMS performs a reconciliation calculation to establish an NPRA for each participant hospital.

(2) CMS—

(i) Calculates the NPRA for each participant hospital in accordance with § 510.305(e) including the adjustments provided for in § 510.305(e)(5); and

(ii) Assesses whether hospitals meet specified quality requirements under § 510.315.

(e) *Calculation of the NPRA.* By comparing the episode target prices described in § 510.300 and the participant hospital's actual episode spending for the performance year and applying the adjustments in paragraph (e)(1)(v) of this section, CMS establishes an NPRA for each participant hospital for each performance year.

(1) *Initial calculation.* In calculating the NPRA for each participant hospital for each performance year, CMS does the following:

(i) Determines actual episode payments for each episode included in the performance year (other than episodes that have been cancelled in accordance with § 510.210(b)) using claims data that is available 2 months after the end of the performance year, in accordance with the adjustments in § 510.300(b)(5).

(ii) Multiplies the participant hospital's applicable episode target price, including necessary adjustments for voluntary reporting of outcome data (§ 510.400(b)) for each type of episode being tested and time period (as determined in accordance with § 510.300) by the number of episodes being tested in the performance year to which that episode target price applies.

(iii) Aggregates the amounts computed in paragraph (e)(1) of this section across all episodes being tested for that participant hospital in that performance year.

(iv) Subtracts the aggregate actual episode payments for all of the participant hospital's episodes being tested in that performance year from the calculated amount from paragraph (e)(2) of this section.

(v) Makes the following adjustments:

(A) *Increases in post-episode spending.* If the average post-episode spending for a participant hospital in any given performance year is greater than 3 standard deviations above the regional average post-episode spending for the same performance year, then this amount would be applied to the NPRA.

(B) *Limit on financial responsibility for high episode payment cases.* Actual episode payments for an episode are capped at 2 standard deviations above the mean episode payment for purposes of calculating the episode target prices (§ 510.300) and for purposes of comparing the actual episode payments with the applicable episode target price to calculate the NPRA.

(C) *Limitation on loss.* The total amount any participant hospital is responsible for repaying to Medicare for a performance year cannot exceed the following:

(*1*) For performance year 2 only, 10 percent of the amount calculated in paragraph (e)(1)(ii) of this section for the performance year.

(*2*) For performance years 3, 4, and 5, 20 percent of the amount calculated in paragraph (e)(1)(ii) of this section for the performance year.

(D) *Limitation on gain.* The total amount of any reconciliation payment Medicare would make to a participant hospital for a performance year cannot exceed 20 percent of the amount calculated in paragraph (e)(1)(ii) of this section for the performance year.

(E) *Financial loss limits for SCHs, MDHs, and RRCs.* If a participant hospital is an SCH, an MDH or RRC, then for—

(*1*) Performance year 2, the total repayment amount for which the participant hospital is responsible cannot exceed 3 percent of amount calculated in paragraph (e)(1)(ii) of this section; and

(*2*) Performance years 3 through 5, the total repayment amount cannot exceed 5 percent of the amount calculated in paragraph (e)(1)(ii) of this section.

(f) *Determination of reconciliation or repayment amount*—(1) *Determination of the reconciliation or repayment amount.* (i) For performance year 1, the reconciliation or repayment amount is equal to the NPRA.

(ii) For performance years 2 through 5, results from the subsequent reconciliation calculation for a prior year's reconciliation, as described in paragraph (i)(3) of this section, are applied to the current year's NPRA in order to determine the reconciliation or repayment amount.

(2) *Reconciliation payment.* If the amount from paragraph (f)(1) of this section is positive and the participant hospital meets or exceeds all of the quality thresholds described in § 510.400, Medicare pays the participant hospital a reconciliation payment an amount equal to the calculation described in paragraph (f)(1) of this section.

(3) *Repayment amount.* If the amount from paragraph (f)(1) of this section is negative, the participant hospital pays to Medicare an amount equal to the calculation described in paragraph (f)(1) of this section. CMS waives this requirement for performance year 1.

(g) *Determination of eligibility for reconciliation based on quality.* (1) CMS assesses each participant hospital's performance on quality metrics, as described in § 510.400, to determine whether the participant hospital is eligible to receive a reconciliation payment for a performance year.

(2) If the hospital meets the quality thresholds as specified in § 510.400, and is determined to have positive NPRA under paragraph (e) of this section, the hospital is eligible for a reconciliation payment.

(3) If the hospital does not meet the thresholds as specified in § 510.400 for a performance year, the hospital is not eligible for a reconciliation payment.

(h) *Reconciliation report.* CMS issues each participant hospital a CCJR reconciliation report for the performance year. Each CCJR reconciliation report contains the following:

(1) Information on whether the participant hospital met or exceeded the quality thresholds specified in § 510.400.

(2) The total actual episode payments for the participant hospital.

(3) The NPRA.

(4) Whether the participant hospital is eligible for a reconciliation payment or must make a repayment to Medicare.

(5) The NPRA and subsequent reconciliation calculation amount for the previous performance year, as applicable.

(6) The reconciliation payment or repayment amount.

(i) *Subsequent reconciliation calculation.* (1) Fourteen months after the end of each performance year, CMS performs an additional calculation, using claims data available at that time, to account for final claims run-out and any additional overlap between the CCJR model and other CMS models and programs as described in paragraph (i)(2) of this section.

(2) The subsequent reconciliation calculation accounts for CCJR episodes that overlap with the following shared savings programs and models in cases where the participant hospital is a participant in the ACO and the beneficiary in the episode is assigned to the ACO:

(*i*) The Pioneer ACO model.

(*ii*) The Medicare Shared Savings Program.

(*iii*) The Next Generation ACO model.

(*iv*) The Comprehensive ESRD Care Initiative (CEC).

(3) The additional calculation occurs concurrently with the reconciliation process for the most recent performance year. If the result of the subsequent calculation is different than zero, CMS applies the stop-loss and stop-gain limits in paragraph (e) of this section to the calculations in aggregate for that performance year (the initial reconciliation and the subsequent calculation) to ensure the amount does not exceed the stop-loss or stop-gain limits. CMS then applies this amount to the NPRA for the most recent performance year in order to determine the reconciliation amount or repayment amount for the most recent performance year. For the performance year 2 reconciliation report only, the subsequent calculation amount (for performance year 1) is applied to the performance year 1 NPRA to ensure that the combined amount is not less than 0. If the combined amount is less than zero, the subsequent calculation amount would be capped at the amount that would result in a net amount of zero for the combination of the performance year 1 NPRA and subsequent calculation amount.

§ 510.310 Appeals process.

(a) *General.* If a participant hospital believes that there is an error in a calculation that involves a matter in any way related to payment, reconciliation amounts, repayment amounts, or determinations associated with quality measures impacting payment, the hospital is required to provide written notice of the error, in a form and manner specified by CMS.

(1) Unless the participant hospital provides such notice, the CCJR reconciliation report is deemed final 30 calendar days after it is issued.

(2) If CMS receives a timely notice of a calculation error as provided in paragraph (d) of this section, CMS responds in writing within 30 calendar days to either confirm or refute the calculation error, although CMS reserves the right to an extension upon written notice to the participant hospital.

(3) If a participant hospital does not submit timely notice of a calculation error in accordance with the timelines and processes specified by CMS, then CMS deems final the CCJR reconciliation report and proceeds with the payment or repayment processes, as applicable, as determined by the NPRA reflected in the CCJR reconciliation report.

(b) Participant hospitals may appeal the NPRA or any calculations impacting NPRA, reconciliation amounts or repayment amounts on the grounds that CMS or its representative made an error in calculating such amounts using the dispute resolution process defined in paragraph (e) of this section.

(c) Only participant hospitals may utilize the dispute resolution process.

(d) To begin the dispute resolution process, a participant hospital must submit a notice of calculation error in a timely manner, as specified by CMS.

(e) *Dispute resolution process.* (1) If the participant hospital is dissatisfied with CMS's response to the notice of a calculation error, the participant hospital may request a reconsideration review in a form and manner as specified by CMS.

(i) The reconsideration review request must provide a detailed explanation of the basis for the dispute and include supporting documentation for the participant hospital's assertion that CMS or its representatives did not accurately calculate the NPRA in accordance with § 510.305.

(ii) If CMS does not receive a request for reconsideration from the participant hospital within 10 calendar days of the issue date of CMS's response to the participant hospital's notice of calculation error, then CMS's response

to the calculation error is deemed final and CMS proceeds with reconciliation payment or repayment processes, as applicable, as described in § 510.305.

(iii) Where the participant hospital contests a matter that does not involve an issue contained in, or a calculation which contributes to, a CCJR reconciliation report, a calculation error form is not required. An example of such a matter is termination of the participant hospital from the model. In those instances, if CMS does not receive a request for reconsideration from the participant hospital within 10 calendar days of the notice of the initial determination, the initial determination is deemed final and CMS proceeds with action indicated in the initial determination.

(2)(i) A CMS reconsideration official notifies the participant hospital in writing within 15 calendar days of receiving the participant hospital's review request of the following:

(A) The date, time, and location of the review.

(B) The issues in dispute.

(C) The review procedures.

(D) The procedures (including format and deadlines) for submission of evidence.

(ii) The CMS reconsideration official takes all reasonable efforts to schedule the review to occur no later than 30 days after the date of receipt of the notification.

(iii) The provisions at § 425.804(b), (c), and (e) of this chapter are applicable to reviews conducted in accordance with the reconsideration review process for CCJR.

(iv) The CMS reconsideration official issues a written determination within 30 days of the review. The determination is final and binding.

(3) *Limitations on review.* In accordance with section 1115A(d)(2) of the Act, there is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

(i) The selection of models for testing or expansion under section 1115A of the Act.

(ii) The selection of organizations, sites, or participants to test those models selected.

(iii) The elements, parameters, scope, and duration of such models for testing or dissemination.

(iv) Determinations regarding budget neutrality under section 1115A(b)(3) of Act.

(v) The termination or modification of the design and implementation of a model under section 1115A(b)(3)(B) of Act.

(vi) Decisions about expansion of the duration and scope of a model under section 1115A(c) of the Act, including the determination that a model is not expected to meet criteria described in paragraph (e)(1) or (2) of this section.

§ 510.315 Quality thresholds for reconciliation payment eligibility.

(a) *General.* Participant hospitals are eligible for a reconciliation payment for a performance year only if they meet or exceed the minimum quality thresholds specified in paragraph (b) of this section for the performance year.

(b) *Quality measure thresholds.* A participant hospital's measure result must be at or above the thresholds in paragraphs (b)(1) and (2) of this section for all three quality measures for each performance year of this model to be eligible for additional payments under the CCJR model.

(1) The 30th percentile of the national hospital measure results calculated for all HIQR-participant hospitals for performance years 1, 2, and 3.

(2) The 40th percentile for performance years 4 and 5.

(c) *Low-volume hospital exception.* A participant hospital with an insufficient volume of episodes on which to determine performance on an individual measure, as determined by CMS, is considered to have met the performance threshold for that quality measure.

§ 510.320 Treatment of incentive programs or add-on payments under existing Medicare payment systems.

The CCJR model does not replace any existing Medicare incentive programs or add-on payments. The target price and NPRA for a participant hospital is independent of, and does not affect, any incentive programs or add-on payments under existing Medicare payment systems (as described in § 510.300(b)(5)).

§ 510.325 Allocation of payments for services that straddle the episode.

(a) *General.* Services included in the episode as provided in § 510.200(b) that straddle the episode are prorated so that only the portion attributable to care furnished during the episode are attributed to the calculation of actual episode payments.

(b) *Proration of services.* Payments for services that straddle the episode are prorated using the following methodology:

(1) *Non-IPPS inpatient services and other inpatient services.* Non-IPPS inpatient services, and services furnished by other inpatient providers that extend beyond the end of the episode are prorated according to the percentage of the actual length of stay (in days) that falls within the episode window.

(2) *Home health agency services.* Home health services paid under the prospective payment system in part 484, subpart E of this chapter are prorated according to the percentage of days, starting with the first billable service date (''start of care date'') and through and including the last billable service date, that occur during the fixed duration of the episode. This methodology is applied in the same way if the home health services begin (the start of care date) prior to the start of the episode.

(3) *IPPS services.* IPPS claim amounts that extend beyond the end of the episode are prorated according to the geometric mean length of stay, using the following methodology:

(i) The first day of the IPPS stay is counted as 2 days.

(ii) If the actual length of stay that occurred during the episode is equal to or greater than the MS–DRG geometric mean, the normal MS–DRG payment would be fully allocated to the episode.

(iii) If the actual length of stay that occurred during the episode is less than the geometric mean, the normal MS–DRG payment amount would be allocated to the episode based on the number of inpatient days that fall within the episode.

(iv) If the full amount is not allocated to the episode, any remainder amount is allocated to the post-episode spending calculation (defined in § 510.2).

Subpart E—Quality Measures, Beneficiary Protections, and Compliance Enforcement

§ 510.400 Quality measures and reporting.

(a) *Reporting of quality measures.* The following quality measures are used for public reporting and for determining whether a participant hospital is eligible for additional payments under the CCJR model, as described in § 510.305:

(1) Hospital-level risk-standardized complication rate following elective primary total hip arthroplasty and/or total knee arthroplasty.

(2) Hospital-level 30-day, all-cause risk-standardized readmission rate following elective primary total hip arthroplasty and/or total knee arthroplasty.

(3) Hospital Consumer Assessment of Healthcare Providers and Systems Survey.

(b) *Requirements for successful data submission of patient reported outcomes.* To be eligible for the discount factors that apply to participant hospitals that successfully submit the voluntary patient reported outcomes data described in § 510.300(c), participant hospitals must submit data

on the hospital-level performance measure(s) of patient-reported outcomes following elective primary total hip and/or total knee arthroplasty, including but not limited to the pre-operative and post-operative data elements, for at least 80 percent of the eligible elective primary total hip and/or total knee arthroplasty beneficiaries within 60 days of the end of the most recent performance period.

(c) *Public reporting.* CMS—

(1) Makes the quality measurement results calculated for the readmission, complication, and patient survey quality measures for each participant hospital in each performance year publicly available on the CMS Web site in a form and manner as determined by CMS.

(2) Shares each participant hospital's quality metrics with the hospital prior to display on the Web site.

(3) Does not publicly report the voluntary patient reported outcome data during this 5 year model.

§ 510.405 Beneficiary choice and beneficiary notification.

(a) *Beneficiary choice.* The CCJR model does not restrict Medicare beneficiaries' ability to choose any Medicare participating provider or supplier, or any provider or supplier who has opted out of Medicare.

(b) *Required beneficiary notification.* (1) Each participant hospital must provide written notice to any Medicare beneficiary that meets the criteria in § 510.205 of his or her inclusion in the CCJR model. The beneficiary notification must contain all of the following:

(i) A detailed explanation of the model and how it might be expected to affect the beneficiary's care.

(ii) Notification that the beneficiary retains freedom of choice to choose providers and services.

(iii) Explanation of how patients can access care records and claims data through an available patient portal, and how they can share access to their Blue Button® electronic health information with caregivers.

(iv) A statement that all existing Medicare beneficiary protections continue to be available to the beneficiary. These include the ability to report concerns of substandard care to Quality Improvement Organizations (QIO) and 1–800–MEDICARE.

(2) A participant hospital must require any physician with whom it has a CCJR sharing arrangement to provide written notice of the existence of such an arrangement to any Medicare beneficiary that meets the criteria for inclusion in the model specified in § 510.205.

(c) *Timing of the required beneficiary notification.* The participant hospital provides the written notice described in paragraph (b) of this section upon the beneficiary's admission for an anchor hospitalization.

§ 510.410 Compliance enforcement.

(a) *General.* Participant hospitals must comply with all of the requirements outlined in this part.

(b) *Failure to comply.* CMS may do one or more of the following if a participant hospital fails to comply with any of the requirements outlined in this part:

(1) Issue a warning letter to the participant hospital.

(2) Require the participant hospital to develop a corrective action plan.

(3) Reduce or eliminate a participant hospital's positive NPRA.

(4) Terminate the participant hospital's participation in the CCJR model, if the participant hospital, or an individual or entity with which the participant hospital has a participation agreement, does any of the following:

(i) Takes any action that threatens the health or safety of patients.

(ii) Avoids at-risk Medicare beneficiaries, as this term is defined in § 425.20 of this chapter.

(iii) Avoids patients on the basis of payer status.

(iv) Is subject to sanctions or final actions of an accrediting organization or federal, state, or local government agency that could lead to the inability to comply with the requirements and provisions of this part.

(v) Takes or fails to take any action that CMS determines for program integrity reasons is not in the best interests of the CCJR model.

(vi) Is subject to action by the Secretary to redress an allegation of fraud or significant misconduct, including intervening in a False Claims Act qui tam matter, issuing a pre-demand or demand letter under a civil sanction authority or similar actions.

Subpart F—Financial Arrangements and Beneficiary Incentives

§ 510.500 Financial arrangements under the CCJR model.

(a) *General.* To assist participant hospitals in aligning the financial incentives of other providers and suppliers caring for beneficiaries in CCJR episodes with the quality and efficiency goals of the CCJR model, participant hospitals may, consistent with applicable law, elect to enter into financial arrangements that contain CCJR sharing arrangements with CCJR collaborators, as defined in this section.

(1) All such financial arrangements must comply with all relevant laws and regulations, including the fraud and abuse laws and all applicable payment and coverage requirements.

(2) CMS reserves the right to review any CCJR sharing arrangement to ensure that it does not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care.

(b) *Required records.* When a participant hospital enters into a CCJR sharing arrangement with a CCJR collaborator, the participant hospital, and all of its CCJR collaborators must maintain copies of the following records:

(1) All original copies of CCJR sharing arrangements that the participant hospital signs with a CCJR collaborator in connection with the hospital's participation in CCJR. Each CCJR sharing arrangement must include, but is not limited to the following:

(i) A specific methodology and accounting formula for calculating and verifying the internal cost savings generated by the participant hospital entering into a CCJR sharing arrangement with a CCJR collaborator based on the care redesign elements specifically associated with the particular CCJR collaborator.

(ii) Specific methodologies for accruing and calculating internal cost savings from the participant hospital, where the hospital intends to share internal cost savings through a CCJR sharing arrangement with a CCJR collaborator. The specific methodologies for accruing and calculating internal cost savings must be transparent, measurable, and verifiable in accordance with generally accepted accounting principles and Government Auditing Standards (The Yellow Book). The methodology must set out the specific care redesign elements to be undertaken by the participant hospital or the CCJR collaborator or both.

(iii) A description of the methodology and accounting formula for calculating the percentage or dollar amount of a reconciliation payment that will be paid from the participant hospital to the CCJR collaborator.

(iv) A description of the methodology, frequency of distribution, and accounting formula for distributing and verifying any and all gainsharing payments.

(v) A description of the arrangement between the participant hospital and the CCJR collaborator regarding gainsharing payments and alignment payments, including safeguards to ensure that such alignment payments are made solely for purposes related to sharing responsibility for funds need to repay

Medicare in the CCJR model. This description must include the following:

(A) A methodology.

(B) Frequency of payment.

(C) Accounting formula for payment.

(D) Receipt of any and all alignment payments.

(E) Plans regarding care redesign.

(F) Changes in care coordination or delivery that is applied to the participant hospital or CCJR collaborators or both.

(G) Any description of how success will be measured.

(vi) Management and staffing information, including type of personnel or contractors that will be primarily responsible for carrying out changes to care under the model.

(2) The participant hospital must keep records of the following:

(i) All CCJR collaborators.

(ii) Its process for determining and verifying the eligibility of CCJR collaborators to participate in Medicare.

(iii) Information confirming the organizational readiness of the participant hospital to measure and track internal cost savings.

(iv) Plan to track internal cost savings.

(v) Information on the accounting systems used to track internal cost savings.

(vi) A description of current health information technology, including systems to track reconciliation payments and internal cost savings.

(c) *Participant agreement.* The participant agreement must obligate the parties to comply, and must obligate the CCJR collaborator to require any of its employees, contractors or designees to comply, without limitation, to the following:

(1) An individual or entity's participation in the CCJR sharing arrangement is voluntary, and there is no penalty for nonparticipation.

(2) Any gainsharing payments made under the CCJR sharing arrangement may be made only from the participant hospital to the entity or individual with whom the participant hospital has a signed CCJR sharing arrangement.

(3) Any alignment payments made in accordance with a CCJR sharing arrangement may be made only to the participant hospital from the entity or individual with whom the participant hospital has signed a participation agreement containing a CCJR sharing arrangement. A CCJR collaborator entering into a CCJR sharing arrangement must be in compliance with all Medicare provider enrollment requirements at § 424.500 of this chapter, including having a valid and active TIN or NPI.

(4) Any internal cost savings or reconciliation payments that the participant hospital seeks to share through CCJR sharing arrangements must meet the requirements set forth in this part and must be administered by the participant hospital in accordance with generally accepted accounting principles.

(i) The participant hospital may not distribute any amounts that are not comprised of dollars that are either internal cost savings or a reconciliation payment, as those terms are defined in this part.

(ii) All amounts deemed internal cost savings by the participant hospital must reflect actual, internal cost savings achieved by the participant hospital through implementation of care redesign elements identified and documented by the participant hospital in the manner described in this section.

(iii) Internal cost savings may not reflect ''paper'' savings from accounting conventions or past investment in fixed costs.

(5) Any alignment payments that the participant hospital receives through a CCJR sharing arrangement must meet the requirements set forth in this section and be administered by the participant hospital in accordance with generally accepted accounting principles. In no event may the participant hospital receive any amounts from a CCJR collaborator under a CCJR sharing arrangement that are not alignment payments.

(6) Provisions that require CCJR collaborators to share all records related to a CCJR Sharing Arrangement, including at a minimum the following:

(i) Each participation agreement between the participant hospital and a CCJR collaborator must obligate the CCJR collaborator to provide the participant hospital and CMS with access to the CCJR collaborator's records, information, and data for purposes of monitoring and reporting and any other lawful purpose.

(ii) Records, information, and data demonstrating compliance with the gainsharing payment must—

(A) Have sufficient detail to verify compliance with all material terms of the CCJR sharing arrangement; and

(B) Be fully substantiated and documented, as to both statements and numbers.

(7) Participation agreements must require all CCJR collaborators to comply with any evaluation, monitoring, compliance, and enforcement activities performed by CMS or its designees for the purposes of operating the CCJR model.

(d) *Gainsharing payment and alignment payment conditions and restrictions.* Participant hospitals must adhere to the following conditions and restrictions concerning gainsharing payments and alignment payments made under a CCJR sharing arrangement:

(1) No entity or individual, as a party to a participation agreement or not, may condition the opportunity to receive gainsharing payments in CCJR on the volume or value of past or anticipated referrals or other business generated to, from, or among the participant hospital and any CCJR collaborators.

(2) Participant hospitals are not required to share reconciliation payments, internal cost savings, or responsibility for repayment to CMS with other providers and suppliers.

(i) If a participant hospital elects to engage in those activities, such activities are limited to the terms of this section.

(ii) Gainsharing payments, if distributed, must be distributed on an annual basis.

(iii) Alignment payments from a CCJR collaborator to a participant hospital may be made at any interval that is agreed upon by both parties, and must—

(A) Be clearly identified;

(B) Comply with all provisions in this section;

(C) Comply with all applicable laws, statutes, and rules.

(3) No entity or individual, as a party to a participation agreement or not, may condition the opportunity to send or receive alignment payments in CCJR on the volume or value of past or anticipated referrals or other business generated to, from, or among the participant hospital and any CCJR collaborators.

(4) In a calendar year, the aggregate amount of the total gainsharing payments distributed by a participant hospital that are derived from a CCJR reconciliation payment may not exceed the amount of the reconciliation payment the participant hospital receives from CMS.

(5) In a calendar year, the aggregate amount of the total alignment payments received by the participant hospital may not exceed 50 percent of the participant hospital's repayment amount due to CMS. If no repayment amount is due, then no alignment payments may be received by the participant hospital.

(6) The participant hospital must retain at least 50 percent of its responsibility for repayment, pursuant to the repayment amount reflected in a reconciliation report, under the CCJR model to CMS.

(7) A single CCJR collaborator may not make an alignment payment to a participant hospital that represents an amount greater than 25 percent of the

repayment amount reflected on a reconciliation report.

(8) Gainsharing payments and alignment payments must not induce any of the following parties to reduce or limit medically necessary services to any Medicare beneficiary:

(i) The participant hospital.

(ii) CCJR collaborators.

(iii) Employees, contractors, or designees of the participant hospital or CCJR collaborators.

(9) Individual physician and nonphysician practitioners must retain their ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

(10) Methodologies for calculating gainsharing payments and alignment payments must not directly account for volume or value of referrals, or business otherwise generated, between or among the participant hospital and CCJR collaborators.

(11) Gainsharing payments must be derived solely from reconciliation payments or internal cost savings or both.

(12) The total amount of gainsharing payments for a calendar year paid to an individual physician or nonphysician practitioner who is a CCJR collaborator must not exceed 50 percent of the total Medicare approved amounts under the Physician Fee Schedule (PFS) for services furnished to the participant hospital's CCJR beneficiaries during a CCJR episode by that physician or nonphysician practitioner.

(e) *Documentation and maintenance of records.* All participant hospitals and CCJR collaborators who enter into CCJR sharing arrangements must:

(1) Provide to CMS, the OIG, and the Comptroller General or their designee(s) scheduled and unscheduled access to all books, contracts, records, documents, and other evidence (including data related to utilization and payments, quality performance measures, billings, and CCJR sharing arrangements related to CCJR) sufficient to enable the audit, evaluation, inspection, or investigation of the participant hospital's compliance, as well as the compliance of any CCJR collaborator that has a CCJR sharing arrangement with the participant hospital, with CCJR requirements, the participation agreement, the quality of services furnished, the obligation to repay any reconciliation payments owed to CMS, or the calculation or both, distribution, receipt, or recoupment of gainsharing payments or alignment payments.

(2) Maintain all such books, contracts, records, documents, and other evidence for a period of 10 years from the last day of the participant hospital's participation in the CCJR model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

(i) CMS determines that there is a special need to retain a particular record or group of records for a longer period and notifies the participant hospital at least 30 calendar days before the normal disposition date; or

(ii) There has been a dispute or allegation of fraud or similar fault against the participant hospital or any CCJR collaborator, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

(f) *Compliance responsibility.* Notwithstanding any CCJR sharing arrangements between the participant hospital and CCJR collaborators, the participant hospital must have ultimate responsibility for adhering to and otherwise fully complying with all provisions of the CCJR model.

(g) *OIG authority.* OIG authority is not limited or restricted by the provisions of the CCJR model, including the authority to audit, evaluate, investigate, or inspect the participant hospital, CCJR collaborators, or any other person or entity or their records, data, or information, without limitation.

(h) *Other authorities.* None of the provisions of the CCJR model limits or restricts any other government authority permitted by law to audit, evaluate, investigate, or inspect the participant hospital, CCJR collaborators, or any other person or entity or their records, data, or information, without limitation.

§ 510.505 Beneficiary incentives under the CCJR model.

(a) *General.* Participant hospitals may choose to provide in-kind patient engagement incentives to beneficiaries in CCJR episodes for free or below fair market value, subject to the following conditions:

(1) The incentive must be provided to the beneficiary during a CCJR episode of care.

(2) The item or service provided must be reasonably connected to the beneficiary's medical care, as well as be a preventive care item or service or an item or service that advances a clinical goal, as listed in paragraph (b) of this section, for a beneficiary in a CCJR episode by engaging the beneficiary in better managing his or her own health.

(b) *Goals of the CCJR model.* The following are the particular clinical goals of the CCJR model, which may be advanced through beneficiary incentives:

(1) Beneficiary adherence to drug regimens.

(2) Beneficiary adherence to follow up care plan or care.

(3) Reduction of readmissions and complications resulting from lower-extremity joint replacement procedures.

(4) Management of chronic diseases and conditions that may be affected by the lower-extremity joint replacement procedure.

(c) *Beneficiary incentives.* Participant hospitals are required to maintain a list of items and services furnished as beneficiary incentives that exceed $10, including the following:

(1) The date the incentive is provided.

(2) The identity of the beneficiary to whom the item or service was provided.

(d) *Technology provided to a beneficiary.* (1) Items or services involving technology provided to a beneficiary may not exceed $1,000 in value for any one beneficiary in any one CCJR episode.

(2) Items of technology exceeding $50 must—

(i) Remain the property of the participant hospital; and

(ii) Be retrieved from the beneficiary at the end of the CCJR episode. The participant hospital must maintain documentation of the date of retrieval.

Subpart G—Waivers

§ 510.600 Waiver of direct supervision requirement for certain post-discharge home visits.

(a) *General.* CMS waives the requirement in § 410.26(b)(5) of this chapter that services and supplies furnished incident to a physician's service must be furnished under the direct supervision of the physician (or other practitioner) to permit home visits as specified in this section. The services furnished under this waiver are not be considered to be ''hospital services,'' even when furnished by the clinical staff of the hospital.

(b) *General supervision of qualified personnel.* The waiver of the direct supervision requirement in § 410.26(b)(5) of this chapter applies only in the following circumstances:

(1) The home visit is furnished during the episode to a beneficiary who has been discharged from an anchor hospitalization.

(2) The home visit is furnished at the beneficiary's home or place or residence.

(3) The beneficiary does not qualify for home health services under sections 1835(a) and 1814(a) of the Act at the time of any such home visit.

(4) The visit is furnished by a licensed clinician, either employed by a hospital

or not, under the general supervision of a physician employee or a contractor of the participant hospital.

(5) No more than 9 visits are furnished to the beneficiary during the episode.

(c) *Payment.* Up to 9 post-discharge home visits per CCJR episode may be billed under Part B by the physician or nonphysician practitioner or by the participant hospital to which the supervising physician has reassigned his or her billing rights.

(d) *Other requirements.* All other Medicare rules for coverage and payment of services incident to a physician's service continue to apply.

§ 510.605 Waiver of certain telehealth requirements.

(a) *Waiver of the geographic site requirements.* CMS waives the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act for all episodes being tested in the CCJR model, but only for services that—

(1) May be furnished via telehealth under existing requirements; and

(2) Are included in the episode in accordance with § 510.200(b).

(b) *Waiver of the originating site requirements.* CMS waives originating site requirements under section 1834(m)(4)(C)(ii)(I) through (VIII) of the Act for all episodes being tested in the CCJR model to permit a telehealth visit to originate in the beneficiary's home or place of residence, but only for services that—

(1) May be furnished via telehealth under existing requirements; and

(2) Are included in the CCJR episode in accordance with § 510.200(b). The facility fee normally paid by Medicare to an originating site for a telehealth service is not paid if the service is originated in the beneficiary's home.

(c) *Other requirements.* All other requirements for Medicare coverage and payment of telehealth services continue to apply, including the list of specific services approved to be furnished by telehealth.

§ 510.610 Waiver of SNF 3-day rule.

(a) *Waiver of the SNF 3-day rule.* For all episodes being tested in the CCJR model in performance years 2 through 5, CMS waives the SNF 3-day rule for coverage of a SNF stay for a beneficiary following the anchor hospitalization, but only if the SNF is rated an overall of 3 stars or better in the Five-Star Quality Rating System for SNFs on the Nursing Home Compare Web site (*www.medicare.gov/NursingHome Compare/*).

(b) *Other requirements.* All other Medicare rules for coverage and payment of Part A-covered SNF services continue to apply.

§ 510.615 Waiver of certain post-operative billing restrictions.

(a) *Waiver to permit certain services to be billed separately during the 90-day post-operative global surgical period.* CMS waives the billing requirements for global surgeries to allow the separate billing of certain post-discharge home visits, including those related to recovery from the surgery, as described in paragraph (b) of this section, for all episodes being tested in the CCJR model.

(b) *Services to which the waiver applies.* Up to 9 post-discharge home visits, including those related to recovery from the surgery, per CCJR episode may be billed separately under Part B by the physician or nonphysician practitioner, or by the participant hospital to which the physician or nonphysician practitioner has reassigned his or her billing rights.

(c) *Other requirements.* All other Medicare rules for global surgery billing during the 90-day post-operative period continue to apply.

Dated: July 1, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: July 6, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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