

FINAL RULE: MEDICARE PROGRAM; COMPREHENSIVE CARE FOR JOINT REPLACEMENT PAYMENT MODEL FOR ACUTE CARE HOSPITALS FURNISHING LOWER EXTREMITY JOINT REPLACEMENT SERVICES [CMS-5516-F]

SUMMARY

On November 16, 2015, the Centers for Medicare & Medicaid Services (CMS) posted a final rule implementing a new Medicare Part A and B payment model, called the Comprehensive Care for Joint Replacement (CJR¹) model, as a demonstration project under section 1115A of the Social Security Act. Under the model, acute care hospitals in 67 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 is included in the episode of care. Participation is mandatory for hospitals in areas selected to be in the demonstration. The demonstration project begins April 1, 2016.

The rule is published in the November 24th issue of the *Federal Register*. The policies in the final rule take effect on April 1, 2016.

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¹ Note that in the final rule CMS changes the acronym to CJR even though the name of the program remains the Comprehensive Care for Joint Replacement model.

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SUMMARY OF FINAL RULE: COMPREHENSIVE CARE FOR JOINT REPLACEMENT PAYMENT MODEL FOR ACUTE CARE HOSPITALS FURNISHING LOWER EXTREMITY JOINT REPLACEMENT SERVICES

I. and II. Executive Summary and Background

CMS notes its authority under section 1115 of the Social Security Act (the "Act") for the proposed CJR model and briefly summarizes the purpose of the model. With exceptions, acute care hospitals in certain selected geographic areas would receive bundled payments for episodes of care where the diagnoses at discharge included lower extremity joint replacement or attachment of a lower extremity that was furnished by the hospital. The bundled payment would be paid retrospectively through a reconciliation process; hospitals and other providers would continue to receive FFS payment via the usual FFS payment systems. All related care under Medicare Parts A and B within 90 days of hospital discharge from the joint replacement procedure would be included in the episode of care.

CMS proposes, under the authority at section 1115A of the Act, that new Part 510-Comprehensive Care for Joint Replacement Model be added to Subchapter H- Health Care Infrastructure and Model Programs. Subpart A—General Provisions lays out the basis and scope of the CCJM model (510.0) and Definitions (510.2). Proposed regulations for Subpart B through Subpart G are addressed in what follows.

Comments and CMS Response:

CMS addresses comments it received that relate to the CJR model generally, including potential benefits to the parties involved; concerns about the model's impact on stinting of care; challenges that it lacks the legal authority to mandate hospital participation; and queries on the relationship of the CJR model with models currently operating under the Bundled Payments for Care Improvement (BPCI) initiative.

It is clear that CMS views the CJR model as a positive step for beneficiaries who should have a better care experience during a lower extremity joint replacement (LEJR) procedure and follow-up care by reason of improved care coordination and care redesign activities by the anchor hospital and post-acute care (PAC) providers that are CJR collaborators. Hospitals, PAC providers, physicians and other practitioners can benefit through the availability of financial incentives to redesign care processes as well as the availability of shared savings through reconciliation payments. CMS also envisions benefits for beneficiaries of better quality care and for the taxpayers of greater efficiencies in care delivery and related lower spending.

Like several commenters, CMS is very concerned with the potential for stinting on care, patient steering, and the provision of medically unnecessary care and has built into the CJR model safeguards designed to prevent those activities; additionally, CMS plans to vigorously monitor and evaluate participants in the model.

Many commenters felt that CMS is acting outside its legal authority under the Social Security Act by compelling participation of all hospitals within selected Metropolitan Statistical Area (MSAs) noting that their interpretation of section 1115A of the Act permits only voluntary participation of providers of services and suppliers under models tested pursuant to that section. Commenters also voiced concerns about loss of appeals rights for beneficiaries and for providers and suppliers; they also believe that CMS has sidestepped legal safeguards that prevent it from imposing new models prior to adequate testing and evaluation.

CMS disagrees with these views. It believes there is ample legal authority to make hospital participation mandatory under the CJR model pursuant to section 1115A of the Act as well as the authority vested in CMS to promulgate regulations to administer the Medicare program under sections 1102 and 1871 of the Act. CMS notes that section 1115A is silent on the issue of voluntary versus mandatory provider participation in models tested by the Center for Medicare and Medicaid Innovation (CMMI) and that it interprets this as a grant of broad authority for the agency to test various payment and service delivery models that address deficits in care leading to poor outcomes or potentially avoidable expenditures. CMS believes that the CJR model addresses both of these areas and that it will permit a more comprehensive assessment of whether LEJR episodes payment models should be expanded nationally.

CMS also states that neither beneficiaries nor providers lose any existing appeals rights with respect to claims. CMS does acknowledge that providers may not appeal their selection to participate in the CJR model, but it feels that what it describes as its comprehensive notice and comment rulemaking process has helped address stakeholder concerns.

On the issue of the relationship of the CJR model with BPCI models, CMS states that the CJR model is a new model—not an expansion of BPCI. CMS notes that it believes that BPCI models require further evaluation before expansion is warranted. It makes the obvious comparison that CJR mandates hospital participation while BPCI is a voluntary model and that the design features between the two models differ (i.e., under BPCI, providers may select among clinical episodes and episode length). CMS feels mandatory participation in the CJR model is necessary to provide additional information on episode payment across a variety of hospitals and in a range of geographic areas. It notes that all inpatient prospective payment system (IPPS) hospitals in the selected MSAs that are not participating in BPCI Model 1 or Phase II of Models 2 or 4 for LEJR episodes would be included in the CJR model; it also intends that the current performance year's policies will be in effect for any new entrants in the CJR model.

Many commenters requested that CMS treat physicians who enter into sharing arrangements with CJR participant hospitals as eligible professionals for purposes of the Merit-based Incentive Payment System (MIPS) or as qualifying APM participants under section 1833(z)(2) of the Act. CMS responds that it will address these issues in its rulemaking to implement the Medicare Access and Chip Reauthorization Act of 2015 (MACRA). Commenters also suggested different episode payment models or significant changes to the CJR model (e.g., vesting financial authority in a PAC provider versus a hospital); CMS declines to act on any of these ideas at this time but notes that it is constantly considering modifications to existing models and the creation of new models for CMMI to test and evaluate.

III. Provisions of the Model

A. Definition of the Episode Initiator and Selected Geographic Areas

1. Background

CMS notes that the CJR model differs in some respects from the BPCI. Whereas BPCI is voluntary, the CJR will require all hospitals (with limited exceptions) in selected geographic areas to participate. This design will enable CMS to test the effects of episode-based payment for lower extremity joint replacement (LEJR) procedures furnished by hospitals with a variety of historic utilization patterns; roles in their local markets; volume of services provided; access to financial, community or other resources; and density of population and health care providers. A design that requires hospital participation in selected geographic areas will enable CMS to test bundled payments without introducing selection bias such as that inherent in the BPCI model due to self-selected participation.

2. Definition of Episode Initiator (§510.100)

CMS finalized its proposed policy that episodes begin with an admission to an acute care hospital (as defined in 1866(d)(1)(B) of the Act) for an LEJR procedure paid under MS-DRGs 469 or 470. They will end 90 days after the date of discharge from the hospital. Acute care hospitals will be the only episode initiators. A hospital is excluded from being a participant hospital if the hospital is an episode initiator for an LEJR episode in the risk-bearing period of Models 2 or 4 of BPCI or the hospital is participating in Model 1 of PBCI. These exclusions cease to apply as of the date that the hospital no longer meets these conditions. CMS says that this definition will permit examination of the results from a more generalized payment model than other demonstrations.

Maryland Hospital Exception. CMS finalized its proposal to exclude all acute care hospitals in Maryland from the CJR because of the state's All-Payer Model, which is operating under CMS waivers, effective January 1, 2014. CMS notes that under that model, Maryland will develop its own strategy to encourage higher quality care and efficiencies across clinical settings beyond hospitals, including but not limited to CEJR episodes of care. (Payments to Maryland hospitals will also be excluded in the regional pricing calculations described in III.C. 4.) CMS has also finalized that, for purposes of the model, the term "hospital" only encompass hospitals currently paid under the IPPS. This has the effect of excluding Maryland hospitals from participating in the CJR model.

In response to comments that Maryland's All Payer model could be hurt by inclusion in the CJR should CMS decide to do that, CMS is adopting its proposed exclusion as final. CMS notes, however, that it remains concerned that certain aspects of that model make it challenging for Maryland to be included in other payment and delivery innovations being launched by CMS' Innovation Center and that it does not want Maryland to fall behind in payment and delivery innovation. CMS is interested in the state's strategy to be accountable for the total cost of care

beyond hospital services (to be implemented in 2019) and looks forward to working with the state on its total cost of care model.

3. Financial Responsibility for the Episode of Care

CMS finalized its proposal to make hospitals financially responsible for the episode of care. It retains from the proposed rule's preamble its explanation for this decision noting how in the approach tested under the BPCI Model 2. CMS notes that most hospitals have some infrastructure related to health information technology, patient and family education and discharge planning (including post-acute coordination) upon which hospitals can build to achieve efficiencies under this episode-based payment model throughout the LEJR episode. CMS also notes the recent alignment of many hospitals with community providers under other CMS models and programs and CMS believes that hospitals are more likely than other providers to have an adequate number of episode cases to justify episode-based investment for this model.

In response to comments that the financial responsibility be placed with or shared instead with orthopedic surgeons, physician practices, and/or post-acute care (PAC) providers, CMS restates its reasons for not altering its design in this manner, concluding that significant challenges would arise from that design. CMS may consider, through future rulemaking, other episode of care models in which physician group practices or PAC providers are financially responsible for the costs of care.

CMS reiterates that effective care redesign for LEJR episodes requires collaboration among the array of providers involved in patient care and that it is essential for key providers to be aligned and engaged, financially and otherwise with hospitals, with the potential to share financial responsibility with those hospitals. Depending on the extent of a hospital's current clinical integration, new and different contractual relationship between the hospital and other providers may be important for CJR model success in a community. CMS notes the role of the convener relationship in the BPCI initiative (where another entity assumes financial responsibility) but concludes that if a convener were to be included in the CJR model, CMS could not then assess how a variety of hospitals can succeed in a relationship with CMS in which the hospitals bear financial risk for the episode of care. That said, CMS does not intend to restrict the ability of hospitals to enter into administrative risk sharing arrangements related to this model (see III C. 10 on potential financial arrangements between participant hospitals and other providers and suppliers).

In response to comments expressing opposition to the compulsory nature of the CJR model for varying reasons, including potential harm to the hospital and/or its patients, CMS says that its experience with several types of large voluntary episode payment models, the relatively narrow scope of the CJR model (LEJR episodes only), the phasing in of full financial responsibility over multiple years, and its plan to engage with hospitals to help them succeed with the model through the provision of claims data, will aid hospitals in succeeding. Moreover, as discussed in section III.C.2, CMS is also finalizing that the model's first performance period will begin April 1, 2016, instead of on January 1, 2016 as originally proposed. This will allow hospitals more

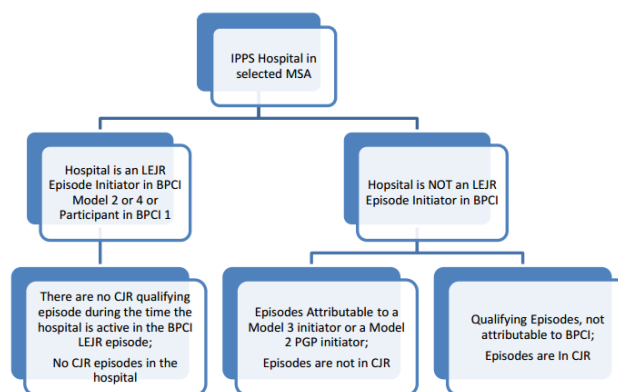
time to prepare for participation by identifying care redesign opportunities, beginning to form financial and clinical partnerships with other providers and suppliers, and using data to assess financial opportunities under the model.

In response to comments that implementation of mandatory CJR model participation will lead to confusion and competing incentives for hospitals already participating in voluntary initiatives, CMS says that simultaneous testing of multiple bundled payment models is appropriate in many situations, depending on the care targeted under each model. In section III.C.7, CMS lays out its policies for accounting for overlap between models. Concerns about potential beneficiary harm, including stinting of care, which CMS says are unfounded, are addressed in section III.F. CMS adds that the CJR model pricing structure, discussed in III.C., also includes features to protect against such potential harm, such as responsibility for post-episode spending increases, stop-gain policies that set a maximum threshold a hospital can earn for savings achieved during episodes, and other policies as detailed in that section.

Excepted hospitals (BPCI participants). CMS proposed and has now finalized an exception to its requirement that all hospitals in a selected area participate in the CJR model. 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 phases of Model 2 or 4 of BPCI as of October 1, 2015 (and not July 1, 2015, as stated in the proposed rule) will be excluded from participating in CJR during the time that their qualifying episodes are included in one of the BPCI models. 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 Models 2 or 3 (where the surgery takes place at the participant hospital) will be excluded from the CJR. Otherwise qualifying LEJR episodes (those not part of a Model 3 BPCI LEJR episode or a Model 2 physician group practice-initiated LEJR episode) at the participant hospital will be included in the CJR.

Many commenters reportedly expressed concern with the interaction between BPCI and the proposed CJR model due to instances where LEJR episodes excluded from CJR because of BPCI would cause a low volume issue for certain hospitals. Others stated that the proposed CJR model would penalize providers that are voluntarily participating in the BPCI initiative and suggested that hospitals in selected MSAs be allowed to choose between participation in BPCI and the CJR model. CMS finalized its proposed policy but clarifies that it will utilize current information on BPCI participation to determine whether a given hospital is included in CJR. In response to concerns regarding the interaction between BPCI and CJR and the potential for too few LEJR episodes at a given hospital to remain under the CJR model, CMS defers its discussion to section III.A.4.b.

CMS provides the following chart to illustrate the inclusion of episodes in CJR relative to CPCI.



CMS also responds to commenters' requests to allow participating hospitals in certain ACOs to opt-out of the CJR model by saying that these hospitals have already established a base for augmenting the efforts needed under the CJR model and thus it sees no compelling reason to exempt them. However, adjustments to account for overlaps with other innovations center models and CMS programs are discussed in section III.C.7.

Finally, CMS clarifies that CJR participation of hospitals will be based on their physical location, which is tracked through the CMS Certification Number (CCN). The CJR will therefore administer model-related activities at the CCN level, including physical location. It is the physical location associated with the CCN at the time of the model start that will be used to determine whether that CCN is located in a selected MSA. For hospitals that share a CCN across various locations, all hospitals under that CCN will be required to participate in the CJR model if the physical address associated with the CCN is in the MSA, unless otherwise excluded. Similarly, all hospitals under the same CCN, even if some are physically located in the MSA selected for participation, will not participate in the CJR model if the physical address associated with the CCN is not in the MSA. (CMS' analysis of the hospitals in the selected MSAs indicates that this phenomenon is not present in the selected areas.)

4. Geographic Unit of Selection and Exclusion of Selected Hospitals (§510.105)

CMS finalized its proposed methodology for the geographic unit of selection and exclusion without modification. CMS reiterates its proposed rule discussion of its considerations in determining which hospitals to include in the CJR model in terms of low-volume or high volume of procedures and certain or all hospitals in particular geographic areas, noting the implications for each with respect to testing the effects of episode payment. In its view, the best approach to select geographic areas was to use a stratified random sampling method, require all hospitals paid under the IPPS in those selected areas to participate in the CJR model and be financially responsible for the cost of the episode, with certain exceptions, as noted above. CMS cites its authority under section 1115A(a)(5) of the Act, in this regard, which allows the Secretary to elect to limit testing of a model to certain geographic areas.

a. Overview and Options for Geographic Area Selection

In determining the geographic area selection for this model, CMS 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 Rural Referral Regions (HRR) status; or (3) certain states. CMS repeats its discussion of the implications of each of these different options but finalizes its conclusion in favor of entire MSAs (as opposed to sub-divisions of MSAs) as the geographic area. An MSA is characterized by counties associated with an urban core population of at least 50,000.

The CJR model will therefore require participation of all hospitals, with the exceptions noted above, paid under the IPPS that are physically located in a county in an MSA selected through a stratified random sampling methodology. A hospital will be determined to be located in an area selected if the hospital is physically located within the boundary of any of the counties in that MSA as of the date the selection is made. Although MSAs are revised periodically, CMS will maintain the same cohort of selected hospitals throughout the 5-year performance period of the model with limited exceptions, described below. This is to maintain the consistency of the participation in the model. CMS will retain the possibility of adding a hospital that is owned or incorporated within one of the selected counties after the selection is made and during the period of the performance.

CMS asked for comment on its proposal to include participant hospitals for the CJR model based on the physical location of the hospital in one of the counties included in a selected MSA. There were some concerns regarding particular circumstances of commenters' MSAs (e.g., that it was too large or too small); potentials for patient shifting in or outside of the MSA, and competitive issues resulting from whether a hospital is in or out of the MSA. After weighing the comments, CMS continues to believe that MSAs are the most appropriate compromise for the choice of geographic unit of selection and finalized that decision.

b. MSA Selection Methodology

CMS finalizes its proposed MSA selection methodology with modifications as discussed below.

(1) Exclusion of Certain MSAs.

CMS had proposed to exclude from the selection of geographic areas those MSAs that met the following criteria between July 1, 2013 through June 30, 2014: (1) had fewer than 400 LEJR episodes; (2) had fewer than 400 non-BPCI LEJR episodes but had more than 50 percent of otherwise qualifying (BPCI or non-BPCI) episodes in phase 2 of the BPCI Model 2 or 4 with hospital episode initiators or 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. After applying these four

exclusions, 196 MSAs remained out of the 388 total number of MSAs to be stratified for purposes of its proposed selection methodology.

In response to comments that CMS exclude additional MSAs or that it add additional selection criteria, CMS responds that it re-examined the exclusion rules based on an updated list of providers participating in the BPCI initiative for LEJR episodes. It also examined the potential impact on selection of MSAs that incorporating an updated list of BPCI participants would have. **This resulted in removing 8 selected MSAs that will now be excluded on the basis of the updated BPCI participation numbers.** Alternative approaches were explored but CMS decided to adopt this approach. CMS notes that the MSAs are distributed fairly evenly throughout the distribution of average episode payments and says that their removal will not preclude the agency from undertaking a rigorous statistical evaluation of the model. Table 1, reproduced below, provides a list of the excluded MSAs. **The remaining 67 MSAs selected in the proposed rule will be required to participate in the CJR model.** (See Table 4 below for the final list of included MSAs.)

TABLE 1: MSAs THAT WERE PREVIOUSLY SELECTED THAT ARE NO LONGER INCLUDED IN CJR.

CBSA TITLE	Revised Exclusion Rule 2 Status	Revised Exclusion Rule 3 Status
Colorado Springs, CO	Fail	Pass
Evansville, IN-KY	Fail	Pass
Fort Collins, CO	Fail	Pass
Las Vegas-Henderson-Paradise, NV	Fail	Fail
Medford, OR	Fail	Pass
Richmond, VA	Fail	Pass
Rockford, IL	Fail	Pass
Virginia Beach-Norfolk-Newport News, VA-NC	Pass	Fail

In summary, the final rule at 510.105(c) provides for the following criteria for excluding a MSA from the CJR:

- (1) Had fewer than 400 episodes between July 1, 2013 and June 30, 2014.
- (2) Had fewer than 400 non-Model 1, 2, or 4 BPCI episodes as of October 1, 2015.
- (3) Failed either or both of the following rules regarding participation in BPCI: (i) More than 50 percent of eligible episodes initiated in a BPCI Model 2 or 4 initiating hospital.
(ii) More than 50 percent of eligible episodes that included SNF or HHA services, where the SNF or HHA services were furnished by a BPCI Model 3 initiating HHS or SNF.
- (4) For MSAs including both Maryland and non-Maryland counties, more than 50 percent of eligible episodes were initiated at a Maryland hospital.

In response to commenters who argued against including low volume hospitals in the model (and their various reasons, such as lack of capacity to care for these patients in a cost-effective manner or the disproportionate adverse impact on costs of outlier cases), CMS says that although it appreciates the interest of these hospitals in receiving reconciliations payments under CJR while minimizing the possibility of reduction in revenue, CMS believes that the modification of the treatment of hip fractures (which have a high likelihood of being cared for in low volume settings because they tend to present as emergencies) in its payment methodology should allay many of these concerns. Further, CMS acknowledges that providers with low volumes of cases may not find it in their financial interests to make systematic care redesigns or engage in an active way with the model. Such providers may decide that their resources are better targeted to other efforts because they do not find the financial incentive present in the CJR sufficiently strong to cause them to shift their practice patterns. It also acknowledges that low volume hospitals may achieve fewer savings because they did not or could not make the necessary changes to the treatment of their qualifying beneficiary population. CMS believes this choice is similar in nature to that made as hospitals decide their overall business strategies and where to focus their attentions.

(2) Selection Strata

CMS had proposed creating selection strata based on two dimensions: MSA average wage-adjusted historic LEJR episode payments and MSA population size. CMS finalized its proposal, with modifications to include 67 of the original 75 selected MSAs (see above). The list of participant hospitals in the selected MSAs is at: <https://innovation.cms.gov/initiatives/cjr>. This list will be updated throughout the model's duration to account for circumstances such as hospital mergers, BPCI termination, and new hospitals within the selected MSAs. The following summarizes CMS' selection strata methodology in more detail.

(a) MSA Average Wage-adjusted Historic LEJR Episode Payments. CMS selected the mean MSA episode payment to classify and divide MSAs according to their typical patterns of care associated with LEJR episodes. The average episode payments in an area may vary in response to the MS-DRG mix and thus the presence of complicating conditions; readmission rates; practice patterns associated with type of PAC provider(s) treating beneficiaries; variations of payments within those PAC providers, and the presence of any outlier payments.

The average episode payments used in CMS' analysis were calculated based on the episode definition for CJR 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.² 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

² Available at: 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 hospital where the LEJR was performed. CMS 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. CMS's second dimension used for the selection strata is the number of persons in the MSA. Measures considered included overall population in the 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. All of 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. Because these were highly correlated with one another, one measure could substitute for the others in the definition of the stratum. CMS selected the MSA population to use, classified according to the MSA's 2010 census population.

(c) Analysis of Strata. CMS used factor analysis to classify the MSAs according to their average LEJR episode payment into four categories based 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 2 reproduced below.³

	Payment in lowest quarter	Payment in 2nd lowest quarter	Payment in 3rd lowest quarter	Payment in highest quarter	Total Eligible
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

³ Information on the non-excluded MSAs, their wage adjusted average LEJR episode spending, their population and their resultant group assignment are available at: <https://innovation.cms.gov/initiatives/cjr>.

TABLE 2: 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 Eligible
MSAs deemed eligible in the proposed rule (80 FR 41198) 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

(3) Factors Considered but Not Used in Creating Strata

CMS considered alternative measures and dimensions. Some of those alternatives, as well as other measures, will be considered in determining which MSAs are appropriate comparison markets for the CJR model evaluation. They also may be 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 to facilitate a robust statistical analysis of CJR's effects led CMS to conclude that it needed to include between 50 and 100 MSAs (CMS has reduced this from 150 MSAs in the proposed methodology) and CMS proposed to select 75 MSAs. As explained above, the revision of the MSA exclusion rules in the final rule results in 67 MSAs, which CMS says is still within the acceptable range for an MSA count as determined by its analysis. CMS notes that in finalizing this analysis, it is undertaking a test in as few markets as possible while still allowing it to be confident in its results and generalize from the model to the larger national context. In this context, CMS that it is seeking to detect is a 2 percent reduction in wage adjusted episode spending after 1 year of experience in its impact statement. This amount was chosen because it is the anticipated amount of the discount that will be applied to target prices in CJR. Due to the revised exclusion rules described above and its expectation that it can achieve the reliability it needs with modeling improvements, CMS believes that 67 MSAs

will provide adequate statistical power. (CMS explains its revised thinking related to the number of selected MSAs at pages 89-92 of the display version.)

(5) Method of Selecting MSAs

CMS describes its methodology for selecting 67 MSAs (again, down from 75 in the proposed rule) from its 8 selection groups. After looking at various options, CMS 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.

CMS notes that this approach makes it less likely for the MSAs in the lowest spending category to be selected for inclusion, which CMS considers appropriate because the lowest expenditure MSAs have the least room for possible improvement and are already performing relatively efficiently compared to other geographic areas. Thus, experience with the CJR model in these areas may be relatively less valuable for evaluation purposes. At the same time, CMS believes it important to include some MSAs in this group in order to assess the performance of this model in this type of circumstance. CMS also says it is appropriate for higher payment areas to be included. The MSAs may be higher due to 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 CMS to observe the impact of the CJR model on areas with these various practice patterns in the baseline period.

CMS finalizes its proposed method of disproportionate selection between the strata: 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 resulted in the selection of the 75 originally selected MSAs out of the 196 eligible. The number of MSAs originally chosen as well as the final selection counts within the eight selection groups is shown in Table 3, reproduced below.

TABLE 3: 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 per Proposed Rule (80 FR 41198)	33	19	22	24	98

TABLE 3: 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
Proportion x Number	9.9	6.65	8.8	10.8	
Number initially selected from	10	7	9	11	37
Number finally selected from group	8	6	8	11	33
More Than Median Population (Group #)	(5)	(6)	(7)	(8)	
Number Eligible MSAs per	16	30	27	25	98
Proportion x Number	4.8	10.5	10.8	11.25	
Number initially selected from	5	11	11	11	38
Number finally selected from group	5	10	9	10	34
Total Eligible MSAs per Proposed Rule	49	49	49	49	196
Number initially selected	15	18	20	22	75
Number finally selected from group	13	16	17	21	67

The MSAs for the CJR model were selected within each of the eight selected groups through random sample. 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 affected even if they are not part of the core urban area.

CMS stated in the proposed rule that the MSAs selected could change if the methodology changed in response to comments on the proposed methodology. CMS asked for comment on the randomized selection methodology. CMS received some comments, including that the number of MSAs selected was too many and that it should test a model in a more limited pool of MSAs before going larger scale. In response, CMS asserts that its methodology is sound and finalizes the proposal, with the modification to use 67 of the 75 originally selected MSAs. Table 4 lists the final selected MSAs. **Those that have dropped off the list as a result of the reduction in MSAs are noted with a strikethrough.** CMS is posting the list of the participant hospitals in the selected MSAs on the website at <https://innovation.cms.gov/initiatives/cjr>. This list will be updated throughout the model, to account for circumstances such as hospital mergers, BPCI termination, and new hospitals within the selected MSAs.

TABLE 4. MSAs INCLUDED IN THE CJR MODEL	
MSA	MSA Name
10420	Akron, OH
10740	Albuquerque, NM
11700	Asheville, NC

TABLE 4. MSAs INCLUDED IN THE CJR MODEL	
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

TABLE 4. MSAs INCLUDED IN THE CJR MODEL	
35300	New Haven-Milford, CT
35380	New Orleans-Metairie, LA
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 (CJR) Model

1. Background

As in the proposed rule, CMS notes in the final rule's preamble that episodes of care have two significant dimensions: a clinical dimension that describes what clinical conditions and associated services comprise the episode and a time dimension that describes the beginning, middle, and end of an episode. The proposed application of these dimensions for the CJR model and issues raised by commenters follows. As further detailed, CMS adopts its proposals as final with few modifications.

2. Clinical Dimension of Episodes of Care

a. Definition of the Clinical Conditions Included in the Episode (§§ 510.100, 510.200)

CMS notes that the vast majority of lower extremity joint replacements (LEJRs) are furnished in the inpatient hospital setting. Moreover, 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. Because little opportunity exists for shifting these surgical procedures under this model to the outpatient setting, CMS believes an episode payment model most appropriately focuses around an inpatient hospitalization.

An episode of care in the CJR model will be triggered by an admission to an acute care hospital stay (hereinafter "the anchor hospitalization") paid under MS-DRGs 469 or 470 under the IPPS during the model performance period. CMS says that this approach offers operational simplicity for both providers and CMS and is consistent with the BPCI initiative approach to identify beneficiaries whose care is included in the LEJR episode for that model. CMS reiterates that LEJRs are paid for under the IPPS through MS-DRG 469 (Major joint replacement or reattachment of lower extremity with Major Complications or Comorbidities (MCC)) and MS-DRG 470 (Major joint replacement or reattachment of lower extremity without MCC). 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 5 (page 102 of the display version of the final rule).

Commenters varied in their concerns and recommendations for changing the CMS proposed approach. Most recommended that CMS limit the model to a subset of beneficiaries that are discharged from the two MS-DRGs, excluding certain cases as a form of risk-adjustment to reduce the heterogeneity of the cases in the model to ensure adequate payment. In their view, CMS' proposed approach failed to take into consideration the variability of service needs of beneficiaries discharged from the two MS-DRGs related to the specific procedure performed, the elective or urgent/emergent nature of the procedure, and the beneficiary's clinical and demographic characteristics. A number expressed concerns about including complex and high-cost patients, such as many with hip fractures, since those episodes could lead to underpayment. Alternative approaches were also identified by commenters, such as defining clinical conditions in the model based on specific MS-DRG and ICD-9-CM procedure code combinations, excluding certain procedures, or that CMS exclude certain clinical conditions involving, for example, hip fractures.

CMS explains, in response to these proposals, that it has decided to risk stratify the target price for each MS-DRG-anchored episode based on a beneficiary's hip fracture status (see III.C.4.b below). This policy allows CMS to maintain beneficiaries who receive LEJR procedures due to hip fractures in the CJR model, while acknowledging their typically greater health care needs. By providing a target price that is based on payment for services furnished in the historical episode data for Medicare beneficiaries with hip fractures, CMS can account for a significant

amount of beneficiary-driven episode expenditure variation. And despite their potential for higher costs, CMS believes that beneficiaries with hip fracture have the potential to benefit substantially from the care pathways and improved care coordination among providers and suppliers that is incentivized by an episode payment model. It also believes there are opportunities for increased efficiency in the care of beneficiaries with hip fracture who receive LEJR procedures with respect to appropriate PAC utilization and care coordination and management of chronic conditions that may be affected by the LEJR procedure or post-surgical care.

CMS also explains its decision to finalize its proposal to include clinical conditions represented by discharge from both MS-DRG 469 and 470 in the CJR model. CMS says that providing separate prices for episodes anchored by the two different MS-DRGs accounts for the differences in typical health care needs of the two groups of beneficiaries, specifically the higher IPPS payment for the anchor hospitalization for beneficiaries discharged under MS-DRG 469, as well as the pattern of service utilization for this group of beneficiaries in the 90 days following discharge.

It is finalizing its proposal to include any lower extremity joint procedure that results in discharge from MS-DRG 469 or 470 in the CJR model, including ankle replacement; lower leg, ankle, and thigh reattachment; and hip resurfacing procedures. Although these less common clinical conditions are likely to be a small number at any specific participant hospital, they too may benefit from care redesign resulting in improved care coordination and quality that are goals of the CJR model. Moreover, CMS does not believe this small number of beneficiaries will put participant hospitals at undue financial risk and further notes that its payment policies, as discussed in section III.C.3.c. and III.C.8. of this final rule, provide a pricing adjustment for high payment episodes and limit hospital financial responsibilities.

Some commenters urged CMS to include in the CJR model LEJR procedures where the procedure that would result in a beneficiary's discharge from MS-DRG 469 or 470 if furnished in the inpatient hospital setting is furnished in the hospital outpatient department (HOPD), ambulatory surgical center (ASC), or other dedicated facility that is not an acute care facility. CMS rejects commenters' arguments and reiterates that because most LEJR procedures are on the OPPS inpatient only list and CMS thus determined that Medicare beneficiaries require an inpatient hospitalization for payment of these procedures to hospitals, it is not changing the current inpatient only list designation of these LEJR procedures for the CJR model.

In response to commenters' concerns that CMS might remove LEJR procedures currently on the OPPS inpatient list during the 5-year performance period of the model without making changes in the pricing, CMS says that if it were to remove an LEJR procedure from that list at any point during the 5-year model test, it would need to consider the effects of such a change on the model pricing methodology, taking into consideration the characteristics of the beneficiaries expected to be in the model due to a procedure furnished in the inpatient hospital setting after the change to the inpatient only list. If changes were determined to be necessary because the beneficiaries in the historical episodes used to set target prices would no longer be similar to

those in the model performance year, CMS would propose such changes through notice and comment rulemaking.

b. Definition of Related Services Included in the Episode (§§ 510.2, 510.200)

CMS finalized its proposed definition of related services included in the episode with several modifications. These include adding a definition of “provider of outpatient therapy services,” removing the term “independent” preceding “outpatient therapy services” in the list of services included in the CJR episodes. CMS has also modified its proposal so that OPSS transitional pass-through payments for devices will be excluded from the episode. Additional technical changes have also been made. Much of CMS’ extensive preamble discussion in the final rule addresses concerns raised by commenters about the inclusion of specific items or services (e.g., prosthetic limbs or orthopedic braces, inpatient psychiatric facility and hospice services) or specific MS-DRGs or conditions in the episode (certain readmissions, fractures, specific principal diagnoses or claims, etc.) that commenters wanted excluded. However, as discussed below, CMS believes that it made the correct policy decisions to ensure that CJR episodes and exclusions from it are appropriately defined.

Under proposed 510.210(a), all episodes being tested in the CCR model would have begun on or after January 1, 2016 and ended on or before December 31, 2020. CMS finalized the rule to provide that all episodes begin on or after April 1, 2016 and end on or before December 31, 2020.

CMS finalized with modifications proposed §510.200(b) related to included services in the CJR. As proposed, the final rule provides that all Medicare Parts A and B items and services be included in the episode except as specified in paragraph (d) of this section. These “related items and services” (as CMS calls them in the preamble), include, but are not limited to: physicians’ services, inpatient hospital services (including hospital readmissions); inpatient psychiatric facility (IPF) services; long-term hospital care (LTCH) services; inpatient rehabilitation facility (IRF) services; skilled nursing facility (SNF) services; home health agency (HHA) services; hospital outpatient services; clinical laboratory services; durable medical equipment (DME); Part B drugs and biologicals; hospice services; and per-beneficiary-per-month (PBPM) payments under models tested under section 1115 of the Act. In response to commenters seeking clarification regarding meaning and scope, however, CMS has deleted “independent” from “outpatient therapy services” and has added a new definition to §510.2 “provider of outpatient therapy services” to mean “a provider or supplier furnishing: (1) outpatient physical therapy services as defined in §410.60 of this chapter, or (2) outpatient occupational therapy services as defined in §410.59 of this chapter, or (3) outpatient speech-language pathology services as defined in §410.62 of this chapter.” CMS has also revised §510.200(b)(10) to remove the word “independent” preceding outpatient therapy services.” The remaining provisions under §510.2(b) have been renumbered accordingly.

Section 510.210(c) as proposed and now finalized attributes all items and services in the episode to the participant hospital at which the anchor hospitalization occurs.

Because CMS is interested in testing inclusive episodes to incentivize comprehensive, coordinated patient-centered care for the beneficiary through the episode, it had proposed to exclude only those Medicare items and services furnished during the episode that are unrelated to LEJR procedures based on clinical justification. Accordingly, all CJR episodes, beginning with the admission for the anchor hospitalization under MS-DRGs 469 or 470 through the end of the proposed episode, would include all “related items and services” as listed above with the exception of certain items and services that are excluded because they are unrelated to the episode. As proposed and now finalized in sections III.C.4 and III.C.6, Medicare spending for related items and services are to 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 will not be included in the historical data used to set target prices or in the calculation of actual episode spending.

In response to comments, CMS finalized, **with a change related to transitional pass-through payments for medical devices**, its proposal at §510.200(d) to exclude the following items and services 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 (this was not in the proposed rule);
- 3) Transitional pass-through payments for medical devices as defined in 419.66 of this chapter; and
- 4) Items and services unrelated to the anchor hospitalization, as determined by CMS.

CMS reiterates in the final rule’s preamble its rationale for excluding hemophilia clotting factors and new technology add-on payments and notes that both will be excluded from both the actual historical expenditure data used to set target prices and from the hospital’s actual episode spending that is reconciled to the target price. With respect to new technology add-on payments, CMS believes it inappropriate for the CJR model to potentially hamper beneficiaries’ access to new technologies that are receiving these add-on payments or to burden hospitals that choose to use these new drugs, technologies or services with concern about these payments counting toward episode actual expenditures. Also, because new drugs, technologies or services approved for the add-on payments vary unpredictably over time in their application to specific clinical conditions, CMS believes it should exclude IPPS new technology add-on payments from episodes.

With respect to CMS’ decision in the final rule to exclude OPPS transitional pass-through payments for medical devices, CMS says that such devices share the same rationale for exclusion as IPPS technology add-on payments. But it adds that it will not, as recommended by some commenters, establish a new process to review innovative technologies and make individual determinations regarding their exclusions from the CJR model episode definition. CMS says that because the CJR model is a retrospective reconciliation model that pays all

providers and suppliers under the regular Medicare program throughout the episode of care, it is more appropriate to rely on the existing processes under the Medicare program to make determinations about separate payment for new technology items and services. If those processes identify new technologies that would qualify for add-on payments under the IPPS or transitional pass-through payment under the OPPS, CMS will exclude them from the episode definition to ensure that access to new technology items and services for beneficiaries is not influenced by their care being included in the CJR model.

CMS finalized its proposed list of specific excluded services. These “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; and

(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 LEJR 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 to be posted on the CMS website and may be revised (see paragraph (e) below);

(iii) Certain PBPM payments under models tested under section 1115A of the Act. PBPM model payments that CMS determines to be primarily used for care coordination or care management services for clinical conditions in excluded categories of diagnoses as described above.

(A) The list of excluded PBPM payments is posted on the CMS website and will be revised on an annual basis, or more frequently as needed.

(B) Notwithstanding the above, all PBPM model payments funded from CMS’ Innovation Center appropriation will be excluded from the episode.

(5) Certain incentive programs and add on payments under existing Medicare payment systems in accordance with §510.300(b)(6) of this chapter.

(6) Payments for otherwise included items and services in excess of two standard deviations above the mean regional episode payment in accordance with § 510.300(b)(5) of this chapter.

CMS notes that the list of exclusions was initially developed for BPCI over two years ago through a collaborative effort of CMS staff with the relevant expertise. It since has been vetted with those entities and individuals participating in one or more phases of BPCI and has been refined in response to stakeholder input.

A number of commenters urged CMS to adopt an episode definition for the CJR model that is flexible and condition-specific. One concern about the proposed approach, for example, was that hospitals might be more cautious about treating patients with complex medical status, especially if CMS also did not risk adjust the target prices for the episode based on beneficiary characteristics and specific procedures. Hip fractures, for example, were described as being of particular concern because of the likely frailty and multiple illnesses of patients with such fractures. In response, CMS reiterates much of its rationale presented in the proposed rule's preamble and says that the payment policies of the model as described in sections III.C.3 and III.C. 8 to adjust pricing for high payment episodes and to provide stop-loss limits will provide sufficient protections for participating hospitals from excessive financial responsibility for high payment cases that may result from its broad episode definition. CMS also notes that in section III.C.4.b, it finalizes a policy that will risk stratify the target prices based on the presence or absence of a hip fracture for CJR model beneficiaries. This should account for patient-specific expenditure variation both directly resulting from more intense care due to the hip fracture itself and indirectly resulting from the higher prevalence of chronic conditions of hip fracture patients.

The complete final lists of excluded MS-DRGs for readmissions and excluded ICD-9-CM codes for Part B services are posted at: <http://innovation.cms.gov/initiatives/cjr>.

Updating the list of excluded services. In §510.200(e), CMS finalized its proposal without change 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, and to address any other issues brought to its attention. Specific standards are specified for revising the list of excluded services for reasons other than to reflect annual coding changes: CMS **will not** exclude any items or services that are: (i) 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 (ii) for chronic conditions that may be affected by the LEJR procedure or post-surgical care such as diabetes). CMS **will exclude** items and services for: (i) chronic conditions that are generally not affected by the LEJR procedure or post-surgical care (such as removal of the prostate) and (ii) acute clinical conditions not arising from existing episode-related chronic clinical conditions or complications of LEJR surgery from the episode (such as appendectomy). CMS will post the potential revised exclusions, which may include additions to or deletions from the exclusions list, to the CMS website to allow for public input, and then adopt changes to the exclusions list with posting to the CMS website of the final revised exclusions list after its consideration of the public input.

ICD-10-CM Codes. CMS stated in the proposed rule that, as it moved to implement ICD-10-CM, it would develop the exclusions that would map to the final ICD-9-CM exclusions for CJR available in the ICD-10-CM format as well. With ICD-10-CM implementation beginning in October 2015, CMS is making available the final CJR model Part B exclusions list in ICD-10-CM format as additional worksheet tabs to the final exclusions list posted at: <https://innovation.cms.gov/initiatives/cjr>. This is the same list of exclusions that will be used for LEJR episodes under BPCI. This list will be applied to claims for services furnished on or after

October 1, 2015 and that report ICD-10-CM codes. For ease of understanding by the public, CMS' objective was to present the ICD-10-CM excluded codes as ranges of excluded ICD-10-CM categories, just as it presents the ICD-9-CM excluded codes as ICD-9-CM ranges.

In the final rule preamble, CMS also describes changes to CJR model exclusion list that result from revision for the FY 2016 IPPS (see pp. 155-6 of the display version).

3. Duration of Episodes of Care

a. Beginning and Middle of the Episode and Beneficiary Care Inclusion Criteria (§510.205, §510.210)

As discussed below related to the determination of the episode, CMS has adopted as final its proposed policy that the episode begins with the admission of a Medicare beneficiary meeting certain criteria (listed in this paragraph) to a participant hospital for an anchor hospitalization and ends on the 90th day after the date of discharge.

CMS finalized without change its proposed criteria for episodes tested in the CJR model. Episodes include only those in which care is furnished to beneficiaries who meet all of the following criteria upon admission to the anchor hospitalization. (CMS notes that these criteria are consistent with Model 2 of BPCI as well as most other CMMI models that do not target a specific subpopulation of beneficiaries). The criteria are: (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; (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; and (5) Medicare is the primary payer. 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), discussed below).

CMS explains that these criteria allow for as broad as feasible inclusion in the model, representing all LEJR episodes for which CMS believes it has comprehensive historical Medicare payment data that allow it to appropriately include Medicare payment for all related services during the episode in order to set appropriate episode target prices. This approach will permit CMS to assess the effects of the CJR model on expenditures and quality for beneficiaries of the widest variety of ages and comorbidities. Because most Medicare beneficiaries undergoing an LEJR procedure will be included in the model, CMS says it will allow participant hospitals the greatest opportunity to benefit financially from systematic episode care redesign.

CMS received some comments that the episode should begin before the date of the anchor hospitalization (when pre-surgical care and programs that could support the continuum of care may be provided). In response, CMS says that it finalized its policy as proposed because beginning the episode too far in advance of the LEJR surgery would make it difficult to avoid bundling unrelated items and starting it prior to the hospital admission is more likely to

encompass costs that vary widely among beneficiaries. That would make the episode more difficult to price appropriately.

With respect to CMS' proposed inclusion criteria for the model, some commenters urged CMS to exclude beneficiaries who opted out of data sharing from the CJR model because it would be almost impossible to manage risk and improve outcomes without claims data. CMS refers to section III.E for its decision not to finalize the proposal to allow beneficiaries to decline having their data shared.

CMS finalized its proposed policy that the episode be cancelled and not included in the determination of the net payment reconciliation amount (NPRA) if the beneficiary: (1) ceases to meet any of the criterion in §510.205; (2) is readmitted to any participant hospital during the episode for another anchor hospitalization; (3) initiates an LEJR episode under BPCI Models 1, 2, 3, or 4; or (4) dies. In response to comments that the episode be cancelled if the beneficiary dies at any time during the episode, however, CMS has clarified that the episode would be cancelled if the beneficiary dies at any time during the episode (see §510.210(b)(4)). CMS also explains that when an episode is cancelled, the services furnished to beneficiaries prior to and following the cancellation will continue to be paid by Medicare as usual but CMS will not calculate actual episode spending that would otherwise under CJR be reconciled against the target price for the beneficiary's care.

As noted earlier, CMS finalized its proposal that an episode ends 90 calendar days after discharge from the anchor hospitalization. CMS refers to the CJR model episode duration hereafter in the preamble 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 will be prorated so that only the portion attributable to care during the fixed duration of the episode is attributed to the episode spending.

CMS restates in the final rule's preamble its summary of the literature regarding the clinical experiences of patients who have undergone Primary Total Hip (THA) or Total Knee Arthroplasty (TKA) procedures that it consulted in developing the proposed policy. These studies show that the risk of readmission remains significantly elevated from 30 through 90 days post-hospital discharge.

CMS requested comment on its proposal to end the episode 90 days after the date of discharge from the anchor hospitalization, as well as on the alternative of ending the CJR episode 60 days after the date of discharge. Comments were wide-ranging with some advocating more or less days after the date of discharge or for flexibility in choosing a duration based on a patient's clinical condition and comorbidities. Some advocated a hybrid approach whereby CMS would include a broader set of related services in the 30 days following discharge from the anchor hospitalization and a more limited set of related services from days 31 to 90 because of the closer link of a beneficiary's clinical conditions in the first 30 days to the anchor hospitalization itself. CMS responds in turn to these recommended changes but concludes that the proposed policy is the best approach. However, CMS has revised the definition of episode of care to

clarify that the day of discharge itself counts as the first day of the post-discharge period and adds the same clarification to §510.210(a)

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

1. Background

Section III.C. of the rule describes final CJR policies in these areas:

- Attribution of CJR episodes to a participant hospital;
- Methodology for setting episode target prices and comparing Medicare actual episode payments to them;
- Reconciliation of Medicare expenditures based on actual episode spending to the target price;
- Methodology for comparing hospital quality of care for CJR episodes against quality thresholds established under the model;
- Determination of payments to or repayment amounts from participant hospitals so that, on average, Medicare pays the episode target prices for CJR episodes; and
- Establishing protections for participant hospitals from excessive risk due to high payment cases.

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

a. Performance Period

Comments and CMS Response: CMS finalizes its proposal that the CJR model have 5 performance years, which several commenters supported. A large number of commenters, however, objected to the proposed start date of January 1, 2016 and requested a delay of 3, 6, 9 or 12 months or longer to gain additional time for activities such as developing a new infrastructure with respect to provider networks, which would include identifying and establishing contracts with collaborators as well as determining appropriate incentives and gainsharing structures; identifying and developing new care pathways and performance metrics; and developing as well as modifying accounting and IT systems. Some commenters requested even longer delays or postponement of the project, or a phase-in. Commenters also were concerned about not receiving baseline and episode-level data until after the proposed start date.

CMS disagrees with commenters advocating long delay or a phase-in but agrees that some additional time is needed and postpones the start date until April 1, 2016. The final rule establishes 5 performance years for the CJR model, beginning April 1, 2016, as shown in Table 8 below. CMS will make participating hospitals' baseline data available upon request in early 2016 in advance of the April 1, 2016 start date.

TABLE 8: PERFORMANCE YEARS FOR CJR MODEL

Performance year	Calendar year	Episodes included in performance year
1	2016	Episodes that start on or after April 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

Note that performance year 1 is shorter than the other performance years with respect to the length of time over which an anchor hospitalization could occur. Performance years 2 through 5 could include episodes that began in a prior year.

b. Retrospective Payment Methodology

As discussed in section B above, an episode 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 only limited exclusions and adjustments, which are discussed later in the summary. CMS applies the CJR episode payment methodology retrospectively, with all providers and suppliers caring for Medicare beneficiaries in CJR episodes continuing to bill and be paid as usual under the applicable Medicare payment system throughout the performance years.

Beneficiaries continue to have free choice of any Medicare enrolled provider or supplier, or any physician or practitioner who has opted out of Medicare, with the same costs, copayments and responsibilities as they have with other Medicare services. Participant hospitals can enter into sharing arrangements with certain providers and suppliers and these preferred providers and suppliers can be recommended to beneficiaries provided the recommendations are made consistent with the constraints of current law.

Comments and CMS Response: Many commenters supported the proposed retrospective model because it builds upon existing payment system infrastructures and processes and is administratively more feasible and straightforward with fewer infrastructure changes and logistical challenges compared to a prospective model. The retrospective model also maintains a predictable cash flow for all participants in the model, including physicians and post-acute care providers.

Many other commenters, however, opposed the retrospective model and urged a prospective payment model, asserting that the retrospective model was complex, complicated due to variation in payment policies across Medicare FFS payment models, and needed further refinement. They believed that a retrospective model would be less effective at holding providers accountable or in stimulating the kinds of behavior changes that are needed to achieve the goals of the CJR program. They also believed that beneficiaries would not be able to realize cost-sharing reductions when a provider achieves savings under a retrospective model.

Commenters identified various prospective approaches that CMS could consider, including:

- Establishing an extended DRG that includes hospital, physician, and PAC services for some period of time (for example, 30, 60, 90 days);
- Making a prospective payment to hospitals that are then distributed to their partners based on volume, acuity, quality, and efficiency;
- Withholding some percentage of the total payment intended for downstream partners, with hospitals subsequently distributing these payments to partners based on their ability to meet quality and efficiency targets;
- Moving toward a prospectively negotiated case rate to foster collaboration among all clinicians involved in patient care and provide predictable pricing; and
- Allowing physicians to lead a team where the participating physician and their patient decide which other providers and suppliers would be involved and what the treatment plan would be for the episode.

On the other hand, many commenters were concerned that a prospective model would allow hospitals complete authority to allocate payments among participating providers and suppliers or to be empowered with functions and authorities typically given to Medicare Administrative Contractors (MACs). A prospective payment methodology also could exacerbate anti-competitive concerns.

CMS agrees with many of the commenters' conflicting points: the complexities and potential complications associated with a retrospective model (while noting that they are not significantly different than what occurs with other Medicare payment models, especially Innovation Center models); the advantages and challenges of a prospective model; and beneficiaries not realizing a cost-sharing reduction (while noting that this is not unique to the CJR model or a reason not to test it, and adding that beneficiaries could benefit from improved quality of care and outcomes). CMS observes that both retrospective and prospective models have support and concludes that a retrospective model can accomplish its objective of testing episode payments with a broad group of hospitals. Thus, CMS finalizes a retrospective payment model for the CJR.

After a CJR performance year closes, CMS groups Medicare claims for services into episodes, aggregates payments, assesses episode quality and actual payment performance against episode quality thresholds and target prices, and determines if Medicare will make a payment to the hospital (reconciliation payment) or if the hospital owes money to Medicare (resulting in Medicare repayment). CMS again notes that a retrospective episode payment approach is currently being utilized under BPCI Model 2.

c. Two-sided Risk Model

As proposed, the final rule establishes target prices for each participant hospital for each performance year and employs a two-sided risk model in which hospitals meeting or exceeding quality performance thresholds and achieving cost efficiencies relative to CJR target prices receive episode reconciliation payments, while hospitals that exceed their CJR target prices for any of performance years 2 through 5 are responsible for repaying Medicare, with some limitations, as discussed later in the summary.

Comments and CMS Response: Several commenters supported establishing downside risk, with very few requesting the elimination of risk from the model. One comment stated that it was unfair to require hospitals to bear risk given that there were no limitations on beneficiary choices. Most commenters requested a more gradual phase-in of risk and several were concerned about the impact on small or low-volume hospitals.

CMS disagrees that it is unfair to require hospitals to bear risk while beneficiaries can choose among providers, noting that the same is true with other new payment models such as the Medicare Shared Savings Program. Regarding concern about the impact on small or low-volume hospitals, CMS believes its methodology for selecting geographic units, as discussed in section III.A. above, together with the additional protections for certain kinds of these hospitals, as discussed in section III.C.8. below, sufficiently address these concerns.

CMS finalizes its proposal that participant hospitals not be required to pay Medicare back if episode actual spending is greater than the target price for performance year 1. CMS phases in repayment responsibility beginning with performance year 2, with hospitals responsible for excess spending in performance years 3 through 5. Responding to commenters seeking a more gradual transition, the final rule further limits financial risk to hospitals in performance years 2 and 3 by lowering stop-loss limits from 10 percent to 5 percent in year 2, and from 20 percent to 10 percent in year 3, as discussed in section III.C.8. later in this summary.

3. Adjustments to Payments Included in Episode

CMS finalizes its proposals to make three adjustments to Medicare Part A and Part B payments accumulated in the CJR episodes: 1) to account for special payment provisions under existing Medicare payment systems; 2) to adjust payment for services that straddle the end of an episode; and 3) to adjust for high payment episodes. CMS also makes adjustments to account for overlaps with other Innovation Center models and CMS programs, as discussed later in this summary.

CMS does not adjust hospital-specific or regional components of target prices for any Medicare repayment or reconciliation payments made under the CJR model; CJR repayment and reconciliation payments are not included per the episode definition in section III.B. above. CMS believes that including reconciliation payments and Medicare repayments in target price calculations would perpetuate the initial set of target prices once CJR performance years are

captured in the 3- historical-years of data used to set target prices but may reexamine this policy in the future.

Each of these areas is discussed below, together with comments on the proposed rule and CMS' response.

a. Treatment of Special Payment Provisions under Existing Medicare Payment Systems

Reflecting the intent of the CJR demonstration to test episode payment incentives to improve quality and efficiency, CMS finalizes its proposal to exclude these special payment provisions in setting target prices and in calculating actual episode payments:

- Hospital Readmissions Reduction Program (HRRP)
- Hospital Value-Based Purchasing (HVBP) Program
- Hospital-Acquired Condition (HAC) Reduction Program
- Hospital Inpatient Quality Reporting Program (IQR) and Outpatient Quality Reporting Program (OQR)
- Medicare Electronic Health Record (EHR) Incentive Program for IPPS and critical access hospitals (CAHs)
- Medicare Disproportionate Share Hospital (DSH) and Uncompensated Care
- Indirect Medical Education (IME)
- Low volume add-on payments
- New technology add-on payments
- Enhanced payments to sole community hospitals (SCHs) or Medicare-dependent hospitals (MDH) based on cost-based hospital-specific rates
- Quality programs affecting IRFs, SNFs, IPFs, HHAs, LTCHs, hospice facilities and ambulatory surgical centers (ASCs)
- Physician quality programs, including the Medicare EHR Incentive Program for Eligible Professionals, the Physician Quality Reporting System (PQRS), and the Physician Value-based Modifier Program
- All special add-on payments for IRFs (rural add-on, low-income percentage (LIP) payments, teaching program payments), HHAs (rural add-on), and SNFs (payments for treating beneficiaries with human immunodeficiency virus (HIV))

These adjustments are excluded in 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. Excluding them avoids artificially improving or worsening actual episode payment performance because of payment reduction penalties or incentives or enhanced or add-on payments based on special payment provisions. Their exclusion maintains the focus of the CJR model on improving quality and efficiency. CMS believes that not excluding them would create incentives that are not aligned with the intent of the CJR model.

To operationalize the exclusions, CMS applies the CMS Price (Payment) Standardization Detailed Methodology, which is the same as used for the HVBP program's Medicare spending per beneficiary metric and which is described on the QualityNet website at <http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=OnetPublic%2FPage%2FOneTier4&cid=1228772057350>. CMS also adjusts actual episode payments to account for the effects of sequestration.

CMS also normalizes episode spending in setting target prices to adjust for wage variations, as described in section III.C.4.b(4) below.

Comments and CMS Response: Commenters generally supported excluding the special payment provisions. Addressing some concern about how hospitals would be paid the special payment adjustments, CMS responded that they will continue to be paid as usual under the applicable Medicare payment systems, but their effects will be excluded when reconciliation payment and repayment to Medicare determinations are made retrospectively.

Many commenters requested that CJR reconciliation payments made to participant hospitals be included when updating the set of 3-historical-years used for calculating CJR episode target prices. They stated that the participant hospitals would undertake activities that promote care coordination and improved quality of care but are not directly reimbursed under applicable Medicare FFS payment systems. These services would then, instead, be funded by reconciliation payments. CMS agrees and adds that this logic could be extended to include repayments to Medicare also in comparable manner to the inclusion of reconciliation payments. CMS notes, however, that it did not propose an alternative to include reconciliation payments and repayments when updating the set of historical years used to calculate target prices. It further notes that the first time this policy would take effect would be for performance year 3 (2018) and states that it may revisit the policy in future rulemaking and allow for public comment.

CMS responds to commenters inquiring whether payments to physicians who have opted out of Medicare are included in CJR episodes, saying they are not but the impact of not capturing expenditures from physicians who have opted out of Medicare will be small. CMS believes only a small proportion of physicians opt out, and it estimates that physician services comprise less than 15 percent of the average CJR episode expenditure. CMS identifies situations in which participant hospitals could benefit or lose due to this exclusion, an effect CMS believes to be small in either case.

In response to a comment, CMS clarifies that it will include IPPS capital payments in target price and actual episode expenditure calculations since IPPS capital payments are included in Medicare FFS payments. The rule acknowledges that this is a different policy than under BPCI, which excludes IPPS capital payments.

b. Treatment of Payment for Services that Extend Beyond the Episode

CMS finalizes its proposal to prorate payments for post-discharge services when Medicare payment for services in an episode cover a period of care that extends beyond the episode. CMS attributes only the portion of the payment representing the overlap period to the CJR episode. Proration is based on the percentage of actual length of stay (in days) that falls within the episode window for stays involving non-IPPS inpatient hospitals (for example, CAH) and inpatient PAC providers (for example, SNF, IRF, LTCH, IPF) services. Home health stays are prorated based on the percentage of days, starting with the first billable service date ("start of care date") through and including the last billable service date, that fall within the CJR episode. A similar allocation is made to a home health care episode initiated before the anchor CJR admission and continuing after the admission within the 90-day post-hospitalization episode period.

For IPPS services that extend beyond the episode (for example, readmissions included in an episode), CMS prorates the normal MS-DRG payment amount based on the geometric mean length of stay, comparable to the calculation under the IPPS PAC transfer policy at §§412.4(f). Under this policy, the first day for a subset of MS-DRGs (indicated in Table 5 of the IPPS/LTCH PPS final rules) is 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 overlapping 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.

Payments for services that extend into the 30-day post-episode period (described later in this summary) are prorated using a comparable allocation methodology.

The final rule includes several examples of the application of these proration policies.

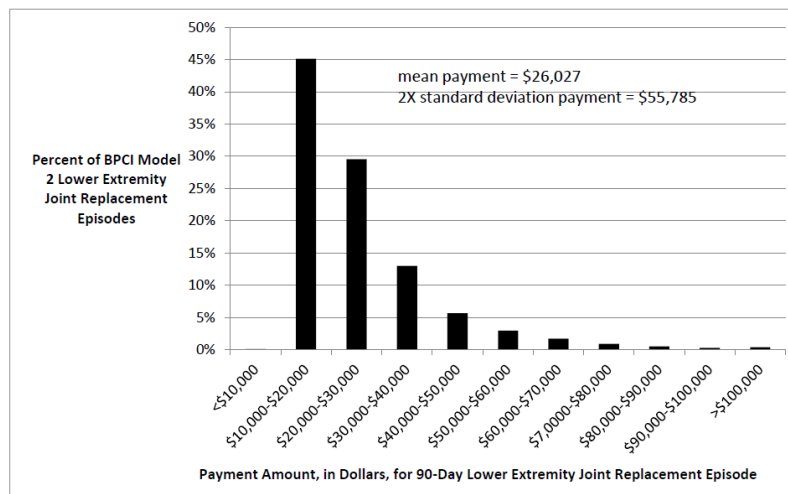
Comments and CMS Response: Commenters generally supported the proration policies. One commenter stated that the first day for pro-rated surgical MS-DRGs paid under IPPS should be weighted by more than the two-times weight proposed, and believed that a multiplier of up to 4.5 would more accurately describe hospitals' costs for the first day of surgical inpatient admissions. CMS agrees that costs for inpatient stays may not be equal for each day of an inpatient admission, and the distribution of costs may differ between surgical and non-surgical inpatient stays. CMS does not, however, change the policy in order to maintain consistency with the IPPS per diem transfer policy that uses a two-times weight.

c. Pricing Adjustment for High Payment Episodes

The proposed rule observed that clinical scenarios for LEJR cases each year may differ significantly and unpredictably. The mean episode payment amount for LEJR cases in BPCI Model 2, which uses a similar episode definition as CJR, is about \$26,000. Five percent of all

episodes have payments two standard deviations or more above the mean payment, an amount of nearly \$56,000, more than 2 times the mean episode payment amount (see Figure 2 below).

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.

To provide protection from repayment risk for especially high payment CJR episodes, CMS proposed to apply a high payment ceiling set at two standard deviations above the mean episode payment amount in calculating the target prices and in comparing actual episode payments during a performance year to target prices. To set the ceiling level, CMS proposed to identify for each anchor MS-DRG (MS-DRG 469 and MS-DRG 470) in each Census region the episode payment amount that is two standard deviations above the mean payment (after removing the effects of the special payment provisions discussed above).

CMS finalizes this policy with modification to accommodate its decision, discussed in section III.C.4.b. below, to risk stratify MS-DRG 469 and MS-DRG 470 based on patients' hip fracture status. Specifically, instead of calculating and applying high payment episode ceilings for each region and anchor MS-DRG combination, CMS will calculate and apply high payment episode ceilings for each region, anchor MS-DRG, and hip fracture status combination.

Comments and CMS Response: Commenters generally supported the high payment ceiling to help limit financial exposure to participant hospitals from outlier episodes. Some commenters requested the option of choosing specific risk tracks as provided under BPCI (for example, high episode payment ceiling at 75th, 95th, or 99th percentile). CMS responds that the blending of regional and hospital-specific historical episode expenditure data to calculate target prices precludes the use of different risk tracks or outlier protection policies to different hospitals in CJR.

4. Episode Price Setting Methodology

a. Overview

CMS finalizes its proposal to establish multiple CJR target prices for each participant hospital based on three years of historical Medicare payment data grouped into episodes of care. CMS applies Medicare payment system updates (for example, IPPS, OPPI, IRF PPS, SNF PPS, PFS, etc.) to the historical episode data. The specific set of 3 historical years used are updated every other performance year.

Commenters responded on several of the proposed pricing features, including how quality performance would affect payment and on the importance of hip fractures to cost and treatment. The final rule makes three significant changes, discussed in more detail in succeeding sections:

- 1) risk stratifies and sets different prices based not just different on anchor MS-DRGs but also patients' hip fracture status;
- 2) uses lower discount factors for purposes of determining the hospital's responsibility for excess episode spending not only in performance year 2, but also in performance year 3; and
- 3) provides different levels of effective target price discount factors based on participant hospitals' quality performance.

The final rule sets different target prices (i) for episodes anchored by MS-DRG 469 versus MS-DRG 470; (ii) for episodes with hip fracture versus no hip fracture; and (iii) for episodes initiated between April 1 and September 30 vs. between October 1 and December 31 for performance year 1, and between January 1 and September 30 vs. between October 1 and December 31 for performance years 2 through 5. Using the different time periods accounts for annual pricing updates occurring on a fiscal year or calendar year basis. Unlike the proposed rule, recognizing whether a hospital successfully submits data on the voluntary patient-reported outcome measure does not require separate target prices but instead is incorporated in the new methodology for combining payment and quality performance, as discussed in section III.C.5 below.

CMS will calculate and communicate episode target prices to each participant hospital prior to the performance period in which they apply. For episodes beginning in performance years 1, 4, and 5, a participant hospital will have eight potential target prices, as shown in the table below:

Episodes Anchored by...	Episode with Hip Fracture?	and Initiated Between...of the Performance Year
MS-DRG 469	Yes	January 1* and September 30
MS-DRG 470	Yes	January 1* and September 30
MS-DRG 469	Yes	October 1 and December 31
MS-DRG 470	Yes	October 1 and December 31
MS-DRG 469	No	January 1* and September 30

Episodes Anchored by...	Episode with Hip Fracture?	and Initiated Between...of the Performance Year
MS-DRG 470	No	January 1* and September 30
MS-DRG 469	No	October 1 and December 31
MS-DRG 470	No	October 1 and December 31

*For performance year 1, the period is between April 1 and September 30 rather than between January 1 and September 30.

For episodes beginning in performance years 2 and 3, a participant hospital will have 16 potential target prices, which would include the combinations above but with one set for determining potential reconciliation payments and another for determining potential Medicare repayment amounts, reflecting the lower discount amount applicable to target prices for determining potential repayment amounts as part of phasing in two-sided risk, as discussed in section III.C.6 below.

Summary of methodology for setting CJR target prices (from section III.C.4.c. of final rule)

The methodology for setting CJR target prices includes these 10 steps:

- 1) Calculate historical CJR episode payments for episodes that were initiated during the 3 historical years for all CJR eligible hospitals for all Medicare Part A and B services included in the episode. Specific per beneficiary per month (PBPM) payments may be excluded from historical episode payment calculations as discussed in section III.C.7.d. below.
- 2) Remove effects of the special payment provisions identified in III.C.3.a. above and normalize for wage index differences (described in section III.C.4.b.(7) below) by standardizing Medicare FFS payments at the claim-level. [The final rule indicates (in section III.C.4.b.(7)) that wage differences are reintroduced in a later calculation step of determining the target prices. In the proposed rule, reintroduction occurred immediately before application of the discount factor, which is step 10) below, but that step seems to have been inadvertently omitted in the enumeration of calculation steps in section III.C.4.c. of the final rule.]
- 3) Prorate Medicare payments for included episode services that span a period of care that extends beyond the episode, as discussed in section III.C.3.b. above.
- 4) Trend forward the 2 oldest historical years of data to the most recent year of historical data using separate national trend factors for each combination of anchor MS-DRG (469 vs. 470) and hip fracture status (with hip fracture vs. no hip fracture) (discussed in section III.C.4.b.(3) below).
- 5) Cap high episode payment episodes with a region and MS-DRG anchor-specific high payment ceiling, as discussed in section III.C.3.c. above, using the episode output from the previous step. CMS has posted region specific historical average episode payments on the CJR final rule website at <http://innovation.cms.gov/initiatives/CJR/>.

- 6) Calculate anchor factor and participant hospital specific weights (discussed in section III.C.4.b.(8) below) using the episode output from the previous step to pool together MS-DRG 469 and 470 anchored episodes with and without hip fracture, resulting in participant hospital specific pooled historical average episode payments. Similarly, calculate region specific weights to calculate region specific pooled historical average episode payments.
- 7) Calculate participant hospital specific and region specific weighted update factors (discussed in section III.C.4.b.(4) below). 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.
- 8) 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) below. Participant hospitals that do not have the minimum episode volume across the historical 3 years will use 0.0 percent and 100 percent as the proportions for hospital and region, respectively. CMS defines the output of this step as the pre-discount target price for MS-DRG 470 anchored episodes without hip fracture.
- 9) Multiply the output of step (8) by the appropriate anchor factors (step (6) of this target price calculation process and discussed in section III.C.4.b.(8) below) for MS-DRG 469 anchored episodes with hip fracture, MS-DRG 469 anchored episodes without hip fracture, and MS-DRG 470 anchored episodes with hip fracture. CMS defines the outputs of this step as the pre-discount target prices for MS-DRG 469 anchored episodes with hip fracture, MS-DRG 469 anchored episodes without hip fracture, and MS-DRG 470 anchored episodes with hip fracture.
- 10) Multiply the pre-discount target prices for MS-DRGs 469 and 470 episodes with and without hip fracture by the appropriate effective discount factor that incorporates any quality incentive payment, as briefly described in section III.C.4.b.(9) below and more specifically described in section III.C.5. below and Tables 19, 20, and 21. The results of these calculations will be participant hospitals' target prices for MS-DRG 469 anchored episodes with hip fracture, MS-DRG 469 anchored episodes without hip fracture, MS-DRG 470 anchored episodes with hip fracture, and MS-DRG 470 anchored episodes without hip fracture.

As noted, these 10 steps are used to calculate target prices for episodes that begin between January 1 (or April 1 in performance year 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 for each performance year differ on account of the update factors used in step (7).

b. Pricing Features

(1) Different Target Prices for Episodes Anchored by MS-DRG 469 versus MS-DRG 470

In the proposed rule, CMS set separate target prices for MS-DRG 469 and MS-DRG 470 to account for the clinical and resource variations that exist and that impact hospitals' cost of providing care, including the higher hospital costs for hip and knee procedures with major complications or comorbidities that are grouped in MS-DRG 469. CMS did not propose to make risk adjustments based on patient-specific clinical indicators, citing the lack of a reliable approach to incorporate these factors. CMS also rejected adjusting target prices based on the participant hospital's average Hierarchical Condition Category (HCC) score for patients with anchor CJR hospitalizations, noting that the CMS-HCC risk adjustment model is used to predict annual total Medicare expenditures and may not be appropriate for use in predicting expenditures over a shorter period of time, such as the CJR episode, or for a focus on lower extremity joint replacements.

Comments and CMS Response: Commenters asserted that proper risk adjustment is necessary to account for differences in episode spending arising from patient variations beyond providers' control. MS-DRGs may capture variations in patient cost within the inpatient setting but do not reflect cost variations post-discharge, so only using anchor MS-DRG-specific pricing is not sufficient. Inappropriate risk adjustment could lead to access issues for higher risk patients and increased volume of LEJR procedures for younger/healthier patients by participant hospitals looking to lower their average episode expenditures.

Most commenters who wrote on the issue suggested risk adjustment or complete exclusion for episodes with hip fractures, partial hip replacements, and emergent (versus non-emergent or elective) procedures, among other suggestions. Commenters disagreed with CMS that there is no widely accepted standard risk adjustment, citing examples such as Optum's Procedure Episode Grouper (PEG), Truven's Medical Episode Grouper (MEG), Health Care Incentives Improvement Institute's (HCI3) risk adjustment model, CMS's HCCs model, and CMS's risk-adjusted quality/efficiency metric for elective LEJR episodes: Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode of Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).

CMS conducted further analyses and agrees that hip fracture patients are more costly, finding that these patients have approximately 70 percent greater historical average CJR episode expenditures than CJR episodes without hip fractures, even for episodes within the same anchor MS-DRG. CMS continues to disagree, however, that there is an already existing, widely accepted risk adjustment methodology for CJR episodes and discusses the limitations of the ones suggested by commenters. For example, commercial groupers have not been validated for a Medicare population; and the aforementioned CMS risk-adjusted quality/efficiency metric for elective LEJR episodes was developed for a different episode definition and excludes emergent episodes while the CJR episode definition includes them. CMS may explore how a

comprehensive risk adjustment model such as those may be adapted for the CJR model in the future.

As an interim adjustment, CMS will risk stratify, or set different target prices, both for episodes anchored by MS-DRG 469 vs. MS-DRG 470 and for episodes with hip fractures vs. without hip fractures. Adding hip fracture status captures a significant amount of patient-driven episode expenditure variation and has the advantage of reflecting patients' clinical status rather than being based on the type of procedure (partial hip replacements or emergent procedures), which are influenced by providers' care delivery decisions. Due to high correlation between incidence of hip fractures, partial hip procedures, and emergent procedures, CMS concludes there is no need to add any procedure-specific and emergent status factors for risk stratification. It also continues to believe that PAC intensity does not vary significantly between TKA and THA for beneficiaries without hip fractures.

CMS identifies episodes with hip fractures using ICD-9-CM or ICD-10-CM diagnosis codes, where the hip fracture diagnosis is the principal diagnosis on the anchor hospitalization claim for an LEJR procedure. To develop the list of relevant ICD-9-CM hip fracture diagnosis codes, CMS is using a subregulatory process similar to the one that it will use for the episode definition exclusions list described in section III.B.2 above. It will use this process on an annual, or more frequent, basis to update the ICD-CM hip fracture diagnosis code list and to address issues raised by the public.

CMS will assess the diagnosis codes using these standards:

- The ICD-CM diagnosis code is sufficiently specific that it represents a bone fracture for which a physician could determine that a hip replacement procedure, either a partial hip arthroplasty or a THA, could be the primary surgical treatment; and
- The ICD-CM diagnosis code is the primary reason (that is, principal diagnosis code) for the anchor hospitalization.

Coincident with the final rule, CMS developed an ICD-9-CM hip fracture diagnosis code list to use to identify historical anchor hospitalizations for beneficiaries with hip fracture for purposes of determining episode spending in the historical period and developing initial target prices for the CJR model. The potential ICD-9-CM hip fracture diagnosis code list is posted on the main CJR website at <https://innovation.cms.gov/initiatives/cjr/> or at this direct link to the list <https://innovation.cms.gov/Files/worksheets/cjr-hisfracturecodes.xlsx>. **Public comments must be submitted within 14 days after the public release of this final rule** via an e-mail address posted on the aforementioned CJR website. **The comment period closes at 5:00 PM on November 30.** CMS will post the final ICD-9-CM hip fracture diagnosis code list to the same CMS website and the list will be used to calculate the first set of target prices communicated to participant hospitals.

Within 30 days of public release of the final rule, CMS will again initiate its subregulatory process to identify ICD-10-CM hip fracture diagnosis codes by posting the potential ICD-10-CM hip fracture diagnosis code list on the CMS website and seeking public input. CMS will

provide the final list of ICD-10-CM hip fracture diagnosis codes prior the beginning of the model's first performance year that begins on April 1.

(2) Three Years of Historical Data

CMS proposed to use 3 years of historical CJR episodes for calculating CJR target prices and to update the set of 3 historical years every other year.

- Performance years 1 and 2 would use historical CJR 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.

Comments and CMS Response: Several commenters expressed concern that updating the 3 years of historical CJR episode data every other year would effectively make participant hospitals compete against themselves to qualify for reconciliation payments without consideration of whether they are already efficient. They noted that the CJR proposal differed from policies in BPCI and the Medicare Shared Savings Program. Commenters also said that previous reconciliation payments and repayments to Medicare for the participant hospitals should be included in updating the historical data, an issue discussed in section III.C.3 above. Commenters suggested an inflation update or a negotiations/bidding process as alternatives for updating the historical data.

CMS notes differences between BPCI and CJR especially that the former retrospectively applies a national trend factor to historical episode expenditure data and capture changes in nationwide practice patterns. CJR, on the other hand, establishes episode targets prospectively. CMS recognizes that it may be unsustainable for already efficient participant hospitals to continuously improve, but states that by performance year 3 when the first update to historical episode data would occur, the majority of the target price would be based on the regional component, not the hospital-specific component. CMS finalizes its proposal, without modification, to use three years of historical expenditures, updated every other year, to set target prices.

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

To mitigate the effects of Medicare payment system updates and changes in national utilization practice patterns within the 3 years of historical CJR episodes, CMS proposed to update the older two historical years using national trend factors similar to what is done in BPCI Model 2. CMS proposed to apply separate national trend factors for episodes anchored by MS-DRG 469 versus MS-DRG 470. For example, when using 2012-2014 historical episode data to establish target prices for performance years 1 and 2, CMS 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 2014 to that of 2012 would be used to trend 2012 MS-DRG 470 anchored episode payments to 2014.

CMS finalizes its proposal to trend historical data to the most recent of the 3 being used to set target prices, but instead of calculating different national trend factors just for anchor MS-DRGs 469 vs. 470, it will calculate different national trend factors for each combination of anchor MS-DRG (469 vs. 470) and hip fracture status (with hip fracture vs. without hip fracture).

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

The historical episode payments are updated to reflect ongoing payment system updates for these programs: IPPS, IRF PPS, SNF PPS, PFS, HHA, and other services. As noted, CMS calculates target prices separately for episodes initiated between January 1 and September 30 versus October 1 and December 31 of each performance year to account for calendar year versus fiscal year program updates. The target price in effect as of the day an episode is initiated is the target price for the entire episode.

Corresponding to the different target prices, a different set of update factors is calculated for January 1 through September 30 versus October 1 through December 31 episodes each performance year. The six update factors reflecting each of the six programs are hospital-specific and are combined to create a single update factor by weighting and summing each of the six update percentages according to the proportion of Medicare payments each of the six components represents in a hospital's historical episodes. The weighted update factors are applied to the historical hospital-specific average payments.

Region-specific update factors are calculated in the same manner as the hospital-specific update factors. Rather than using historical episodes attributed to a specific hospital, region-specific update factors are based on all historical episodes initiated at any CJR eligible hospital within the region. For this purpose, CJR eligible hospitals were defined in the proposed rule 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 CJR model.

Comments and CMS Response: CMS agrees with several commenters who recommended that the definition of "CJR eligible hospitals," – the term used to identify hospitals included in calculations for the regional component of target prices – should not exclude hospitals participating in BPCI Model 1 or in the risk bearing period of Models 2 or 4 for LEJR episodes. Some regions may have a greater proportion of such BPCI participants, and excluding them from the calculations for the regional component of target prices would not accurately reflect the region's historical expenditures. Also, with fewer hospitals included, the regional component of target prices would be more significantly impacted by the performance of just CJR participant hospitals.

CMS modifies the definition of "CJR eligible hospitals" to include these BPCI hospitals so that their data is included in the regional component of target prices. CMS will treat these BPCI participants the same as any other non-BPCI-participating hospital – it will not apply the BPCI

discount factor to claims payments nor include BPCI reconciliation or repayments for these BPCI hospitals. CMS renames "CJR eligible hospitals" to be "CJR regional hospitals."

CMS clarifies that BPCI LEJR episodes also will be included in the historical data used to calculate the hospital-specific component of target prices. There may be some CJR participant hospitals who were previously participants in BPCI Model 2; there may be some BPCI Model 2 episodes in the historical data initiated by physician group practices (PGPs) for which the LEJR procedure took place at the CJR participant hospital; or there may be some BPCI Model 3 episodes in the historical data for which the LEJR procedure took place at the CJR participant hospital.

Several commenters noted that the Medicare payment system update factors are complicated to calculate; some proposed using national update factors rather than hospital-specific and regional; and others requested to have a single set of target prices for the entire calendar year, as opposed to two different sets of target prices that would account for intra-year Medicare FFS payment systems updates. CMS acknowledges the complexity but believes it is necessary to account accurately for FFS payment system changes and to ensure that the CJR program incentivize hospitals based on historical utilization and practice patterns, not Medicare payment system rate changes that are beyond hospitals' control.

As it had also done in the proposed rule, CMS rejected trending the historical episode payments forward to the upcoming performance year using ratios of national average episode payment amounts, similar to how it proposes to trend the 2 oldest historical years forward to the latest historical year in determining historical CJR episode payments. While this approach would have the advantage of capturing changes in national utilization patterns in addition to payment system updates between the historical years and the performance year, it would need to be done retrospectively after average episode payments are calculated for the performance year.

(a) Inpatient Acute Services Update Factor

The update factor applied to the IPSS component of each participant hospital and region's historical average episode payments is based on how inputs for the Medicare IPSS have changed between the latest year used in the historical 3 years of episodes and the upcoming performance period under CJR. The average MS-DRG weight is 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 are calculated by averaging the MS-DRG weight for all the IPSS MS-DRGs included in the historical episodes attributed to each participant hospital and attributed to CJR regional hospitals, respectively (including MS-DRGs for anchor admissions as well as those for subsequent readmissions that fall within the episode definition).

The final rule modifies the formulas used to calculate update factors for the IPSS and other payment systems that apply annual updates to their rates effective October 1 of each year. Rather than calculating the update factors for inpatient acute, SNF, and IRF services using the

values applicable at the end of the latest historical year used to calculate target prices, CMS will use a weighted blend of the values applicable during the latest historical year.

- (b) Physician Services Update Factor
- (c) IRF Services Update Factor
- (d) SNF Services Update Factor
- (e) HHA Services Update Factor
- (f) Other Services Update Factor

Similar update factors are calculated for the other service components, as summarized in the table below. Note that the update factors for IPPS, SNF and HHA account for changes in average case-mix and price but the update factors for the other service types only account for price changes. Also, note that the update factors are hospital-specific and region-specific for all services except IRF and other services. The numerators in the formulas are based on values applicable for the upcoming performance period for which a target price is being calculated and the denominators are based on values applicable at the end of the latest historical year used in the target price calculations for physician, home health and other services; as noted, the denominators for IPPS, SNF and HHA are based on a weighted blend of the values applicable during the latest historical year.

Component	Inputs Used	Calculation Formula*	Hospital-specific, region-specific	Does formula recognize changes in case-mix?
IPPS	IPPS base rates and average of MS-DRG weights (as defined in the IPPS/LTCH final rules for the relevant years) for IPPS services in the historical episodes of relevant hospitals	$(\text{Base Rate}_{PP} * \text{average MS DRG weight}_{PP}) / (\text{Base Rate}_{TP} * \text{average MS DRG weight}_{TP})$	Yes	Yes
Physician services	Relative Value Unit (RVU)-weighted geographic practice cost indices (GPCIs) calculated by taking the proportion of RVUs for work, practice expense, and malpractice liability for physician services in the historical episodes of relevant hospitals, and multiplying each hospital-specific proportion by the relevant GPCI; national conversion factors from PFS final rule for the relevant years	$(\text{RVU-weighted GPCI}_{PP} * \text{Conversion factor}_{PP}) / (\text{RVU-weighted GPCI}_{TP} * \text{Conversion factor}_{TP})$	Yes	No

Component	Inputs Used	Calculation Formula*	Hospital-specific, region-specific	Does formula recognize changes in case-mix?
IRF	IRF standard payment conversion factor, as defined in the IRF PPS final rule for the relevant years	$(\text{IRF Standard Payment Conversion factor}_{PP}) / (\text{IRF Standard Payment Conversion factor}_{TP})$	No	No
SNF	Average resource utilization group (RUG-IV) case-mix adjusted federal rates for the Medicare SNF PPS (from the SNF PPS final rule for the relevant years) calculated for SNF services in the historical episodes of relevant hospitals	$(\text{Average RUG IV Case Mix Adjusted Federal Rate}_{PP}) / (\text{Average RUG IV Case Mix Adjusted Federal Rate}_{TP})$	Yes	Yes
HHA	Hospital-specific average home health resource group (HHRG) case-mix weights for HHA services in the historical episodes of relevant hospitals; HHA PPS base rate from HHA PPS final rule for the relevant years; Low Utilization Payment Adjustment (LUPA) claims are excluded	$(60 \text{ Day Episode Rate}_{PP} * \text{average HHRG weight}_{PP}) / (60 \text{ Day Episode Rate}_{TP} * \text{average HHRG weight}_{TP})$	Yes	Yes
Other services**	Medicare Economic Index (MEI)	Percent change in the MEI	No	No

Note: In this table, “relevant hospitals” refers to participant hospitals for the hospital-specific target prices and to CJR regional hospitals for the regional target prices.

*Performance period (PP); Target price (TP)

**The other services update factor would apply to payments for services included in the episode and not paid under the IPPS, PFS, IRF PPS, SNF PPS, or HHA PPS (except for LUPA claims). It would include episode payments for home health LUPA claims and CJR related readmissions at CAHs.

(5) Blend Hospital-specific and Regional Historical Data

CMS finalizes its proposal to calculate CJR episode target prices using a blend of hospital-specific and regional historical average CJR episode payments, including CJR episode payments for all CJR regional hospitals in the same region.

The blend proportions are shown in the table below:

Year	Blend Proportion
Performance years 1 and 2 (2016 and 2017)	Two-thirds of the hospital-specific episode payments and one-third of the regional episode payment
Performance year 3 (2018)	One-third of the hospital-specific episode payments and two-thirds of the regional episode payment
Performance years 4 and 5 (2019 and 2020)	Based fully on regional historical CJR episode payments

CMS considered establishing episode target prices using only historical CJR hospital-specific episode payments for all 5 performance years or, alternatively, using only historical CJR regional episode payments for all 5 performance years. These were rejected because CMS believes that the proposed blends combined with the transition to regional prices provides the best combination of incentives for both less historically efficient hospitals and more efficient hospitals to deliver high quality and efficient care.

CMS finalizes an exception to the blended hospital-specific and regional pricing approach for hospitals with low historical CJR episode volume, i.e., those with fewer than 20 CJR episodes in total across the 3-historical-years used to calculate target prices. For this group of hospitals, CMS will use 100 percent regional target pricing for each performance year. As the 3 historical years used to calculate target prices changes over the course of the model, the twenty episode threshold will be applied to the new set of historical years. CMS estimates that about 5 percent of hospitals would be affected by the proposed low historical CJR episode volume provision.

CMS also finalizes an exception to the blended hospital-specific and regional pricing policy 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 may be new hospitals or new hospitals may have formed due to a merger between or split from previously existing hospitals. CMS will strive to incorporate into the target prices all the historical episodes that represent the agency's best estimate of CJR historical payments for participant hospitals with new CCNs. For example, for mergers or an organizational change leading to a hospital changing to an already existing CCN, CMS will calculate hospital-specific historical payments using the episodes attributed to all relevant previously existing hospitals. For participant hospitals with new CCNs that are new hospitals altogether, CMS will use the same regional pricing approach as applies to hospitals with fewer than 20 CJR episodes across the 3 historical years used to calculate target prices.

Comments and CMS Response: Many commenters supported calculating target prices using a blend of hospital-specific and regional historical episode data, while others recommended using only hospital-specific pricing because any definition of region would not properly account for variations such as patient characteristics, socioeconomic factors, and access to care. Some commenters recommended delaying the transition to regional pricing. CMS states that using hospital-specific pricing would not reward already efficient participant hospitals for maintaining

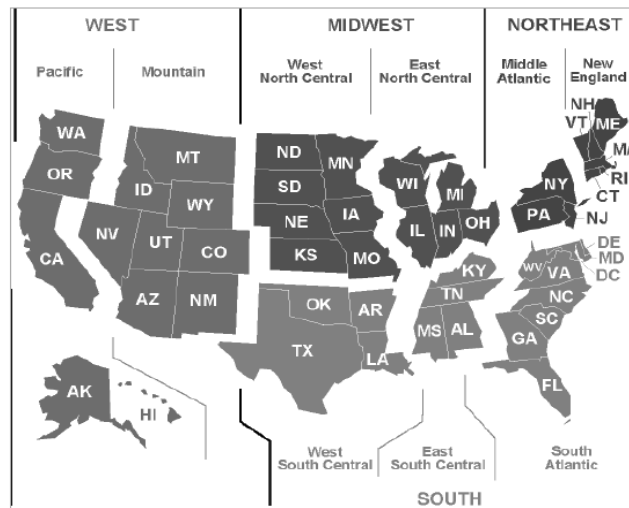
high performance because they could find it challenging to improve on their own high performance. It acknowledges that the pace to regional pricing may benefit some participant hospitals more than others, but concludes that the proposed (and finalized) transition getting to 100 percent regional pricing in the fourth year strikes an appropriate balance. Regarding regional prices inadequately reflecting hospital-specific patient characteristics, CMS responds that the concern indicates the importance of appropriate risk adjustment and/or risk stratification. It refers readers to the risk stratification adopted for the CJR program and observes again that it may explore more comprehensive risk adjustment approaches (see section III.C.4.b.(1) above).

Several commenters recommended modifying the definition of low volume as it is used to determine which participant hospitals receive 100 percent regional target prices because they do not have a sufficient number of CJR episodes in the 3-historical-years of data used to calculate target prices. Commenters suggested increasing the low volume threshold from 20 to, for example, 100 episodes, because 20 episodes was not sufficient to remove random variation. CMS agrees with commenters that a greater number of participant hospital-specific episodes would better remove the effects of random variation, but notes that blending regional and hospital-specific target prices affords historically less efficient hospitals an opportunity to be rewarded for improvement in the earlier performance years prior to regional pricing. The agency believes that 20 episodes in the 3-historical-years of data used to calculate target prices is an appropriate "low volume" threshold that mitigates effects of random variation while still incorporating hospital-specific historical experience and affording participant hospitals an opportunity to transition to 100 percent regional pricing.

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

CMS finalizes its proposal, with modification, to define “region” as one of the nine U.S. Census divisions, as shown in Figure 3 below.

FIGURE 3: U.S. CENSUS DIVISIONS



Comments and CMS Response: While some commenters supported using US Census divisions as regions, others stated US Census divisions are too large with significant practice and PAC access variations, resulting in different average historical expenditures across hospitals in the same US Census division. Some suggested using MSAs as an alternative to Census regions, noting that MSAs would align with the provider selection process, and the smaller unit would better capture regional practice pattern differences. Other commenters, including MedPAC, stated that CMS should define the entire nation as the region (that is, national pricing) in order to strive towards eliminating regional variations in practice patterns. CMS responds that it believes that the choice of Census regions provides 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.

Several commenters noted that some of the MSAs selected for participation in CJR span two different US Census divisions. They stated that the cost for hospitals in the same MSA would likely not be different, and significant differences in pricing would create unfair market advantages due to a hospital's address within an MSA. CMS agrees and modifies its policy to apply the same regional target price component to target pricing for all participant hospitals within an MSA. Three MSAs in the CJR program span two US Census divisions: St. Louis, Cincinnati, and Cape Girardeau. CMS determined, using 2010 US Census data that at least 75 percent of the population in these MSAs resides in just one of the US Census divisions that the MSA spans. The final rule assigns an entire MSA spanning US Census divisions to the US Census division in which the Census shows the majority of people reside, as shown in Table 9 below; CMS favors this simpler approach to blending the two regional target price components based on the population distribution, as suggested by commenters.

TABLE 9: REGION GROUPING FOR SELECTED MSAS THAT SPAN US CENSUS DIVISIONS

MSA	Original US Census divisions spanned by MSA (state included in MSA)	US Census division used for CJR region
St. Louis, MO-IL	West North Central (MO), East North Central (IL)	West North Central
Cincinnati, OH-KY-IN	East North Central (OH, IN), East South Central	East North Central
Cape Girardeau, MO-IL	West North Central (MO), East North Central (IL)	West North Central

(7) Normalize for Provider-Specific Wage Adjustment Variations

CMS finalizes, with modification, its proposal to normalize for wage index differences in historical episode payments when calculating and blending the regional and hospital-specific components of blended target prices to avoid 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. Such an effect would introduce unintended pricing distortions not based on utilization pattern differences.

CMS had proposed to normalize all historical episode payments in the target price calculation for wage index variations using the IPPS wage index applicable to the anchor hospitalization for each historical episode, using this wage normalization factor: $(0.7 * \text{IPPS wage index} + 0.3)$. The proposed rule observed that 0.7 approximates the labor share in IPPS, IRF PPS, SNF PPS, and HHA Medicare payments.

Comments and CMS Response: Commenters emphasized the importance of accounting for wage differences accurately and expressed concern about using 0.7 as the labor share for the labor-related portions of Medicare FFS payments; the wage index weight varies by Medicare FFS payment system, and even in IPPS, it can be either 0.688 or 0.620, depending on the IPPS hospital's wage index. Commenters also noted that using only the IPPS wage index would not accurately normalize expenditures for PAC providers who have their own wage indices.

CMS agrees and modifies its policy to normalize for wage indices at the claim level for both historical episode expenditures and actual episode expenditures in each performance year by using the wage index normalization algorithm included in the CMS Price (Payment) Standardization Detailed Methodology, the same claim-level standardization methodology discussed in section III.C.3.a. and used to exclude the various special payment provisions in calculating episode expenditures. By normalizing claims for wage indices at the claim level, the final rule more accurately accounts for wage indices and labor shares for various providers and suppliers under the different Medicare FFS payment systems.

CMS does not, however, change how wage index differences will be reintroduced into calculations of historical and actual episode spending. CMS finalizes its proposal to reintroduce wage index differences into calculations of historical and actual episode spending using the IPPS wage index applicable to the anchor hospitalization and 0.7 as the labor cost share. CMS notes the importance of reintroducing wage index variations into the calculations, observing that not doing so would mean calculating reconciliation and repayment amounts that did not capture labor cost variation. Because wage index variations are reintroduced near the end of the target price calculation methodology and after other features, such as blending, pooling, and update factors are applied, CMS does not believe there is a simple approach to reintroduce wage index variations at the claim level.

CMS acknowledges that using the participant hospital's wage index and 0.7 as the labor share is an approximation of the wage index variations, but states that this would not change whether a participant hospital qualifies for reconciliation payments or is obligated to repay Medicare. CMS states that this is because it is applying the more accurate wage index normalization at the claim level for both target price calculations and for calculations of actual episode spending (as discussed in section III.C.6.a. below), and the wage index variation would be reintroduced in the same manner to both target price calculations and actual episode spending calculations (as discussed in section III.C.6.a. below).

Note that while this section clearly indicates that wage differences are reintroduced into the calculations, the enumeration of calculation steps in section III.C.4.c. of the final rule appears to have inadvertently omitted this step. In the proposed rule, wage effects were reintroduced immediately before application of the discount factor, which is step 10) in the final rule's description of calculation steps (section III.C.4.c.).

(8) Combination of CJR Episodes Anchored by MS-DRGs 469 and 470

CMS proposed to pool together historical CJR episodes anchored by MS-DRGs 469 and 470 in order to use a greater historical CJR episode volume and attain more stable target prices. It finalizes this proposal, with a modification to pool episodes from the four groups created by adopting fracture-based risk stratification in the final rule (discussed in section III.C.4.b.(1) above): MS-DRG 469 with and without hip fracture, and MS-DRG 470 with and without hip fracture. Separate target prices, however, would still be calculated for episodes involving each of the four MS-DRG and hip fracture combinations by using three “anchor factors.”

The three “anchor factors,” which have the same value for all participant hospitals, are calculated and used as follows:

- i. Using all episodes attributed to any CJR regional hospital, calculate three anchor factors as the ratio of national average historical episode payments for each of the other three groups to national average historical episode payments for the MS-DRG 470 without hip fracture group, as indicated by these formulas:

anchor factor for MS – DRG 469 with hip fracture

$$= \frac{\text{Natl. avg. MS – DRG 469 with hip fracture episode spend}}{\text{Natl. avg. MS – DRG 470 without hip fracture episode spend}}$$

anchor factor for MS – DRG 469 without fracture

$$= \frac{\text{Natl. avg. MS – DRG 469 without hip fracture episode spend}}{\text{Natl. avg. MS – DRG 470 without hip fracture episode spend}}$$

anchor factor for MS – DRG 470 with hip fracture

$$= \frac{\text{Natl. avg. MS – DRG 470 with hip fracture episode spend}}{\text{Natl. avg. MS – DRG 470 without hip fracture episode spend}}$$

- ii. For each participant hospital, calculate a hospital weight using the formula below, where episode counts refer to the number of episodes in the 3 historical years used in target price calculations for the hospital and the anchor weights are from the first step:

Count of MS DRG 469 and MS DRG 470 anchored episodes

$$\frac{\text{MS DRG 469 anchored with hip fracture episode count} \times \text{anchor factor for MS-DRG 469 with hip fracture} + \text{MS-DRG 469 anchored without hip fracture episode count} \times \text{anchor factor for MS-DRG 469 without fracture} + \text{MS-DRG 470 anchored with hip fracture episode count} \times \text{anchor factor for MS-DRG 470 with hip fracture} + \text{MS DRG 470 anchored without hip fracture anchored episode count}}{\text{MS DRG 469 anchored with hip fracture episode count} \times \text{anchor factor for MS-DRG 469 with hip fracture} + \text{MS-DRG 469 anchored without hip fracture episode count} \times \text{anchor factor for MS-DRG 469 without fracture} + \text{MS-DRG 470 anchored with hip fracture episode count} \times \text{anchor factor for MS-DRG 470 with hip fracture} + \text{MS DRG 470 anchored without hip fracture anchored episode count}}$$

- iii. For each hospital, calculate a hospital-specific pooled historical average episode payment by multiplying the hospital's hospital weight (from the previous step) by its combined historical average episode payment for all episodes (with and without hip fracture) in MS-DRGs 469 and 470. Thus, the combined historical average episode payment equals the sum of MS-DRG 469 and 470 anchored historical episode payments divided by the number of MS-DRG 469 and 470 historical episodes.

The hospital weight essentially counts each MS-DRG 469 triggered episode, with hip fracture, as more than one episode (assuming MS-DRG 469-anchored episodes with hip fracture have higher average payments than the denominator, MS-DRG 470-anchored episodes without hip fracture), so that the pooled historical average episode payment, and subsequently the target price, is not skewed by the hospital's relative proportion of MS-DRG 469 and 470 anchored historical episodes, split by hip fracture status. A similar contribution to the hospital weight occurs with MS-DRG 469 without hip fracture and MS-DRG 470 with hip fracture, assuming that MS-DRG 470-anchored episodes without hip fracture have the lowest average payments of the four groups.⁴

CMS reports that in FY 2013 across all IPPS hospitals, there were more than 10 times as many MS-DRG 470 anchored episodes compared to MS-DRG 469-anchored episodes and that for FY 2014 CJR episodes initiated by MS-DRG 469 had payments almost twice as large as those initiated by MS-DRG 470.

CMS calculates region-specific weights and region-specific pooled historical average payments following the same steps.

In the final step of the calculation of episode target prices, the updated, blended, wage-adjusted and discounted hospital-specific pooled calculations are "un-pooled" by setting the MS-DRG 470 anchored episode without hip fracture target price for each participant hospital equal to the resulting calculations, and by multiplying that value by the hospital-specific anchor factor for each MS-DRG/fracture group to calculate the hospital's target prices for the other three groups:

⁴ If one of the groups had lower average payments, the ratio simply would be less than 1.0 and each triggered episode in that group would count less than 1.0.

MS-DRG 469 anchored episodes with hip fracture, MS-DRG 469 anchored episodes without hip fracture, and MS-DRG 470 anchored episodes with hip fracture.

(9) Discount factor

In setting the episode target price – the spending level for which the hospital would be fully, or partly, accountable for a performance period – CMS proposed to apply a 2% discount to the hospital's hospital-specific and regional blended historical payments. Actual episode spending during the performance period would be compared to this target price. The discount comprises Medicare's portion of reduced expenditures from the CJR episode, with any episode expenditure below the discounted target price potentially available as reconciliation payments to the participant hospital where the anchor hospitalization occurred if the hospital satisfies the quality requirements discussed in section III.C.5. below.

CMS believes that hospitals have significant opportunities to improve the quality and efficiency of care furnished during LEJR episodes. The proposed 2% discount is similar to the range of the discounts used for episodes in the Medicare Acute Care Episode (ACE) demonstration, which included orthopedic procedures such as those in CJR. ACE discounts that participant hospitals negotiated with Medicare ranged from 2.5% to 4.4% of all Part A orthopedic services and 0.0% to 4.4% of all Part B orthopedic services during the inpatient stay (excluding PAC). Including PAC in the CJR payment model may enhance the opportunity for savings since PAC spending accounts for approximately 25 percent of CJR episode payments and has more than 2 times the episode payment variation. The proposed 2% discount also is consistent with 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%).

As discussed in section III.C.2 above, CMS proposed that participant hospitals would not be required to pay Medicare back if actual episode spending is greater than the target price for performance year 1. CMS proposed to phase in repayment responsibility beginning with performance year 2 with a reduced discount of one percent for purposes of determining the hospital's responsibility for excess episode spending. As proposed, the full 2% discount would be applied in performance years 3 through 5, with hospitals fully responsible for excess spending in those years. The proposed rule maintained the 2% discount for all performance years for purposes of determining a hospital's opportunity to receive reconciliation payments for actual episode spending below the target price.

Finally, CMS proposed to provide incentives to encourage hospitals to voluntarily submit data for a patient-reported outcome measure. Under the proposal, hospitals that successfully submitted data would have their discount percentage reduced by 0.3 percentage points.

Comments and CMS Response: Many commenters expressed concern about participant hospitals taking on financial risk in the CJR model, as discussed in section III.C.2 above. CMS responds that it incorporates several design elements to phase-in risk, such as imposing no risk in performance year 1 and reducing the discount factor by 1 percentage point for purposes of

calculating repayment amounts in performance year 2 and, as discussed earlier, extending this reduced discount factor to apply also in performance year 3.

As alternatives to the proposed rule, commenters offered a variety of suggestions to link quality and payment in the CJR model, including varying the discount percentage incorporated in the target price at reconciliation based on the participant hospital's quality performance. In the final rule, CMS adopts a policy to link the discount percentage and quality, as summarized here and described fully in section III.C.5. below.

Several commenters requested that CMS not apply a discount factor to hospitals that are already efficient because they would not be able to achieve further efficiencies and would find it challenging to qualify for reconciliation payments. CMS responds that blending hospital-specific and regional prices in performance years 1, 2, and 3 and adopting 100 percent regional prices in performance years 4 and 5 mitigates this concern. It also notes that the final rule links the discount factor to quality performance and provides lower effective discount factors for participant hospitals with better quality performance.

Commenters requested assistance with upfront investments to fund care delivery (for example, care coordination), infrastructure, and quality reporting changes that participant hospitals may need to make, similar to how some Accountable Care Organizations (ACOs) use upfront investments in other models and programs. CMS does not believe that an additional upfront payment mechanism such as a per-beneficiary-per-month payment or an additional payment per episode is necessary for hospitals to successfully participate in the CJR model. It notes that in BPCI, a similar episode-based payment model, participants have been able to improve episode expenditure performance without such additional upfront payment mechanisms.

Final rule discount factor: CMS modifies its discount policy to use a composite score methodology that links quality and payment in the CJR model. Before application of a possible quality incentive payment, each hospital will face a discount factor of 3 percent. This discount factor is reduced by 1 percentage point to 2 percent in performance years 2 and 3 for purposes of calculating repayments to Medicare, reflecting the phase-in of risk. The 3 percent discount factor will be used in all years for purposes of determining eligibility for reconciliation payments.

Each participant hospital may qualify for a quality incentive payment. The quality incentive payment is not a separate payment stream, but rather is used to determine the effective discount factor used to calculate a hospital's target prices. Depending on a participant hospital's quality performance, in performance years 1, 4, and 5, the quality incentive payments could result in effective discount factors ranging from 3 percent to 1.5 percent. In performance years 2 and 3, the quality incentive payments could result in effective discount factors for purposes of calculating reconciliation payments ranging from 3 percent to 1.5 percent, and for purposes of calculating repayment amounts from 2 percent to 0.5 percent. The summary includes a table in section III.C.5 below showing the exact relationship between quality scores and the discount factor.

CMS states that if hospitals' quality performance during the CJR model is similar to historical quality performance, it would expect the majority of the participant hospitals to qualify for an effective discount factor of 2 percent each performance year for purposes of reconciliation payment calculations, the same discount factor proposed for all participant hospitals in the proposed rule. By using a range of discount factors, it offers more participant hospitals an opportunity to qualify for reconciliation payments, compared to quality requirements in the proposed rule, and enables the CJR program to better reward the highest quality participant hospitals.

Section III.C.5 below provides more details on quality incentive payments, effective discount factors, the link between quality and payment, and how participant hospitals may perform based on historical quality performance.

5. Use of Quality Performance in the Payment Methodology

CMS finalizes a quality performance policy for the CJR that is substantially different from the one that was proposed; it is a modified version of the composite quality score alternative that CMS described in detail in the proposed rule but elected not to propose at that time. Under the proposed rule methodology, a CJR hospital would have had to meet or exceed a minimum performance threshold on each of three proposed measures for a performance year in order to qualify for reconciliation payments (in addition to having episode spending below the target price for the performance year.) A hospital that failed to meet the threshold in a year for one or more of the three measures would not be eligible for reconciliation payments. (This minimum performance threshold was proposed to be set at the 30th percentile for the first three years and then increased to the 40th percentile for years four and five.) In addition, hospitals that voluntarily submitted data on patient-reported outcomes of THA/TKA would have received an adjustment to the discount percentage used to set the target price in the episode payment methodology. Specifically, instead of applying the standard discount percentage of 2.0 percent, hospitals successfully submitting the specified data would have received a discount of 1.7 percent.

The quality measures on which hospital performance will be assessed for determining CJR payments are described in further detail in section III.D below. That section addresses measure specifications, reporting periods, and public display of participating CJR hospital performance. The final measures relate to THA/TKA complications and patient experience as measured by the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. CMS had additionally proposed to require a third measure involving THA and TKA readmissions, but this measure is not included in the final policy. Voluntary data submission on patient-reported outcomes on elective THA and TKA procedures will be built into the composite quality score and is discussed in section III.D.

CMS Response to Comments on Proposed Quality Performance Methodology

In changing direction from the proposed rule, CMS says it is addressing concerns raised in numerous comments on its proposed approach for incorporating quality performance into the CJR payment methodology. CMS agrees with concerns raised by commenters about the number of hospitals under the proposed rule method with quality performance levels that would make them ineligible for reconciliation payments, even if they achieved episode savings during a performance year. CMS says this is about one-third of hospitals, while commenters estimated this to be one half. Regardless, CMS agrees that the proposed thresholds would provide insufficient quality and cost improvement incentives for a substantial portion of hospitals participating in the CJR model. While CMS abandons the proposal to require hospitals to achieve the 30th percentile on each measure in order to qualify for reconciliation payments, it continues to believe that assigning hospital measure results to a percentile distribution is an appropriate way to categorize variation in hospital performance.

CMS concludes that the composite score methodology it is finalizing is the most appropriate approach to achieve its goal of incentivizing high-value care through episode-based payments for LEJR procedures, and that a “substantial proportion” of commenters supported a composite score approach or other method that would provide greater financial reward to hospitals with higher quality performance. CMS notes that the Hospital Value-Based Purchasing (VBP) and Hospital Acquired Condition (HAC) Reduction programs and the Medicare Shared Savings Program (MSSP) incorporate similar composite scoring methods. CMS says that rather than using a definitive cut off performance level such as was proposed, the final composite quality score methodology provides hospitals with multiple possible combinations of quality performance that can result in eligibility for a reconciliation payment. When it elected not to propose this approach in the proposed rule in favor of applying the 30th percentile threshold for each measure, CMS offered three reasons: (1) the limited set of measures could diminish the importance of each measure, (2) the measures represent clinical goals that all participating hospitals should focus on, and (3) assessing performance using absolute values is the most appropriate way of providing achievable and predicable quality targets.

CMS now believes that despite the small number of CJR measures, they represent clinical outcomes and patient experience and each carries substantial value in the composite quality score. Further, it says that overall performance should be considered and rewarded rather than performance on each individual measure, and that the composite score methodology will permit the addition of measures in the future.

CMS disagrees with commenters who maintained that CMS should not use a point estimate for the THA/TKA complications and readmissions measures and instead use confidence intervals such as those used on Hospital Compare. For example, some commenters suggested that CMS determine as ineligible for reconciliation payments only those hospitals that have performance displayed as “worse than national rate.” CMS says that the intervals were developed only for Hospital Compare reporting and not as part of the measures themselves. In addition, so few

hospitals fall into the “worse than national rate” category that CMS believes using this standard would essentially eliminate pay-for-performance in the CJR model.

Commenters recommended that CMS take improvement into account as well as achievement in determining quality performance. This is a feature in the hospital VBP Program and in the MSSP, but was not part of the proposed methodology. CMS believes that the composite quality score policy will indirectly reward quality improvement and in response to comments further establishes a policy to refine the composite quality score to reflect performance improvement.

CMS does not agree with commenters suggesting that it require only quality reporting for the first year of the CJR model. Because the two final measures are already used in other CMS quality programs, it expects hospitals to be focused on improving performance on them.

Numerous other comments on the proposed rule quality performance approach are described, and the final rule also includes discussion of comments on alternatives that CMS had described in the proposed rule.

Description of Final Policy

Calculation of Composite Quality Score. Under the final policy, a CJR hospital will receive a composite quality score based on its performance on the following three components, weighted as shown in the table below. (The final weights differ from the proposed rule discussion of the composite quality score alternative because the THA/TKA readmission measures is not being finalized, requiring CMS to redistribute the 20 percent weight for that measure. CMS does so by adding 10 percent to the weights for each of the two required measures.)

Quality Measure	Weight in Composite Quality Score
THA/TKA complications	50%
HCAHPS	40%
THA/TKA patient-reported outcome measure and limited risk variable data submission	10%
Note: These measures are discussed in section III.D	

The hospital’s score for the THA/TKA complications and HCAHPS measures will be based on the performance percentile in which the hospital falls relative to national performance on each measure. Table 18 (shown below) provides the scale of points for the two measures; these points reflect the relative weights given to the components of the quality composite score, shown above. Because the 40% weight for HCAHPS is equal to 80% of the 50% weight given to the THA/TKA complications measure, the points that will be given for HCAHPS performance are equal to 80% of the points given for the complications measure at the same level of performance.

Hospitals performing below the 30th percentile on a measure will receive zero points for that measure. CMS believes that quality performance below this level on what it describes as “well established measures” should not receive points.

Missing values will occur if a hospital does not meet a measure’s case minimum; these are described in section III.D below. If a hospital does not have a value for one of the measures it will be assigned to the 50th percentile for that measure. CMS notes that a missing value may also occur in a rare case if an error is found in the data used to calculate the THA/TKA complications measure that results in suppression of the Hospital Compare data for that measure. Further, CMS notes that because the THA/TKA complications measure only includes primary elective THA/TKA procedures, a participant hospital may have LEJR episodes but no cases that meet the measure criteria.

Performance Percentile	THA/TKA Complications Measure Quality Performance Points (1 additional point available for improvement)	HCAHPS Quality Performance Points (0.8 additional points available for improvement)
≥ 90 th	10.00	8.00
≥ 80 th and <90 th	9.25	7.40
≥ 70 th and <80 th	8.50	6.80
≥ 60 th and <70 th	7.75	6.20
≥ 50 th and <60 th	7.00	5.60
≥ 40 th and <50 th	6.25	5.00
≥ 30 th and <40 th	5.50	4.40
<30 th	0.00	0.00

The total composite quality score for a hospital will equal:

- Quality performance points received on the two measures according to the scale in the table above, plus
- Two points if a hospital successfully submits the THA/TKA patient reported outcome voluntary data described in III.D, plus
- Any improvement points earned on the THA/TKA complications (1.0 improvement point) or HCAHPS (0.8 improvement points).

Improvement points equal to 10 percent of the maximum score for a measure (1.0 point for the THA/TKA complications measure and 0.8 points for the HCAHPS) will be awarded for a performance period to hospitals that have improved their individual performance by three deciles or more on the measure when compared with the prior year. CMS says that based on historical Hospital Compare data, a three decile improvement is a “...challenging but attainable threshold for hospitals and reflects “true improvement in quality performance...” It agrees with

commenters that it should directly reward quality improvement under the CJR model, in particular because this will provide incentives to hospitals with quality performance that is lagging. However, CMS believes that the actual level of quality performance should be more highly valued, with a smaller contribution to the score for quality improvement. Because the improvement points are equal to 10 percent of the maximum score, CMS notes that when hospitals are awarded improvement points on a required measure, the total points for that measure will be slightly greater than the measure performance points awarded to a hospital in the next higher performance decile. CMS estimates that 55 participant hospitals would qualify for improvement points on the THA/TKA complications measure and 30 hospitals on HCAHPS, based on performance over the most recent two years.

Measure results from the prior year will be used to assess improvement. In performance year 1, the prior year time frame is July 1, 2015 through June 30, 2015 for the HCAHPS measure, and it is April 1, 2012 through March 31, 2015 for the THA/TKA complications measure.

Composite Quality Score Effect on Reconciliation Payment Eligibility and Discount Percentage. The hospital's composite quality score will place them into one of four "quality categories," which are used to determine whether they are eligible for reconciliation payments and the discount that applies in calculating the hospital's target price and therefore determines its reconciliation payment or repayment amount for a performance year. Tables 19 through 21 of the final rule (summarized into a single table below) show how the composite score and quality category will be translated into reconciliation eligibility and the discount percentages in each of the five performance years. (These scoring ranges differ from the proposed rule discussion of this alternative because as noted above, the THA/TKA readmission measure is not being finalized, and because the final rule includes improvement points, which were not part of the proposed rule discussion.)

Under the final rule, in each of the five CJR model years, hospitals must achieve a composite quality score of at least 4.0 in order to qualify for reconciliation payments or quality incentive payments. However, a score below 4.0 will not affect the calculation of a hospital's repayment amount if the hospital's actual spending exceeds the target price. CMS believes that establishing a minimum composite quality score is necessary to protect beneficiaries from excessive reductions in utilization that may result from the financial incentives under the episode payment approach. Based on current hospital quality measures performance, CMS estimates that 90 percent of participant hospitals would have a composite quality score of 4.0 or greater.

Before taking the quality composite score into account, the discount percentage used to determine whether a hospital qualifies for reconciliation payments or repayments is 3.0 percent. (While the proposed rule included a baseline discount percentage of 2.0 percent, a 3.0 percent discount was included in the description of this quality performance alternative in the proposed rule.) Hospitals with a composite quality score that places them in the "Good" or "Excellent" quality categories will have more favorable discount percentages of 2.0 and 1.5, respectively.

CMS emphasizes that hospitals can benefit from high quality performance even if they do not achieve savings. For example, in performance year 4, a hospital in the “Excellent” category that does not achieve savings would have its reconciliation repayment amounts reduced by 1.5 percent of the pre-discount target price. By contrast, in that year, a hospital that achieved savings but had quality performance rated as “Acceptable” would have a 3.0 percent reduction built into its target price.

CMS notes that under the adopted methodology, the final stop-loss and stop-gain limits that are described in section III.C.8 below do not change for hospitals in different quality categories.

RELATIONSHIP OF COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT PERCENTAGE EXPERIENCED AT RECONCILIATION, BY PERFORMANCE YEAR					
Composite Quality Score	Quality Category	Eligible for Reconciliation Payment	Eligible for Quality Incentive Payment	Effective Discount Percentage for Reconciliation Payment	Effective Discount Percentage for Repayment Amount
Performance Year 1 (From Table 19)					
<4.0	Below Acceptable	No	No	3.0%	Not applicable
≥4.0 and <6.0	Acceptable	Yes	No	3.0%	Not applicable
≥6.0 and ≤13.2	Good	Yes	Yes	2.0%	Not applicable
>13.2	Excellent	Yes	Yes	1.5%	Not applicable
Performance Years 2 and 3 (From Table 20)					
<4.0	Below Acceptable	No	No	3.0%	2.0%
≥4.0 and <6.0	Acceptable	Yes	No	3.0%	2.0%
≥6.0 and ≤13.2	Good	Yes	Yes	2.0%	1.0%
>13.2	Excellent	Yes	Yes	1.5%	0.5%

RELATIONSHIP OF COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT PERCENTAGE EXPERIENCED AT RECONCILIATION, BY PERFORMANCE YEAR					
Composite Quality Score	Quality Category	Eligible for Reconciliation Payment	Eligible for Quality Incentive Payment	Effective Discount Percentage for Reconciliation Payment	Effective Discount Percentage for Repayment Amount
Performance Years 4 and 5 (From Table 21)					
<4.0	Below Acceptable	No	No	3.0%	3.0%
≥4.0 and <6.0	Acceptable	Yes	No	3.0%	3.0%
≥6.0 and ≤13.2	Good	Yes	Yes	2.0%	2.0%
>13.2	Excellent	Yes	Yes	1.5%	1.5%

CMS provides the following estimates of how hospitals would be distributed among these categories, based on current quality measure performance of participant hospitals:

- 10 percent would be placed in the "Below Acceptable" quality category, and therefore not eligible for reconciliation payments;
- 12 percent would be eligible for reconciliation payments through placement in the "Acceptable" quality category but would not receive quality incentive payments;
- 64 percent would be placed in the "Good" quality category and therefore eligible for reconciliation payments and for quality incentive payments valued at 1.0 percent of the hospital's benchmark episode price; and
- 14 percent would fall into the "Excellent" quality category and therefore eligible for reconciliation payments and for quality incentive payments valued at 1.5 percent of the hospital's benchmark episode price.

Changes to regulatory text. The regulatory text at 42 CFR 510.315 sets forth the final pay-for-performance methodology, and the text at §510.305(f)(2), (g)(2) and (g)(3) is changed from the proposed rule to reflect the final composite quality score policy. In addition, definitions of 'composite quality score', 'quality improvement points' and 'quality performance points' are added at §510.2.

6. Process for Reconciliation

a. Net Payment Reconciliation Amount (NPRA)

Each participant hospital's actual episode payment performance is compared to its target prices. A participant hospital could have multiple target prices for episodes ending in a given performance year, based on:

- the MS-DRG anchor (MS-DRG 469 vs. MS-DRG 470, with fracture vs. without fracture),
- the performance year when the episode was initiated, and
- 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, or October 1 through December 31 of the prior performance year).

CMS determines the applicable target price for each episode, and the difference between each CJR episode's actual payment and that target price (calculated as target price minus the CJR actual episode payment) is aggregated for all episodes for a participant hospital within the performance year. The aggregate result is referred to as the raw Net Payment Reconciliation Amount (NPRA). CMS finalizes its proposal to apply these steps:

- 1) Identify episode payments and corresponding target prices for episodes attributed to CJR eligible hospitals;
 - exclude CJR episodes that overlap with BPCI episodes and exclude PBPM payments for certain programs and models (both are discussed in section III.C.7 below)
- 2) Make the following adjustments in the same manner that they were made to historical spending in setting the target prices (as discussed in section III.C.4. above):
 - remove the effects of special Medicare payment provisions and adjustments and normalize for wage differences;
 - prorate spending related to services that extend beyond the episode time period; and
 - cap actual episode payments at anchor MS-DRG and region-specific high episode payment ceilings
- 3) Include adjustments to account for hospital responsibility for increases in post-episode payments (discussed in section III.C.8.d. below); and
- 4) Include adjustments for stop-loss and stop-gain limits (discussed in section III.C.8.b. below).

CMS finalizes its proposal to exclude any CJR reconciliation payments or repayments to Medicare under the CJR model for a given performance year from the NPRA for a subsequent performance year.

Comments and CMS Response: Commenters emphasized the need to accurately account for wage index differences when calculating target prices and conducting reconciliation activities. CMS responds that this rule finalizes a target price calculation policy to normalize for wage index differences at the claim level and to reintroduce wage index differences based on the participant hospital's wage index and labor cost share. To maintain consistency with the target

price calculations, and to more accurately normalize for the effects of wage index differences, CMS will apply the same claim-level wage index normalization to claim payments included in actual episode expenditures for each performance year when calculating a hospital's NPRA.

Similarly, CMS will reintroduce wage index differences when calculating NPRA by applying the participant hospital's wage index and 0.7 as the labor cost share. Thus, the reconciliation process exactly follows the target price calculation approach for accounting for wage index differences. Both the claims-level wage normalization and the reintroduction of wage differences are described in section III.C.4.b.(7) above.

CMS disagreed with a comment that it should perform reconciliation calculations differently when a beneficiary in a CJR episode receives PAC from a SNF or HHA not recommended by the CJR hospital discharge planners. CMS does not believe it would be appropriate to make adjustments to a given hospital's NPRA based on the choice of PAC facility for beneficiaries discharged from that facility.

b. Payment Reconciliation

CMS finalizes its proposal to reconcile a participant hospital's CJR actual episode payments against the target price 2 months after the end of the performance year. It will calculate the NPRA based on claims submitted by March 1 following the end of the performance year and make a reconciliation payment or initiate repayment from hospitals responsible for repayment, as applicable, approximately 6 months after the end of the performance year in the 2nd quarter of following year.

CMS also finalizes its proposal to calculate the prior performance year's episode spending and NPRA a second time during the following performance year's reconciliation process in order to account for final claims run-out (i.e., calendar year claims submitted after March 1) as well as overlap with other CMS payment models such as BPCI. The subsequent reconciliation calculation also will account for potential changes in the effective discount percentage or quality incentive payment under the CJR model following decisions on an IQR program appeal (as discussed in section III.D. below).

The subsequent reconciliation calculation will occur approximately 14 months after the end of the prior performance year. If the re-calculation produces a result other than zero, CMS will apply the stop-loss and stop-gain limits (discussed in section III.C.8.b below) to the calculations in aggregate for that performance year (the initial reconciliation and the subsequent calculation) to ensure the amount does not exceed these limits. CMS then will apply 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.

During the reconciliation process for performance year 2 only, the subsequent calculation amount (for performance year 1) will be applied to the performance year 1 NPRA to ensure that the combined amount is not less than 0. If a CJR hospital has a positive NPRA for performance

year 1, and the subsequent calculation for performance year 1 the following year 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), the hospital will only be financially responsible for a repayment amount that would net the performance year 1 NPRA and subsequent calculation for year 1 to zero. For performance years 2 through 5, Medicare will hold the participant hospital responsible for repaying the absolute value of the repayment amount following the rules and processes for all other Medicare debts.

Consistent with BPCI Model 2 operations, 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.

Comments and CMS Response: A few commenters objected to the retrospective reconciliation process and suggested various forms of a prospective bundled payment or a blended reconciliation approach. CMS finds that a blended approach would bring many operational challenges and administrative burden to hospitals. CMS refers readers to section III.C.2.b. for a discussion of the retrospective payment methodology (see that section above in this summary).

Many commenters requested that CMS conduct reconciliation activities quarterly or semi-annually rather than annually to provide revenue and cash flow to hospitals throughout the year to aid in care coordination and redesign efforts, and for other reasons. Other commenters agreed with annual reconciliation but requested that CMS also conduct interim quarterly reconciliation projections to provide hospitals with information on financial performance throughout the performance year.

CMS responds that providers will continue to bill and be paid through normal Medicare FFS processes throughout the model for Part A and Part B services furnished to beneficiaries during a CJR episode. It also notes that beginning in the second quarter of 2017 when the first reconciliation is performed, CJR hospitals will be able to utilize any reconciliation payments they earn to invest in care redesign and coordination efforts on an ongoing basis. It also emphasizes that the delay of financial repayment responsibility until performance year 2 means no hospital will be required to make a repayment to Medicare until the second quarter of 2018 for actual episode spending exceeding the target price.

With respect to quarterly or semiannual reconciliation, CMS reports that in the BPCI reconciliation process, which is quarterly with 3 subsequent reconciliation calculations, BPCI participants have experienced significant fluctuation in financial results between the initial reconciliation and the subsequent calculations. CMS believes its proposed annual reconciliation approach will lead to more stable financial results for providers. CMS says that based on its experience with the BPCI models, a quarterly reconciliation process results in model participants' near constant engagement in the reconciliation and appeals processes. Finally, CMS says that it aligned the annual reconciliation timeline with the ACO models and program in

order to make reconciliation calculations and associated reconciliation amounts and repayment amounts available before the ACO models and program begin their annual financial reconciliation calculations; such a timeline is necessary to be able to account for program and model overlap.

CMS reiterates that it will provide both line-level and summary claims data to model participants on a quarterly basis, as discussed in section III.E. below. These data will provide ongoing feedback to hospitals about their performance under the model, by including both raw claims as well as summary data with information about their episode spending and care patterns.

Several commenters expressed concerns about post-payment denials and Recovery Audit Contractor (RAC) or MAC reviews that may occur after the CJR model reconciliation processes are complete, and asserted that providers could be doubly penalized for such claims if review and denial occurs after the subsequent reconciliation calculation. One commenter urged CMS to exempt all claims attributed to the CJR model from post-payment review and denial.

CMS acknowledges that audits and reviews may occur after our reconciliation processes are complete, but believes that concluding reconciliation processes 14 months after the completion of a performance year provides a reasonable timeframe for claims run-out and subsequent actions on a claim and is consistent with other payment reconciliation processes, such as the reconciliation of hospital cost reports. CMS considered whether it would be appropriate to allow subsequent reconciliations if claims are denied and reprocessed after the second reconciliation and it concluded that this would not be appropriate for several reasons.

CMS states that prohibiting review of all claims submitted for a beneficiary during a CJR episode would not be consistent with its stated goals of the model to monitor for quality and appropriateness of care.

Table 24 below provides the reconciliation timeframes for the CJR model.

TABLE 24: FINAL TIMEFRAME FOR RECONCILIATION IN CJR

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 June 30, 2016 to December 31, 2016	March 1, 2017	Q2 2017	March 1, 2018	Q2 2018

Model Performance Year	Model Performance Period	Reconciliation Claims Submitted By	Reconciliation Payment or Repayment	Second Calculation to Address Overlaps and Claims	Second Calculation Adjustment to Reconciliation
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 CJR hospitals.

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

a. Overview

The final rule identifies current or forthcoming programs and models in Table 25 (reproduced below) as ones with potential overlap with beneficiary episodes under the CJR model.

TABLE 25: CURRENT PROGRAMS AND MODELS WITH POTENTIAL OVERLAP WITH CJR MODEL

Program/Model	Brief Description	Shared Savings?	Per-beneficiary-per-month (PBPM) payments?
Pioneer ACO Model	ACO shared savings model	Yes	No

Program/Model	Brief Description	Shared Savings?	Per-beneficiary-per-month (PBPM) payments?
Medicare Shared Savings Program (Shared Savings Program)	ACO shared savings program	Yes	No
Next Generation ACO Model*	ACO shared savings model	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 PAC services or both	No	No
Oncology Care Model (OCM)*	Multi-payer model for oncology physician group practices (PGPs)	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 (MCCM)*	Hospice concurrent care model	No	Yes

Program overlap presents these potential issues:

- Beneficiaries in CJR episodes could also be part of BPCI Model 2 or 3 LEJR episodes or BPCI non-LEJR episodes, and the clinical services provided as part of each episode may overlap entirely or in part;
- CJR reconciliation payments and 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;
- Some Innovation Center models make PBPM payments to entities for care coordination and other activities, either from the Part A or B Trust Fund or both, or from the Innovation Center's own appropriation under section 1115A(f) of the Act, and these payments may occur during a CJR episode; and
- There could be instances when the expected Medicare savings for a CJR beneficiary's episode (represented by the discount percentage) is not achieved by Medicare because

part of that savings is paid back to the hospital or another entity under the Shared Savings Program or a total cost of care model in which the beneficiary also is included.

In response to a comment that CMS should not limit providers from developing and implementing other episode-based payment models while participating in the CJR model, CMS states that it has not included any limitations on participation in future or current models in this final rule and that the policies in this section are intended to allow CJR hospitals to participate in other models and initiatives concurrently with the CJR model.

b. CJR Beneficiary Overlap with BPCI Episodes

In all such scenarios in which there is overlap of CJR beneficiaries with any BPCI LEJR episode, CMS proposed that the BPCI LEJR episode under Models 1, 2, 3, or 4 would take precedence and CMS would cancel (or never initiate) the CJR episode. Thus, CMS would exclude the CJR episode from the CJR participant hospital's reconciliation calculations in which it compares actual episode payments to the target price under the CJR model.

CMS noted that its policy 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 rejects giving precedence to the CJR episode in these situations, however, believing that steering opportunities will be limited due to the preservation of beneficiary choice of provider in the CJR model and consideration that CJR hospitals will be required to provide patients with a complete list of all available PAC options.

Comments and CMS Response: In response to commenters' request that CMS provide additional examples of overlap situations, CMS indicates that overlap could occur in, but is not limited to, these situations:

- A beneficiary is admitted to a CJR hospital for an LEJR procedure and discharged to a PAC provider participating in BPCI Model 3 for the LEJR episode; the episode is attributed to the BPCI Model 3 PAC provider.
- A beneficiary is admitted to a CJR hospital for an LEJR procedure by a PGP participating in BPCI Model 2; the episode is attributed to the BPCI Model 2 PGP.
- A beneficiary is admitted to a CJR hospital for an LEJR procedure by a PGP participating in BPCI Model 3; the episode is attributed to the BPCI Model 3 PGP.
- A beneficiary is admitted to a CJR hospital for an LEJR procedure, followed by a second phased LEJR procedure within 90 days of the first procedure. The second LEJR procedure is attributed to a PGP participating in BPCI Model 2 or 3 or is followed by admission to a PAC provider participating in BPCI Model 3 for the LEJR episode. The first LEJR episode is canceled and the second episode is attributed to the BPCI provider.

Many commenters supported applying precedence rules that attribute episodes to BPCI PGPs and PAC providers in cases of overlap with CJR, noting the significant investment PGPs and PAC providers have made in BPCI. Other commenters, however, felt it was unfair since BPCI

participants entered models voluntarily, but hospitals in CJR are not given an opportunity to opt out and are at risk for episodes where others did not perceive enough opportunity to voluntarily enter into risk agreements under BPCI. Some commenters suggested that CMS apply a minimum threshold to remove hospitals from the CJR model based on BPCI PGP participation. Commenters also:

- disagreed with giving precedence to BPCI PAC entities who are at risk for a shorter episode duration than the CJR episode;
- expressed concern that the precedence rules would lead to BPCI PGPs capturing lower-risk episodes, leaving CJR hospitals at risk for more high-risk episodes;
- believed that following both the BPCI and CJR rules within the same hospital could be confusing for hospitals and partner providers and suppliers, limiting providers' ability to target care redesign efforts for CJR; and
- requested that CMS publish a public list of BPCI episode initiators whose episodes would take precedence over CJR episodes.

CMS acknowledges that some CJR hospitals could be financially at risk for a small proportion of LEJR episodes initiated at the hospital if there are high-volume PGPs or PAC providers in their community initiating LEJR episodes under BPCI, but it believes those hospitals have opportunity under the CJR model and provides examples to support its belief. CMS also noted the concern that physician and PAC providers participating in BPCI will focus on low-risk beneficiaries, leaving higher-risk beneficiaries to be the participant hospital's responsibility under the CJR model and causing the CJR model beneficiaries in a performance year to differ from those in the baseline period used to set target prices. CMS, however, cites CJR model design features that it believes make this unlikely, including the risk stratification based on hip fracture.

Regarding a list of BPCI episode initiators, CMS provides this link to the publicly available list of current episode initiators in BPCI: <http://innovation.cms.gov/initiatives/Bundled-Payments/Participating-Health-Care-Facilities/index.html>.

Responding to commenters requesting clarification on whether BPCI or CJR episode would have precedence when the same beneficiary could be in a CJR model episode and a BPCI non-LEJR episode for an overlapping period of time, CMS says that it did not propose a calculation to attribute savings between the two models when concurrent episodes occur. It clarifies that each model would continue to perform financial reconciliation activities as usual and that it is possible that savings achieved during one model could also be counted as savings under the other model. It believes such overlap situations will be relatively rare, but provides two examples of potential situations:

- A beneficiary is admitted to a CJR hospital for an LEJR procedure and later readmitted to the same or a different CJR hospital for a congestive heart failure episode under BPCI.
- A beneficiary is in a BPCI PGP Model 2 episode for chronic obstructive pulmonary disease at a CJR hospital and has an LEJR procedure at the same or a different CJR hospital during the post-anchor hospital discharge period of the BPCI episode.

Summary of Final Decisions: CMS finalizes its proposal, without modification, to apply precedence to BPCI Model 2 and Model 3 PGP and PAC LEJR episodes. This means that if for any portion of CJR model episode, a beneficiary would also be in a BPCI LEJR episode under Model 2 or Model 3, CMS will cancel (or never initiate) the CJR episode (see section III.B.3. above for additional detail). CMS also finalizes its proposal, without modification, to allow for overlap between the period of time in which a beneficiary is in a CJR episode and a BPCI non-LEJR episode.

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

To ensure that the full CJR 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, CMS finalizes its proposal, without modification, to make beneficiary-specific information on CJR-related reconciliation payments and repayments available to them. It would calculate beneficiary-specific reconciliation payment or repayment amounts for CJR episodes in addition to determining reconciliation payments and repayments for the participant hospitals and make it available to these other programs and models through the CMS Master Database Management (MDM) System. CMS currently uses this approach to account for overlaps between beneficiaries aligned to Pioneer and MSSP ACOs and BPCI model beneficiaries.

As finalized in this rule and discussed in section III.C. 6 above, CMS does not make separate payments to, or collect repayments from, participating CJR hospitals for each individual episode, but instead makes a single aggregate reconciliation payment or repayment determination for all episodes for a single performance year.

Comments and CMS Responses: Many commenters expressed concern about how the CJR program would affect ACO financial calculations. Because total cost of care models and programs, including the Shared Savings Program and other ACO models, would include the full CJR episode payment (that is, including any reconciliation or repayment amounts) in their annual financial calculations determining the total spending for a beneficiary, most of the savings achieved during a CJR episode would be attributed to the CJR model. Commenters generally supported the proposal to attribute savings to the CJR episode when the CJR hospital is aligned to the ACO as a participant or provider/supplier, but many urged that savings be attributed to the ACO when a beneficiary is assigned to an ACO and initiates a CJR episode at a hospital that is not aligned to the ACO as a participant or provider/supplier.

CMS understands the concern but chooses to maintain the approach it has taken in other episode payment models because it believes the change would be unworkable as well as inconsistent with the approach taken in these other models. CMS identifies three approaches in which it potentially could attribute savings achieved during a CJR episode to the ACO rather than the CJR hospital, but concludes that each option has far-reaching and undesirable implications for the policies and operations of both the CJR model and ACOs. These implications and concerns are developed in some depth in the rule.

CMS also notes that the population health focus of ACOs is much broader than the CJR model. For example, evidence-based conservative management of the underlying clinical condition, most likely long-standing osteoarthritis, may delay the THA or TKA or eliminate the need for it altogether, in which case a CJR model episode would never occur. CMS observes that an ACO's expertise and skill in population health care management may sharply reduce the need for inpatient hospitalization, resulting in substantial direct savings to the ACO and no initiation of an episode under an episode payment model. The rule notes CMS' interest in pursuing both episode-based payment models and ACOs as avenues that can lead to improved care redesign and coordination strategies, and ultimately, improved quality of care for beneficiaries. An important feature of testing and evaluation various innovation models is understanding how various models or programs work alongside other initiatives.

CMS says that it will consider the perspectives offered by the commenters on the CJR model as it designs future episode payment models, considers expansion of successful episode payment models, or considers changes to existing policies.

Responding to a comment that CMS should not account for overlap between models by including reconciliation payments or savings amounts from one model in the financial calculations for another model, CMS cites its fiduciary responsibility to the Medicare Trust Fund payments, including not paying back savings that should be maintained by the Medicare program. CMS notes that under the Shared Savings Program regulations at 425.604(a)(6)(ii), CMS considers all Part A and B expenditures, including payments made under a demonstration or model. Thus, the Shared Savings Program regulations require that these payments be taken into account in calculating shared savings or losses.

CMS rejects providing CJR hospitals with a list of beneficiaries prospectively aligned to ACOs because doing so could potentially lead to patient steering. It also rejects as inappropriate allowing ACOs to opt out of the CJR model for beneficiaries aligned to those ACOs. Finally, it rejects a suggestion that it require CJR hospitals to sign agreements with ACOs in the same MSA to coordinate care for such beneficiaries. CMS does not require specific care coordination agreements or arrangements between entities participating in different CMS models or programs.

d. Accounting for PBPM Payments in the Episode Definition

CMS finalizes its proposals to determine whether the services paid by PBPM payments are excluded from the CJR episode on a model-by-model basis depending on their funding source and clinical relationship to the CJR episode. If CMS finds the services to be clinically related to the CJR episode and the PBPM payment is funded through the Medicare Part A or B Trust Fund, it includes the services in the CJR episode unless the services are otherwise excluded based on the principal diagnosis code on the claim. PBPM model payments that it determines to be clinically unrelated are excluded, regardless of the funding mechanism or diagnosis codes on claims for those payments. All services paid by PBPM payments funded through the Innovation

Center's appropriation under section 1115A of the Act are excluded from CJR episodes, without a specific determination of their clinical relationship to CJR episodes.

CMS makes its determination about whether services paid by a new model PBPM payment that is funded under the Medicare Trust Funds are clinically related to CJR episodes through the same sub-regulatory approach that it uses to update the episode definition for excluded MS-DRGs and ICD-9-CM diagnosis codes (or their ICD-10-CM equivalents). The proposed determination is posted to the CMS website to allow for public input, followed by a final posting after consideration of the public input.

Of the four models with PBPM payments shown in Table 25 and addressed in the rule, three are excluded from CJR episodes and one is included. CMS finalizes its proposal that services financed by PBPM payments made by the Multi-payer Advanced Primary Care Practice (MAPCP) model are included in CJR episodes. These payments are funded through the Trust Fund and support new or enhanced services that coordinate care, improve access, and educate patients with chronic illnesses. CMS expects these services to improve quality and reduce spending for services, such as hospital readmissions. CMS considers them to be clinically related to CJR episodes because the PBPM payments would support care coordination for medical diagnoses that are not excluded from CJR episodes.

CMS excludes these Innovation Center models from CJR episodes:

- Oncology Care Model (OCM): episode-based payment initiated by chemotherapy treatment, a service generally reported with ICD-9-CM (or their ICD-10-CM equivalents) codes that are specifically excluded from the CJR episode;
- Medicare Care Choices Model: palliative care for beneficiaries with a terminal illness means the PBPM payments would pay for services that are clinically unrelated to CJR episodes; and
- Comprehensive Primary Care initiative (CPCi): paid out of the Innovation Center's appropriation and thus is excluded from CJR episodes.

[The Million Hearts model, a fifth model shown in Table 25 as including PBPM payments, was not addressed in the proposed or final rules.]

e. Accounting for Overlap with Medicare Initiatives Involving Shared Savings Programs and Total Cost of Care Models

The rule supports allowing beneficiaries to participate in broader population-based and other total cost of care models⁵, such as ACOs, as well as episode payment models that target a specific episode of care with a shorter duration, such as CJR. Thus, a beneficiary may be in a CJR episode by receiving an LEJR procedure at a CJR hospital and also be attributed to a provider participating in a model or program shown in Table 25 or a similar future model or program. CMS finalizes several policies, as proposed, to address CJR overlap with other

⁵ The rule uses "total cost of care" models to 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.

programs and models to facilitate beneficiary participation without attributing the same savings to more than one model or program. In general, CMS believes that it is most appropriate to attribute Medicare savings accrued during the CJR time period (hospital stay plus 90 days post-discharge) to the CJR model to the extent possible. CMS finalizes these policies to address CJR overlap with other models and programs.

Type of Model Overlapping with CJR	CJR Final Policy
Non-ACO total cost of care models, including these models shown in Table 25: CPCi, OCM, and MAPCP	To the extent that a portion of the CJR discount percentage is paid out as savings or other performance-based payment to a non-ACO model participant, the other model will make an adjustment to their financial reconciliation calculation to the extent feasible.
MSSP and other ACO models when a CJR participant hospital also participates in the ACO and the beneficiary in the CJR episode is also aligned to that ACO	The CJR model will 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 the Shared Savings Program or any other ACO model. If a CJR hospital did not earn a reconciliation payment, no adjustment is made. CMS will not increase the amount of a hospital's repayment amount in order to account for the portion of the discount percentage paid out as savings.
MSSP and other ACO models when a beneficiary receives an LEJR procedure at a participant hospital and the beneficiary is aligned to an ACO in which the hospital is not participating	CMS will <u>not</u> make an adjustment to any CJR reconciliation amount to account for any of the applicable discounts for an episode resulting in Medicare savings that is paid out as shared savings. CMS recognizes that this policy would allow an unrelated ACO full credit for the Medicare savings achieved during the episode and leaves overlap unaccounted.

8. Limits or Adjustments to Hospital Financial Responsibility

a. Overview

The overview provides a brief introduction to the section.

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

(1) Limit on Raw NPRA Contribution to Repayment Amounts

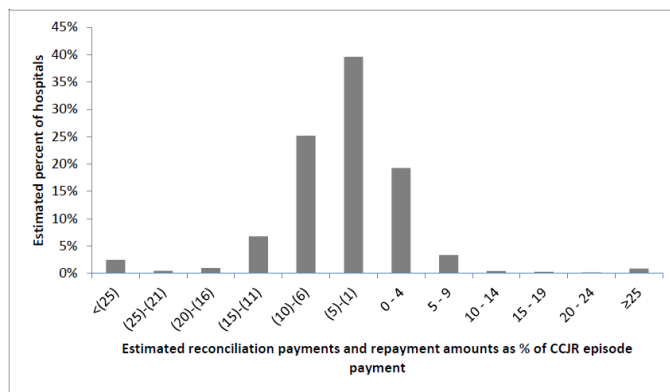
CMS finalizes its proposal that hospitals participating in CJR would begin to bear repayment responsibility beginning in performance year 2 for those episodes where actual episode expenditures are greater than the target price up to the level of the regional episode ceiling, a cap

set at two standard deviations above the mean regional episode payment. (The high episode payment cap is discussed in section III.C.3.c. above).

To provide additional protection to participant hospitals from owing large repayment amounts to Medicare, CMS proposed to limit the repayment amount for performance year 2, the initial performance year in which a hospital could face repayment, to no more than 10 percent of the hospital's target price for the anchor MS-DRG multiplied by the number of the hospital's CJR episodes anchored by that MS-DRG during the performance year, for each anchor MS-DRG in the model. For performance years 3 through 5, CMS proposed to set this "stop-loss" limit, the CMS term of art, to 20 percent.

Based on its national model of results for performance year 2 of the CJR model, CMS reports that the 10 percent stop-loss limit would impact the amount of repayment based on the raw NPRA for about 11 percent of hospitals. For performance year 3, the 20 percent stop-loss limit would affect only about 3 percent hospitals. The stop-loss limit for years 3 through 5 where repayment responsibility is fully implemented is consistent with the BPCI Model 2 policy. (See Figure 4 below.)

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, CJR 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.

Comments and CMS Responses: Several commenters urged that CMS delay downside risk or phase it in more slowly and offered various permutations concerning what the transition to downside risk might be, such as 3 percent in year 3, 6 percent in year 4 and 10 percent in year 5, which would align more with the Shared Savings Program Track 2. CMS agrees that a phase-in would be appropriate and finalizes stop-loss limits of 5 percent in performance year 2, 10

percent in performance year 3 and 20 percent for performance years 4 and 5. CMS disagreed with comments that it should allow hospitals to choose their level of risk among different tracks such as 5 percent stop loss/stop gain, 10 percent stop loss/stop gain or 20 percent stop loss/stop gain limits or that it should use dollar thresholds rather than percentages.

(2) Limit on Raw NPRA Contribution to Reconciliation Payments

CMS proposed a parallel limit on the amount it would pay to a hospital as reconciliation payments based on the raw NPRA. For all 5 performance years of the model, CMS proposed 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.

Using its national model for CJR performance year 2 policies under the assumption that utilization remains constant, CMS estimates that the 20 percent stop-gain limit, as it is called, would impact the reconciliation payment amount based on the raw NPRA for almost no hospitals. CMS notes that a stop-gain limit of 20 percent is consistent with BPCI Model 2 policy.

Comments and CMS Responses: Commenters were generally supportive of the proposed stop-gain limit policy at 20 percent, noting that it aligns with BPCI. To parallel its final policy to phase in the stop-loss limits, CMS adopts corresponding stop-gain limits in the final rule. Specifically, the stop-gain limit is 5 percent in performance years 1 and 2, 10 percent in performance year 3 and 20 percent in performance year 4 and 5.

Policies for Certain Hospitals to Further Limit Repayment Responsibility

CMS proposed 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. For rural hospitals, SCHs, Medicare Dependent Hospitals (MDHs) and Rural Referral Centers (RCCs), CMS proposed a stop-loss limit of 3 percent of episode payments in performance year 2 and a stop-loss limit of 5 percent of episode payments for performance years 3 through 5. That is, in performance year 2, a rural hospital, SCH, RRC or MDH that is a participant hospital would owe Medicare based on 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 CJR episodes with that anchor MS-DRG in the performance year. Additionally, in performance years 3 through 5, such a participant hospital would owe Medicare based on 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 CJR episodes with that anchor MS-DRG in the performance year.

CMS notes that these categories of hospitals often have special payment protections or additional payment benefits under Medicare due to the importance of preserving Medicare beneficiaries' access to care from these hospitals.

For purposes of the CJR model, CMS defines 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. Similarly, for the purpose of these additional protections, CMS refers to the definitions of SCHs in §412.92, MDHs in §412.108, and RRCs in §412.96. CMS proposed 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.

CMS considered excluding these categories of hospitals from the CJR model, but because the goal of the CJR model is to test episode payment for a broad variety of hospitals, CMS concluded that it would be preferable to include these hospitals in the model and provide additional protections from a large repayment responsibility.

Comments and CMS Responses: Several commenters supported the proposal to provide a more protective stop-loss for rural hospitals, SCHs, MDHs and RRCs, with several commenters requesting greater protection or exclusion from the CJR program. CMS responds that it wants to include these categories of hospitals in the CJR program to see the impact of a bundled payment model on providers that may not otherwise participate in a voluntary program and to better understand the generalizability of this model, and it reiterates the protections offered to these hospitals in the model.

CMS agreed with commenters that urban hospitals that reclassify to rural under §412.103 should be considered a rural hospital for the purposes of the CJR model and receive the additional stop-loss protection. CMS notes that rural hospitals were inadvertently excluded from the proposed regulation language at §510.305(e)(1)(v)(E) and corrects this omission in the final rule.

Some commenters suggested that CMS exclude low volume hospitals from the model, remove downside risk for low volume hospitals or provide a lower stop-loss limit for these hospitals, and included various definitions for what qualifies as a low volume hospital. CMS responds that changes made in the final rule, such as the phase-in of risk and stratification for hip fracture, should address these concerns, making special policies for low volume hospitals unnecessary.

CMS rejected commenters' suggestions to apply the protective stop-loss limit to hospitals in bankruptcy, or undergoing major restructuring under State oversight like safety net hospitals under the Medicaid DSRIP waiver in New York; to urban referral centers; and that it provide risk corridors for providers that partner with participant hospitals such as IRFs and SNFs. It does not believe it would be appropriate to carve out additional protections for other types of hospitals at this time because we want to evaluate, in part, the model's generalizability, which becomes challenging if it adds more exceptions. CMS will continue to monitor the effects of the model on different categories of hospitals.

CMS also rejected extending the additional protections to MDH hospitals after the statutory expiration of MDH status in September 30, 2017. After that date, hospitals will lose their MDH designation and their additional Medicare FFS payments provided under the MDH designation.

Final policy: CMS finalizes its proposal to provide for lower stop-loss limits for rural hospitals, RRCs, MDHs and SCHs at a level of 3 percent for performance year 2 and 5 percent for performance years 3 through 5. For the final rule, CMS modifies the proposed rule stop-gain limits to provide a stop-gain limit for these hospitals corresponding to the finalized stop-gain limits for other CJR hospitals. These limits are 5 percent in performance years 1 and 2, 10 percent in performance year 3 and 20 percent in performance year 4 and 5.

d. Hospital Responsibility for Increased Post-Episode Payments

To address a possible incentive to withhold or delay medically necessary care until after an episode ends to reduce actual episode payments, CMS proposed 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, as is consistent with BPCI Model 2. The proposed calculation would include prorated payments for PAC services, such as SNF and HHA, that extend beyond the episode (section III.C.3.b. above).

CMS 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 CJR eligible hospitals in the same region as the participant hospital. CMS proposed 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 discussed above.

Comments and CMS Responses: Some commenters opposed the proposal entirely, others supported monitoring 30-day post-episode spending but requested certain modifications to the proposal, and others supported the rationale but urged a monitoring-only policy without potential hospital repayments. Commenters also requested that the categories of services excluded from the episode definition should be excluded when determining the 30-day post-episode spending because they found it to be inappropriate to hold a hospital responsible for unrelated services, particularly those related to high-cost conditions like the onset of therapy for cancer or the sudden inclusion of clotting factors for hemophilia. CMS does not agree with the comments and references its experience with BPCI in continuing to include the policy.

Final policy: CMS finalizes the policy with a modification to conform to the change made in this final rule from "CJR eligible hospitals" to "CJR regional hospitals." CJR regional hospitals are all IPPS hospitals located in a region, including IPPS hospitals that are participants in BPCI Model 1 or in the risk bearing period of Models 2 or 4 for LEJR episodes. (See section III.C.4.b.(4) above for a discussion of the change to CJR regional hospitals.)

9. Appeal Procedures for Reconciliation (§510.310)

CMS had proposed to establish an appeals process for matters in dispute under the CJR model related to reconciliation and payment as well as other issues, such as enforcement mechanisms. The proposed appeals process would be a two-step process for payment matters consisting of (i) submission to CMS of a calculation error form by a participating hospital and (ii) reconsideration review conducted by a CMS official.

CMS finalizes all its proposals with one modification relating to the deadline by which a participating hospital must submit its calculation error form to preserve its right to seek review.

CMS reports that comments on its proposals varied widely among stakeholders though it notes that commenters that had experience with the BPCI models were generally supportive. A majority of comments indicated that the 30-day timeframe in which a participating hospital must submit its calculation error form to preserve its right to seek review was too short; commenters suggested 45 days, 60 days and 180 days. CMS agrees that 30 days is too short and finalizes a 45-day deadline to submit the error calculation form. CMS notes an extension in the timeframe during which a hospital may submit the form impacts its batch processing methodology which in turn affects reconciliation payments and repayments for all providers, not just those using the dispute resolution process; for this reason it declines to extend the period to 60 or 180 days. The finalized procedures are described below.

Payment

Payment to the hospital or repayment to CMS is determined under the CJR Reconciliation Report for a participating hospital for a performance year. CMS notes that it will immediately and vigorously seek repayment amounts owed to the agency by participating hospitals, including through the use of demand letters, referral to the Treasury Department and all other legal means.

Calculation Error Process

The calculation error process for participating hospitals to contest payment- or reconciliation-related matters requires a participating hospital, upon review of a Reconciliation Report for a performance year, to provide written notice to CMS of any error in the report through a calculation error form specified by CMS within 45 days of the Reconciliation Report issuance date. The default position is that the Reconciliation Report will be deemed final unless the participating hospital submits the written notice within the 45-day timeframe. Failure to timely submit the calculation error form will also result in the loss of appeal rights on matters contained in that report, including (but not limited to) the following:

1. The calculation of the reconciliation amount or repayment amount reflected on a report.
2. The calculation of NPRA.
3. The calculation of the percentiles of quality measure performance to determine eligibility to receive a reconciliation payment.
4. The successful reporting of voluntary PRO THA/TKA data to adjust the reconciliation payment.

Dispute Resolution

The dispute resolution process is only available to participating hospitals. For payment matters, the participating hospital must submit a timely calculation error form with respect to a Reconciliation Report or else it is barred from using the dispute resolution process for payment matters contained in that report for the performance year involved.

Assuming a properly submitted calculation error form, if the hospital is dissatisfied with the CMS response, it must submit a request for reconsideration review by a CMS reconsideration official which includes a detailed explanation of the basis for the dispute and supporting documentation with respect to payment matters.

Reconsideration review is on-the-record (i.e., limited to review of briefs and evidence). The CMS reconsideration official is supposed to “make reasonable efforts” to send the hospital a Scheduling Notice⁶ within 15 days of receipt of the review request and to issue a written determination within 30 days of review. That determination is final and binding.

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

10. Financial Arrangements and Beneficiary Incentives (Subpart F of Part 510)

CMS finalizes requirements for financial arrangements and beneficiary incentives among hospitals and other providers of services and suppliers caring for beneficiaries in CJR episodes of care, most of which are similar to or based on requirements applicable under existing demonstration projects, such as BPCI Model 2. CMS makes a number of modifications to its proposals in response to comments which are discussed in each section below. One of the more significant changes is that physician group practices (PGPs) that are collaborators may retain some or all of a gainsharing payment (subject to certain conditions); CMS also finalizes the process by which a PGP may distribute some or all of a gainsharing payment to individual member physicians or NPPs.

Financial Arrangements (§510.500)

CMS finalizes definitions for certain key terms applicable to the CJR model; these definitions set forth the requirements applicable to financial arrangements.

CJR collaborator means one of the following individuals or entities that enter into a CJR sharing arrangement: skilled nursing facility (SNF), home health agency (HHA), long-term care hospital

⁶ A Scheduling Notice should include the date and time of the review (which should be no later than 30 days after the date of the Scheduling Notice) and a description of the issues in dispute, the review procedures, and the evidence submission requirements.

(LTCH), inpatient rehabilitation facility (IRF), physician, nonphysician practitioner (NPP), outpatient therapy provider, and physician group practice. CMS declines to expand the list of providers and suppliers under this definition at this time though it does express a willingness to consider doing so in the future. CMS clarifies that physicians and NPPs must be enrolled in Medicare as participating or nonparticipating physicians/suppliers. As noted below, selection of CJR collaborators must include criteria for quality of care furnished to CJR beneficiaries.

Sharing arrangement means a financial arrangement between a participating hospital and a CJR collaborator for the sole purpose of sharing the following: (i) Reconciliation payments. (ii) The participating hospital's internal cost savings. (iii) The participating hospital's responsibility for repayment to CMS. The term is renamed to omit references to "CJR." Gainsharing payments may only be made and alignment payments may only be collected by a participating hospital pursuant to a sharing arrangement.

Collaboration agreement means a written, signed agreement between a CJR collaborator and a participating hospital that meets the requirements of §510.500(c) (relating to the parties' obligations under a CJR sharing arrangement, among other requirements). CMS renames the term to avoid potential confusion about the type and purpose of these agreements.

Gainsharing payment means a payment from a participating hospital to a CJR collaborator, under a CJR sharing arrangement, composed of only reconciliation payments, internal cost savings, or both.

Internal cost savings means the measurable, actual, and verifiable cost savings realized by the participating hospital resulting from care redesign undertaken by the hospital in connection with providing items and services to beneficiaries within specific CJR episodes of care. Internal cost savings does not include savings realized by any individual or entity that is not the participating hospital.

Alignment payment means a payment from a CJR collaborator to a participating hospital under a CJR sharing arrangement.

CMS reiterates that CJR sharing arrangements must be solely related to contributions of CJR collaborators to care redesign that achieve quality and efficiency improvements; that CJR collaborators (other than PGPs) must furnish services included in the episode to the CJR beneficiary to be eligible for Gainsharing or Alignment payments; and that Gainsharing and Alignment payments must be proportionally related to CJR beneficiary care. CMS finalizes its proposal to make participating hospitals responsible for ensuring collaborators comply with the terms and conditions of the CJR model through collaborator agreements. CMS also clarifies that these arrangements (collaboration arrangements, sharing arrangements, etc.) are financial not clinical arrangements.

CMS will not conduct program integrity screening of hospitals or CJR collaborators because, in part, it believes that all hospitals that meet the criteria for participation should participate—even those with a history of program integrity issues. CMS also notes it will evaluate the quality of

care and institute beneficiary protections that exceed those under current models and that its evaluation and monitoring provisions exceed those in effect under other CMS models.

Sharing Arrangements – Requirements. Sharing arrangements must be set forth in writing; must be entered into before care is furnished to a CJR beneficiary; and must include the following:

- The specific methodology and accounting formula for calculating and verifying internal cost savings.
 - Where the hospital intends to share internal cost savings through a CJR sharing arrangement with a CJR collaborator, a description of the methodologies for accruing and calculating internal cost savings from the participating hospital (which must be transparent, measurable, and verifiable in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards).
- The methodology and accounting formula for calculating Gainsharing payments as well as for distribution and verification of those payments.
 - In the case of fraud, a provision requiring the hospital to recoup those payments.
- The arrangement for Alignment payments, including provisions limiting such payments to repay CMS under the CJR model.
- Plans for care redesign, care coordination and delivery, and a description of how success is measured.
- Management and staff information.
- Beneficiary notice requirements and record maintenance requirements.

Under the final rule, participating hospitals must maintain and retain the documentation. CMS also considered whether to require periodic reporting of this information to the agency but declines to do so because of administrative burden concerns.

Collaborator Agreements – Requirements. A collaborator agreement must be entered into before care is furnished to a CJR beneficiary and must obligate the parties to comply (and a CJR collaborator to require any of its employees, contractors or designees to comply) with the following:

- Participation in the sharing arrangement must be voluntary; there may not be any penalties for nonparticipation.
- Gainsharing payments may only be made from the participating hospital to those collaborators that have signed the collaborator agreement with the sharing arrangement.
- Alignment payments may only be made to the participating hospital from the collaborator with which the hospital signed the collaborator agreement and must be administered by the hospital in accordance with generally accepted accounting principles (GAAP).
- Internal cost savings/reconciliation payments must meet all finalized requirements and must be administered by the hospital in accordance with GAAP.
 - The hospital may not distribute amounts under CJR sharing arrangements that are not internal cost savings/reconciliation payments; and

- Internal cost savings may not reflect “paper” savings from accounting conventions or past investment in fixed costs.
- Collaborators must comply with all Medicare provider enrollment requirements.
- Sharing arrangements may not include amounts that are not internal cost savings/reconciliation payments.
- Beneficiary notice requirements and record maintenance requirements.
- Requirements for oversight by the hospital’s Board of the hospital’s participation, arrangements with collaborators, Gainsharing and Alignment payments, and the use of beneficiary incentives.
- Requirements to cooperate with HHS site visits and other evaluation, monitoring, oversight and enforcement activities, including access to records and other information.
- Requirements for the participating hospital to recoup Gainsharing payments paid to CJR collaborators if the payment involved funds from a CMS overpayment or were based on the submission of false or fraudulent data.
- The methodology and accounting formula for calculating Gainsharing payments as well as for distribution and verification of those payments; the methodology must be in part based on quality of care.

Gainsharing and Alignment Payments – Requirements. CMS establishes the following conditions and restrictions for these payments under the CJR model:

- No conditioning of payments on the volume or value of referrals or other business generated from the parties.
- No inducement to reduce or limit medically necessary services.
- Individual physicians and NPPs must be able to make decisions in the best interest of the patient, including selection of devices, supplies and treatments.
- Methodologies for determining Gainsharing payments must use quality criteria directly related to CJR episodes of care.
- Gainsharing payments must be distributed annually and via electronic funds transfer (EFT)
 - Gainsharing payments may not be in the form of a loan, advance, or payment for referrals/other business generated;
 - Gainsharing payments may not be made to a collaborator who is subject to program integrity issues, such as noncompliance actions under the model, fraud or abuse, or providing substandard care;
 - Total Gainsharing payments may not exceed the CMS reconciliation payment amount for the year; and
 - Total Gainsharing payments for a year to an individual physician or NPP may not exceed 50 percent of total approved MPFS payments for services furnished to CJR beneficiaries; a similar 50 percent limit applies to PGPs.

- Alignment payments may be made at any time and via EFT
 - Payments may not be made before the Reconciliation Report reflects a negative NPRA;
 - Payments may not be in the form of a loan, advance, or payment for referrals/other business generated; and
 - Total payments received by the hospital may not exceed 50 percent of the hospital's repayment amount owed to CMS, and the most a single collaborator may pay to a single hospital is 25 percent of the repayment amount owed to CMS.

Some commenters objected to the proposed limits on Gainsharing and Alignment payments. Except for PGPs, CMS declines to modify these limits in part because it is concerned that raising those limits creates greater potential for stinting, patient steering or denial of medically necessary care. CMS does not believe higher limits are necessary to test the effectiveness of the CJR model. CMS also believes these limits will help ensure that only physicians and NPPs who actually furnish a service during the CJR episode may be eligible for Gainsharing payments or be responsible for Alignment payments. CMS requires participating hospitals to set forth in writing policies for selecting provider's services and suppliers as CJR collaborators. Those policies must include quality of care as well as a written methodology specifying how Gainsharing payments are determined. Failure of a CJR collaborator to meet quality criteria in a year must result in the ineligibility of that collaborator for Gainsharing payments for that year. CMS also clarifies that collaborator agreements may be entered into for multi-year periods.

Special Provisions for PGPs. As noted above, under the final rule, CMS permits a PGP that is a CJR collaborator to retain some or all of a Gainsharing payment received from a participating hospital and also permits the PGP to distribute some or all of that payment to its member physicians and NPPs who furnished services to CJR beneficiaries during the model. To qualify, a PGP must furnish patient care services; merely furnishing supplies or tests to patients would not suffice. Additionally, PGPs must participate in care redesign activities involving care provided to CJR beneficiaries during the year in which internal cost savings were generated to receive a Gainsharing payment and must have at least one member physician or NPP furnish services to a CJR beneficiary during the year involved.

CMS adds several new defined terms to the regulations that are described below to establish requirements for PGPs as CJR collaborators and for distribution of Gainsharing payments to member physicians and NPPs. CMS requires that a PGP must use a distribution arrangement to distribute Gainsharing payments to practice collaboration agents. A practice collaboration agent is defined as a PGP member who has entered into a distribution arrangement with the same PGP of which he or she is a member and who has not entered into a collaborator agreement with a participating hospital. A distribution arrangement is defined as a financial arrangement between a PGP that is a CJR collaborator and a practice collaboration agent in which the PGP distributes some or all of a Gainsharing payment that it received from a participating hospital. The term distribution payment means a payment made by a PGP that is a CJR collaborator to a practice

collaboration agent under a distribution arrangement. CMS reiterates that a PGP is not obligated to share any or all of a Gainsharing payment.

CMS imposes a number of requirements for distribution arrangements in addition to the conditions that apply to Gainsharing payments described above:

- Arrangements must be in writing and signed by the PGP and practice collaboration agent.
- Participation must be voluntary; no penalties may be imposed for nonparticipation.
- Practice collaboration agents must comply with CJR model requirements.
- Distribution payments may only be made to physicians and NPPs who furnished items and services to CJR beneficiaries during the year for which Gainsharing payments are made.
- The total distribution payments to a practice collaboration agent may not exceed 50 percent of the total approved payment amounts under the MPFS billed by the PGP and furnished by the collaboration agent to the participating hospitals' CJR beneficiaries during a CJR episode.
- The aggregate distribution payments may not exceed the total Gainsharing payment.
- A PGP may not enter into a distribution arrangement with any member of the PGP who has a collaborator agreement in effect with a participating hospital.

Documentation and Records Maintenance. CMS finalizes its proposals on documentation and records maintenance with modifications. Generally, participating hospitals and CJR collaborators must agree to comply with audit and document retention requirements which CMS notes are similar to those under the BPCI Model 2. Both participating hospitals and CJR collaborators must maintain books and records for a 10-year period that begins on the last day of participation under the model; that requirement is extended an additional 6 years in the case of a dispute or allegation of fraud.

Under the final rule, CMS modifies its regulation text to specify that documentation of collaborator agreements must be contemporaneous. Arrangements and agreements must be entered into before care is furnished to CJR beneficiaries. Additionally, as noted above, documentation of these agreements must include a description of the sharing arrangement, the date, the purpose, the provisions and scope of the arrangement, and the financial terms of the arrangements. The same requirements apply for distribution arrangements for PGPs.

Sensitive to burden concerns, CMS declines to require hospitals to periodically submit to CMS documentation on sharing arrangements, lists of CJR collaborators, or documentation on all Gainsharing payments and Alignment payments. However, in the final rule CMS does require each participating hospital to maintain accurate, current, and historical lists of CJR collaborators and to publish on the hospital's website, on a webpage accessible to the general public, an accurate and current list of all CJR collaborators; the list must be update quarterly. PGPs must also maintain documentation on distribution arrangements, including relevant written agreements, amount of any distribution payment, the identity of each practice collaboration

agent who received a distribution payment, and a description of the methodology and accounting formula for determining the amount of any distribution payment.

Additionally, CMS finalizes its proposal that nothing in the CJR model regulations limits or restricts OIG Authority or the ability of any other applicable government authority to audit, evaluate, investigate or inspect participating hospitals, CJR collaborators and other parties under the model.

Beneficiary Incentives (§510.515)

CMS finalizes its proposals to permit participating hospitals (not CJR collaborators) to provide “in-kind patient engagement incentives” to beneficiaries in CJR episodes for free or below fair market value, with several modifications. Generally, beneficiary incentives are subject to the following conditions:

1. The incentive must be provided to the beneficiary during a CJR episode of care.
2. The item or service provided must be reasonably connected to the beneficiary's medical care during a CJR episode of care and engage the beneficiary in better managing his or her own health.
3. The item or service must be a preventive care item or service **or** an item or service that advances one of the following clinical goals:
 - a. Beneficiary adherence to drug regimens.
 - b. Beneficiary adherence to a care plan.
 - c. Reduction of readmissions and complications resulting from LEJR procedures.
 - d. Management of chronic diseases and conditions that may be affected by the LEJR procedure.
4. The incentive must not be tied to the receipt of items or services from a particular provider or supplier. This condition was added in response to comments.
5. The incentive must not be tied to the receipt of items or services outside the CJR episode of care. This clarification was added in response to comments.
6. The item or service may only be provided by a participating hospital directly or through an agent who is under the hospital's control and direction. In the final rule, CMS notes that if a reasonable beneficiary would perceive the item or service as being from the agent rather than the hospital, the incentive would not be treated as provided by the hospital and thus is not eligible for protection under this provision.
7. The cost of the item or service may not be shifted to another federal health care program.

CMS clarifies that a CJR episode of care includes services for chronic diseases and conditions that may be affected by the LEJR procedure or post-surgical care, and if these services are included in the episode, CMS believes it is appropriate to permit beneficiary incentives to manage those diseases and conditions during the CJR episode of care. CMS also does not believe it is necessary or appropriate to require incentives to be offered to all beneficiaries in the model in the same way or to require that hospitals make their policies on beneficiary incentives publicly available. However, CMS notes that these incentives must not be advertised or marketed to beneficiaries.

CMS had proposed that participating hospitals would be required (i) to maintain contemporaneous documentation of beneficiary incentives that exceed \$10 in value and (ii) to include the date the incentive is provided as well as the identity of the beneficiary to whom it was provided. Commenters objected that the dollar threshold was too low; CMS finalizes a higher threshold of \$25 for this documentation requirement.

CMS had proposed to permit a participating hospital to provide items of technology to a beneficiary if the value of the technology does not exceed \$1,000 for any one beneficiary in any one CJR episode and if the hospital retains ownership of the technology where the cost of the technology exceeds \$50. Additionally, the hospital would have to retrieve the technology from the beneficiary at the end of the CJR episode and maintain documentation of the date of retrieval. Commenters were again concerned by the low \$50 threshold. Other comments encouraged CMS to permit hospitals to satisfy the retention requirement by showing a good faith effort to retrieve the technology. CMS responds by increasing the threshold to a \$100 retail value; CMS declines to set a higher threshold because it remains concerned about undue influence on beneficiaries to receive services from the hospital, especially outside the CJR episode of care. While CMS finalizes its policy that technology with a value above the \$100 threshold must be retrieved and that the retrieval date must be documented, the agency will deem “documented, diligent, good faith attempts to retrieve items of technology” to meet the retrieval requirement.

Documentation of beneficiary incentives would have to be maintained for a 10-year period. Some commenters objected to the length of this requirement, but CMS responds that the 10-year retention period is commonly used.

CMS indicates that it will not provide informal compliance advice or provide additional advisory information about specific items or services or other definitions and terms in this final rule.

Compliance with Fraud and Abuse Laws

No waivers of any fraud and abuse (e.g., the CMP law, Federal Anti-kickback statute, and the physician self-referral law) are issued in the final rule. However, CMS directs readers to <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html> and the OIG's website for the fraud and abuse waivers issued in connection with the CJR model.

The “Notice of Waivers of Certain Fraud and Abuse Laws in Connection with the Comprehensive Care for Joint Replacement Model” made public on November 16, 2015, waives section 1877(a) of the Act (i.e., physician self-referral law) and sections 1128B(b)(1) and (2) of the Act (i.e., federal anti-kickback statute) with respect to the distribution of Gainsharing payments and the payment of Alignment payments under a sharing arrangement between a participating hospital and a CJR collaborator provided the CJR arrangement requirements described above are met. The same provisions of law are waived for distribution payments from

a PGP that is a CJR collaborator to a practice collaboration agent who is entitled to receive such distribution.

The Notice also states that it does not waive the “gainsharing” CMP (section 1128A(b)(1) and (2) of the Act) because of the amendment made by section 512 of MACRA which revised the statute so that it prohibits hospitals from knowingly making payments, directly or indirectly, to induce physicians “to reduce or limit *medically necessary* services” provided to Medicare or Medicaid beneficiaries. CMS and OIG conclude that because the statute no longer prohibits payments knowingly made by hospitals to induce physicians to reduce or limit medically unnecessary services, no waiver of the gainsharing CMP is needed.

Additionally, section 1128A(a)(5) of the Act (i.e., the beneficiary inducements CMP) and sections 1128B(b)(1) and (2) of the Act (i.e., the federal anti-kickback statute) are waived with respect to beneficiary incentives furnished to CJR beneficiaries during a CJR episode of care provided the requirements described above are met.

11. Waivers of Medicare Program Rules (Subpart G of Part 510)

CMS finalizes its proposals to waive certain Medicare program rules in order to test the CJR model, including the direct supervision requirement for certain post-discharge home visits, certain telehealth requirements, the SNF 3-day rule, and certain post-operative billing restrictions. CMS believes these waivers are justified in light of models where entities bear financial responsibility for Medicare spending for an episode of care, and the incentives under the model are to increase care coordination, quality and efficiency rather than to encourage over-utilization of services. The waivers are similar to those in effect under other CMMI models.

Waivers of Medicare program rules apply to care of beneficiaries who are in CJR model episodes at the time the services are furnished under the waiver, even if the episode is later cancelled. CMS clarifies that this includes circumstances where the beneficiary’s care is ultimately excluded from the CJR model due to a change in coverage during the episode or other circumstances. CMS notes that 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 CJR model at the time a service under a waiver was furnished, CMS will recoup payment for that service from the provider or supplier who was paid. However, CMS does not finalize its proposal to require that providers of services or suppliers repay beneficiaries for any coinsurance previously collected.

In the proposed rule, CMS sought comments on other possible waivers of program requirements. Commenters responded with many suggestions, including payment waivers (e.g., per diem payment for IRFs), Part B copayment waivers, waivers of manual medical review as well as pre- and post-payment review, waivers of discharge planning requirements, waivers to permit home health pre-surgical counseling and visits, etc. CMS acknowledges receipt of the suggestions and may make future waiver proposals during the CJR model.

Waiver of Direct Supervision Requirement for Certain Post-Discharge Home Visits (§510.600)

Under the CJR model, CMS finalizes its proposal to waive the requirement that “incident to” services and supplies must be furnished under the direct supervision of the physician (or other practitioner) to permit certain home visits furnished during a CJR episode of care to a CJR beneficiary who has been discharged from an anchor hospitalization.

The home visit would be furnished at the beneficiary's home or place of residence. In the final rule, CMS does not waive the “homebound” requirement under sections 1814(a) and 1835(a) of the Act; thus the CJR model home visit does not qualify as a home health visit. CMS clarifies that this does not preclude the provision of home health services for those beneficiaries who are homebound and who meet the other criteria for such services. A CJR beneficiary who is not homebound (and thus is ineligible for covered Medicare home health services) is still eligible for home visits under the final rule. Commenters urged CMS to waive the homebound requirement, but CMS does not believe that is necessary to test this model.

In the final rule, CMS clarifies that home visits will be furnished by a clinical staff (as defined in the CPT coding guidelines)⁷ (other than a physician or NPP) acting under the general supervision of a physician employee or a contractor of the participating hospital. CMS does not spell out the clinical staff who qualify to furnish the post-discharge home visits; rather, it refers readers to the definition noted in the footnote below. CMS does clarify that clinical staff must be considered auxiliary personnel (an employed, contracted or leased employee of the physician/employing organization); thus, home health agencies and other institutional providers of services could not qualify to provide post-discharge home services under this waiver.

CMS finalizes its proposal to limit the number of home visits to 9 during the CJR episode of care. CMS notes it is not prescribing the periodicity, pattern or number of visits for beneficiaries, but it will monitor utilization and may revise the limit in the future.

CMS finalizes its proposals for the methodology for determining payment for the home visits; post-discharge home visits will be billed under Part B by the physician or NPP, or by the participating hospital to which the supervising physician has reassigned his or her billing rights, using HCPCS code G9490. HCPCS code G9490 will have the same RVUs as HCPCS code G9187 (which is used for purposes of post-discharge home visits under the BPCI models) and will be finalized in the MPFS final rule for the year involved. The service may not be billed for a 30-day period covered by a transitional care management code; it would be paid at roughly \$50 under the MPFS. See Table 26 in the final rule.

CMS notes that all other Medicare rules for coverage and payment of “incident to” services continue to apply. Services furnished during a home visit under this waiver are not considered hospital services, even when furnished by the clinical staff of the hospital.

⁷ According to CMS, the "CPT Coding Guidelines, Introduction, Instructions for Use of the CPT Codebook" says that a "clinical staff member is a person who works under the supervision of a physician or other qualified health care professional, and who is allowed by law, regulation and facility policy to perform or assist in the performance of a specific professional service, but does not individually report that professional service."

CMS believes it is appropriate that payment for these home visits is made separately in addition to payment for the surgical procedure if they are furnished during the global surgical period “incident to” the services of the physician who performed the procedure. Thus, it finalizes the proposed waiver regulation at §510.620 to permit separate billing for post-discharge home visits that meet the requirements of the waiver during the 90-day post-operative global surgical period for up to 9 visits.

Waiver of Certain Telehealth Requirements (§510.605)

CMS finalizes its proposal to waive current law limitations on payment for Medicare telehealth services under section 1834(m) of the Act that relate to the geographic area in which telehealth service originating sites may be located and on the scope originating sites for all episodes under CJR model; however these waivers only apply when the telehealth service is furnished in the beneficiary’s home or place of residence. CMS clarifies that these waivers do not permit coverage and payment for telehealth services that are not currently covered and paid for under section 1834(m) and regulations. Additionally, the telehealth services must be included in the CJR episode of care. CMS disagrees with comments that suggested expanding the waiver to other originating sites or to include additional services. In response to a comment, CMS states that it will continue to require that telehealth services under the waiver be furnished using interactive telecommunications systems.

CMS finalizes its proposal to create a specific set of HCPCS G-codes to describe E/M services furnished to CJR beneficiaries in their home/place of residence under this waiver; these codes are comparable to the office and other outpatient E/M visit codes under the 2016 MPFS and adjusted to reflect the patient’s location and include certain key service components. See Table 27 in the final rule for a list and description of the 9 HCPCS codes to be used to report home telehealth E/M visits furnished under the CJR waiver.

While commenters encouraged CMS to expand the types of providers and suppliers eligible to furnish telehealth services, CMS believes it is appropriate to limit the health care professionals who may furnish telehealth services to those authorized to do so under the statute. CMS believes that auxiliary clinical staff should be present for a level 4 or 5 home telehealth visit. It finalizes its proposal that if level 4 or 5 home telehealth visit is furnished and a post-discharge home visit is not billed on the same claim with the same date of service, or the beneficiary is not in a period of authorized home health care, it will require that the physician or NPP furnishing the home telehealth visit document the presence of auxiliary licensed clinical staff in the home or include an explanation in the medical record as to the specific circumstances precluding the need for auxiliary staff for the specific telehealth visit. CMS plans to monitor the distribution of new telehealth home visits, and it will also monitor compliance with these requirements.

No facility fee may be paid to an originating site for a telehealth service if the service originated in the beneficiary's home. CMS also declines to accept a recommendation that it pay a technology fee for telehealth services originating in a beneficiary’s home to defray the cost of technology in the home. CMS believes that either the beneficiary or the visiting clinical staff will have the requisite technology for the telehealth visit.

CMS emphasizes that a telehealth visit under this model may not substitute for a home health visit and notes that the usual Medicare program rules regarding geography and originating site will continue to apply to the face-to-face encounter requirement for purposes of certification for home health services; to meet the face-to-face certification criterion through telehealth, the beneficiary would be required to be at one of the various originating sites listed in the statute.

CMS notes that all other requirements for Medicare coverage and payment of telehealth services also continue to apply, including the list of specific services approved to be furnished via telehealth.

Waiver of SNF 3-Day Rule (§510.610)

CMS finalizes its proposal to waive the 3-day inpatient hospital stay requirement for eligibility for a covered SNF stay (i.e., the SNF 3-day rule) for all episodes tested in the CJR model with minor modifications. Thus, following an anchor hospitalization under an episode of care, CMS will waive the 3-day rule subject to the following limitations:

1. *The waiver only applies if the patient is discharged to a SNF that has an overall rating of 3 stars or better in the Five-Star Quality Rating System for SNFs on the Nursing Home Compare website.* In response to commenter concerns about changes in a SNF's quality performance ratings (changes which may occur month-by-month), CMS modifies this requirement: CMS will determine whether a SNF has an overall rating of 3 stars or better for at least 7 of the 12 preceding months according to the most recent star rating data available for the quarter in which the CJR beneficiary is admitted to a SNF. To facilitate implementation, CMS will prepare and make publicly available lists of eligible SNFs for each of the CJR model performance years based on its review of the most recent rolling 12-month period of SNF star ratings. Thus a qualified SNF is one that is included on the list that CMS will publish and make available on its website before the beginning of each calendar quarter.
2. *The waiver does not apply during performance year 1 but applies thereafter.* This is because participating hospitals are not responsible for excess spending in the first performance year but are responsible for excess spending in subsequent years. Commenters urged CMS to apply the waiver in the first year, but CMS declines to do so.
3. *All other Medicare rules for coverage and payment of Part A-covered SNF services apply, including medical necessity.* For example, CMS notes that the waiver would apply to a beneficiary who is discharged to his or her home less than 3 days from the anchor hospitalization who requires SNF services within 30 days after that discharge, assuming all other conditions of coverage for SNF services are met.

CMS does not provide many details on operational matters; it notes that will publicly release provider education materials (e.g., MLN Matters articles) before the second performance year to educate providers. In the interim, CMS directs readers to educational materials used for purposes of the BPCI Model 2: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8792.pdf>. CMS plans to monitor

patterns of SNF utilization under the model to ensure beneficiaries are not prematurely discharged to SNF care and that there is no patient steering.

Waivers to Allow Reconciliation Payment and Repayment Actions (§510.620)

CMS did not receive any comments on its proposal to waive requirements for all Part A and B payment systems to the extent required to make reconciliation payments or receive repayments based on an NPRA. CMS finalizes its proposals and notes that these payments or repayments do not change beneficiary cost-sharing rules or amounts.

12. Enforcement Mechanisms

CMS finalizes its proposals to enforce the requirements and provisions of the CJR model with one major modification; it will apply the enforcement mechanisms only to participating hospitals. The following enforcement mechanisms may be used for a participating hospital with respect to participating hospitals and entities or individuals furnishing services to CJR model beneficiaries for violations, including a violation or noncompliance identified through CMS monitoring activities: warning letters, corrective action plans, payment penalties, and, on rare occasions, termination from the model. CMS notes that it may institute and apply these enforcement mechanisms in any order it deems appropriate.

CMS clarifies for commenters that providers of services and suppliers must continue to meet Medicare conditions of participation and other requirements; additionally, CMS includes language in the CJR regulations authorizing it to take action against participating hospitals that threaten the health or safety of patients. CMS may also take remedial action against a participating hospital that has a collaboration agreement with a CJR collaborator that is noncompliant with model requirements, such as forcing the hospital to terminate the agreement.

With respect to payment penalties, CMS had proposed to reduce or eliminate a participating hospital's reconciliation amount based on noncompliance with requirements, negative results identified through monitoring, or noncompliance with a corrective action plan. Taking into account recommendations made by commenters, CMS will reduce or eliminate a reconciliation payment based on the severity of noncompliance. In the case where the participating hospital owes CMS a repayment amount, CMS will impose a penalty equal to 25 percent of the repayment amount if the hospital fails to timely comply with a corrective action plan or is noncompliant with model requirements.

CMS does not envision terminating a participating hospital from the model but leaves open the possibility in the case of extremely serious circumstances. A hospital that was terminated from the model would remain liable for any negative NPRA generated from episodes of care before the termination.

CMS could also terminate collaborator agreements where it no longer had funds to operate the model; where it terminates the model under section 1115A(b)(3)(B) of the Act; or where a participating hospital or other participating individual or entity threatens the health or safety of

patients, avoids at-risk beneficiaries, or avoids patients on the basis of payor status. Additionally, termination is available for other program integrity reasons.

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

1. Background

In this section of the proposed rule, CMS describes the measures included in the quality composite score described in section III.C.5 above, the measure performance periods and reporting requirements, and the public display of CJR model measure results on the Hospital Compare website. Related regulatory text appears in 42 CFR 510.400.

2. Quality Measures

Listed below are the components of the quality composite score. CMS notes that the two required final measures have been endorsed by the National Quality Forum (NQF) for inpatient hospital settings and recommended by the Measure Applications Partnership for use in the existing quality programs. The third component of the quality composite score is voluntary reporting of patient-reported outcome and limited risk variable data, described further in item 4 below.

- Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1550)
- Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey (NQF #0166)
- THA/TKA voluntary Patient-Reported Outcome and limited risk variable data submission

An additional measure that was proposed as a required measure is not adopted: 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). Acknowledging the many comments, including one from MedPAC, requesting that it be removed, CMS says that it believes that the two finalized required measures effectively support the intent of the CJR model to decrease costs while ensuring quality of care for LEJR episodes is maintained or improved. Regarding overlap of measures across quality programs, CMS believes that the final CJR measures involve topics of critical importance to quality improvement for THA/TKA patients and that it is appropriate to provide strong incentives to improve patient care by using measures under more than one program or model. It says that measures may exist in multiple programs but used and calculated for distinct purposes.

A detailed discussion of the two finalized required measures is provided, including a rationale for the measure, the inclusion and exclusion criteria, risk adjustment, and measure performance calculation methods. Citations to relevant medical literature are included.

Alignment of Quality Measure and CJR Model Cohorts

In the proposed rule, CMS acknowledged that the THA/TKA complications measure does not capture patients undergoing partial hip arthroplasty procedures, which are included in DRGs 469 and 470. Partial hip arthroplasty was excluded from the measure because this procedure is done for hip fractures, which are not elective procedures, and because partial hip arthroplasty patients are older and frailer and have more comorbidities. CMS believes that the measure will still provide strong incentives for improving care across all joint replacement patients because hospital protocols and quality improvement efforts will affect care for these patients as well; the same surgeons and care teams frequently perform both procedures. CMS also notes that partial hip arthroplasty represents 12 percent of 2014 the administrative claims in the CJR model episode definition, compared with 87 percent for total hip and knee replacements.

A number of commenters raised concerns about the lack of alignment between the quality measure cohorts and the CJR model cohort, particularly that the model includes non-elective THA and TKA patients while the complications measure does not. (The proposed but not finalized THA/TKA readmissions measure is also limited to elective procedures, which commenters noted.) CMS reiterates the points made in the proposed rule and says that it constantly monitors for valid and reliable measures that could be considered for the CJR model and that it may also explore the possibility of further measure development to address the inclusion of non-elective THA/TKA procedures.

With respect to the cohort for the THA/TKA complication and readmission measures, CMS finalizes that the cohort will include all hospitals included in the CJR model, which may “differ slightly” from the Hospital Inpatient Quality Reporting (IQR) Program cohort of hospitals because the CJR cohort is randomly selected and may not include all the IQR Program acute care hospitals.

HCAHPS Scoring

In scoring the HCAHPS for the CJR model, CMS finalizes its proposal to use the HCAHPS Linear Mean Roll-up (HLMR) score, used for the calculation of HCAHPS Star Ratings, which were added to Hospital Compare in April 2015. The HLMR summarizes performance across the 11 HCAHPS measures by taking an average of each of the linear mean scores 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 and can range from 0.00 to 100.00. The scores are then adjusted for patient mix, survey mode, and quarterly weighting. The HCAHPS Star Ratings Technical notes describing the methods in detail, along with other information on the star ratings and adjustments are available at <http://www.hcahponline.org/StarRatings.aspx> and http://www.hcahponline.org/files/HCAHPS_Stars_Tech_Notes_Apr2015.pdf.

CMS Response to Other Comments on the CJR Measures

CMS responds to numerous comments regarding CJR quality measures. CMS emphasizes its view that because the CJR model unit of analysis is the hospital, and the hospital are held financially responsible under the model, it restricted its choice of measures to hospital-level measures. CMS believes that hospitals are more likely than other health care facilities to have resources to appropriately coordinate and manage care throughout the episode. It says there may be future opportunities to broaden the measures to include those in post-acute settings, although CMS elsewhere says that measures of post-acute care cannot be used to assess patient response to the THA/TKA procedure because all the data are collected after the procedure. CMS "...will consider the recommendation for pain management patient experience of care measures that are applied frequently to counterbalance hospital economic interests."

With regard to comments suggesting risk adjustment for socio-demographic or socio-economic status, CMS repeats the position it has taken in other quality programs by reiterating its concern that doing such an adjustment may mask potential disparities in quality or minimize incentives to improve outcomes of care for disadvantaged populations. CMS says that its data show that hospitals that serve large proportions of patients with low sociodemographic status are capable of performing well on quality measures, and cites specifically pages 48-57, 70-73, and 78 of the 2014 Medicare Hospital Quality Chartbook available at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Medicare-Hospital-Quality-Chartbook-2014.pdf>.

Some commenters stated that the HCAHPS measure is inappropriate because it measures experience of all hospital inpatients, not just THA/TKA patients. CMS says it is not aware of any evidence that THA/TKA patient experience differs from those of the larger group of patients, that it would not be feasible to target only those beneficiaries from a survey administration standpoint, and that the number of completed surveys would be too small for many hospitals to support a reliable measurement. Similarly, CMS says it has no evidence that patients excluded from the HCAHPS because they were discharged to nursing homes or SNFs have difference experience of care than other inpatients. CMS also discusses the HCAHPS patient-mix adjustment model variables which includes service line, age, education, self-reported health status, language spoken at home, and lag time between discharge and survey completion. It says that when the adjustment for these factors is taken into account, safety-net hospitals performance on the HCAHPS in the VBP Program is typical of hospitals in general. Finally, CMS says that while there are differences in the HCAHPS measures used in the VBP Program and the CJR model (the former uses achievement, improvement, and consistency points while as explained above the CJR uses the Linear Mean Roll Up score used for the Hospital Compare star rating) the measures rely on the same underlying survey data and are strongly correlated. Because the same survey data are used for both programs as well as the IQR Program, CMS says that quality improvement efforts aimed at any of these programs will benefit the hospital in all three.

With respect to a comment about post-marketing surveillance of medical devices used in THA/TKA procedures, CMS says “We note that the addition of device selection and the ability to capture it through administrative claims codes will impact many other measures and CMS programs. We will evaluate this concern in the future as needed.”

Regarding comments expressing concern about the measures being inadequate to detect whether providers are stinting on care under the CJR model, CMS refers readers to the patient protections under the model, and says that it believes the gap in the current measure set will be addressed through the voluntary data submission initiative, which includes survey instruments that assess activities of daily living and pain management.

3. Form, Manner and Timing of Quality Measure Data Submission

CMS finalizes its proposal to rely on the IQR Program process in calculating the claims-based THA/TKA complications measure and the mechanism for collecting HCAHPS survey measure data. The same case minimums will apply, 25 cases for the THA/TKA complications measure and 100 surveys for the HCAHPS.

The finalized performance periods for each measure are shown in Table 32 in the proposed rule, which is summarized below. For the THA/TKA complications measure, the performance time period is the same 3-year rolling performance period that is used in the IQR program. For the HCAHPS, CMS will use a 4-quarter performance period that overlaps with but is not identical to, the IQR Program performance period. (For CJR model year 1, CMS will use HCAHPS data on patients discharged from July 1, 2015 through June 30, 2016, which it says will be the most recently available 4-quarters of HCAHPS data.) Because HCAHPS survey results are not available until the third calendar quarter of each year, CMS says that using the IQR Program period would not permit the proposed calculation of CJR payment adjustments during the 2nd quarter.

Responding to commenters requesting that CMS provide quarterly releases of measure results to support continuous quality improvement activities, CMS says that the HCAHPS information is made available quarterly, with confidential preview reports provided to hospitals prior to public release of the data. Data on the THA/TKA complications measure are provided annually. This measure has a 3-year performance period, which CMS says is in order to increase the sample size and improve the reliability of the measure. Because of the long performance period CMS does not believe that providing more frequent results on the THA/TKA complications measure would provide sufficiently, new and actionable information to meaningfully enhance hospital quality improvement efforts.

Measure	CJR Model Year				
	1	2	3	4	5
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
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

4. Voluntary Data Submission on Patient-Reported THA/TKA Outcomes

With changes from the propose rule, CMS adopts a voluntary data collection initiative as part of the quality composite score (described in section III.C.5 above). As discussed below, key changes from the proposed rule include a shorter list of reporting elements and a change in the criteria for determining whether a hospital has met the requirements for “successful” submission of the THA/TKA voluntary data.

CMS says the purpose of the data collection initiative is to provide an incentive for CJR participant hospitals to provide outcome data from the patient perspective that is not available from other data sources. These data are sought in conjunction with CMS work in developing a new Patient-Reported Outcome Performance Measure (PRO-PM) for purposes of assessing improvement in patient-reported outcomes following THA/TKA procedures. Because these are common and costly procedures which are specifically intended to improve function and reduce pain, CMS says patient-reported outcomes are the most meaningful outcome metric. The measure in development will assess outcomes separately for THA and TKA, but CMS intends that the results be combined into a composite measure that “...preserves the distinctions in clinical outcomes between the patient groups if needed for adequate sample sizes to ensure stable performance estimates.” Draft measure specifications are available under “Hip and Knee Arthroplasty Patient-Reported Outcomes” in the download section of the CMS Measure Methodology web page at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

CMS states its intention to use the data collected in the initial years of the CJR model to complete and test a THA/TKA patient-reported outcome measure for use in years 4 and 5 of the model. If such a decision is made to implement the measure in the CJR model or other program, it would be proposed through notice and comment rulemaking. CMS notes that hospitals choosing to voluntarily report in years 1 through 3 would be better prepared for the addition of a THA/TKA PRO-PM measure in the later years of the model. Once measure development is completed, CMS intends to submit the THA/TKA PRO-PM to the appropriate NQF project for review and endorsement.

Responding to comments, CMS changes the data elements to be submitted as part of the voluntary PRO data submission initiative. A comparison of the proposed and finalized data elements appears in Table 28 of the final rule, reproduced as an attachment to this summary. In general, the list of elements is shortened to be less burdensome. For example, CMS agrees with some commenters that it is appropriate to replace the proposed collection of the full Hip disability and Osteoarthritis Outcome Score (HOOS) or Knee injury and Osteoarthritis Outcome Score (KOOS) surveys with the shortened “HOOS Jr.” and “KOOS Jr.” instruments. CMS says that the HOOS/KOOS domain of Quality of Life will be captured by the validated generic instruments (VR-12 or PROMIS-Global), and the HOOS/KOOS domain of Function, Sports and Recreational Activities includes questions regarding activities (for example, running) that THA/TKA patients are commonly advised to restrict or avoid after surgery and, as such, is less applicable to this patient population. Further, hospitals may choose either the VR-12 or PROMIS-Global instruments; CMS had proposed both but agrees with commenters that these instruments are highly correlated.

Finally, with respect to risk variables, CMS discusses the comments it received in a joint statement from multiple surgical specialty societies which identified a prioritized list of risk variables. As shown in Table 28, the final rule eliminates proposed risk variables that are not on this list, as well as some that will instead be captured by claims data. The 11 final risk variables required for reporting are: date of birth, race, ethnicity, date of admission to anchor hospitalization, date of eligible THA/TKA procedure, Medicare Health Insurance Claim Number, body mass index, use of chronic narcotics (≥ 90 days), total painful joint count, quantified spinal pain, and the Single Item Health Literacy Screening (SILS2) questionnaire. The risk variables proposed for reporting that will instead be captured by claims data are: age, gender, THA/TKA procedure, date of discharge, presence of live-in home support, presence of retained hardware, history of congenital hip dysplasia (for THA), and presence of deformities of the proximal femur (for THA). Other proposed risk variables that are not finalized are the American Society of Anesthesiologists physical status classification, Charnley classification, joint range of motion in degrees, abductor muscle strength (for THA), use of gait aids, presence of Trendelenberg gait (for THA), femoro-tibial angle (for TKA), and knee extensor strength (for TKA).

Final Requirements for Voluntary PRO Data Submission

Under the finalized requirements, for hospitals seeking to successfully participate in voluntary PRO data collection, CMS requires collection and submission of all of the following list.

- Either VR-12 or PROMIS-Global collected both pre-operatively and post-operatively, **and**
- the revised list of risk variables in Table 28, collected only pre-operatively, **and**
 - For THA patients: Either
 - (A) the HOOS Jr. (6 items total) collected both pre-operatively and post-operatively **or**

- (B) the original HOOS Pain Subscale (10 items), **and** the original HOOS Function, Daily Living Subscale (17 items, for a total of 27 items) collected both pre-operatively and post-operatively.
- For TKA patients: Either
 - (A) the KOOS Jr. (7 items total) collected both pre-operatively and post-operatively **or**
 - (B) the original KOOS Stiffness Subscale (2 items), **and** the original KOOS Pain Subscale (9 items) **and** the original KOOS Function, Daily Living Subscale (17 items, for a total of 28 items) collected both pre-operatively and post-operatively.

As noted, the PROM instrument data will be collected both pre-operatively (90 to 0 days prior to the THA/TKA procedure) and post-operatively (270 to 365 days after the THA/TKA procedure); the risk variables (shown in Table 28) will be collected only pre-operatively (90 to 0 days prior to the THA/TKA procedure). CMS says that the post-operative window was selected based on consultation with clinical experts and clinical literature indicating that patients continue to improve until approximately 180 days after surgery and have generally experienced the full benefit of surgery by 270 to 365 days after THA/TKA, which aligns with a one-year follow-up visits and addresses concerns about a low completion rate if administered prior to 270 days.

CMS says that the risk variables which can be captured via administrative codes or claims data will be considered for possible inclusion in the future PRO-based measure risk model in addition to the publicly available CMS hierarchical condition categories used in risk adjusting other claims measures. Candidate claims-based risk-adjustment variables will be obtained from inpatient, outpatient, and physician Medicare administrative claims data extending 12 months prior to, and including, the index THA/TKA admission.

Voluntary Data Submission Procedures. Hospitals will submit the PRO and risk variable data through a secure file transfer mechanism using a file template. Data must be submitted within 60 days of the end of the most recent performance period. CMS encourages hospitals to collect and transfer the PRO data using the most economically efficient mode for them. It notes that the future THA/TKA PRO-PM may potentially include electronic health records (EHRs) as a collection mechanism, but will not be limited to EHRs.

Data Collection Period for Voluntary Reporting. CMS finalizes the performance periods for pre- and post-operative THA/TKA voluntary data submission, except that the first year performance period is delayed 3 months to reflect the delay in the implementation data of the model. Therefore, as finalized, voluntary reporting for the first year of the CJR model will be for pre-operative data only on cases performed for the two-month period from July 1, 2016 through August 31, 2016. For year 2, voluntary reporting will include 3 months of post-operative data for cases performed from April 1, 2016 through June 30, 2016 and 12 months of pre-operative data for cases performed during the period July 1, 2016 through June 30, 2017. Table 30 in the

final rule (reproduced in an attachment to this summary) spells out these time frames for each year of the model.

Requirements for Successful Voluntary Reporting. The requirements for successful voluntary reporting are modified from the proposed rule to provide a phase-in of the proportion or number of THA/TKA patients for which data must be submitted. In order to qualify as having successfully submitted voluntary data related to the THA/TKA patient-reported outcome measure, for year 1 of the model, a hospital must submit the pre-operative data elements listed in Table 28 of the final rule (and as an attachment to this summary) on either 50 percent of the eligible elective primary THA/TKA patients during the data collection period or a total of 50 or more eligible procedures during the data collection period. These pre-operative requirements (detailed in Table 30 in the attachment) are increased to 60 percent/75 procedures in year 2; 70 percent/100 procedures in year 3; and 80 percent/200 procedures in years 4 and 5. (The proposed rule requirement was 80 percent of patients beginning in year 1.) Post-operative data submission begins in year 2, with the same phase-in schedule (50 percent/50 procedures in Year 2, 60 percent/75 procedures in year 3, 70 percent/100 procedures in year 4, and 80 percent/200 procedures in year 5.)

Response to Comments on voluntary THA/TKA PRO data collection

CMS responds to numerous comments, many of which involve technical recommendations regarding various instruments included in the proposed rule. CMS clarifies that it is not developing a Patient Reported Outcome Measure (PROM) *instrument*, but is instead, for the voluntary data collection, using existing PROM instruments to develop a PRO-PM. CMS believes there are numerous instruments already available in the public domain, from which its Technical Expert Panel recommended those for consideration in developing the PRO-PM. Some comments suggested the use of specific instruments that are proprietary, and CMS says it did not consider these because it sought not to burden hospitals with a proprietary instrument. It focused on instruments that are in the public domain and non-proprietary.

A number of comments urged CMS to include data collection on assessment of functional performance. CMS emphasizes that it decided to focus on patient-reported assessments rather than functional performance assessment, which it says reflects its commitment to patient-centered care. In CMS' view, a functional performance assessment offers an objective evaluation of function, but this may not accurately reflect the patient's own experience and health status. For example, it says that a patient may experience marked improvement in a 6-minute walk test yet unable to rise from a seated position or bend over to tie their shoes. These types of outcomes will be captured in the measure under development, and CMS believes this will address public comments strongly recommending the inclusion of a measure of functional status.

Regarding comments suggesting the use of joint registries to reduce the burden of data collection, CMS says that it has been collaborating with the California Joint Replacement Registry and the American Joint Replacement Registry in developing the THA/TKA PRO-PM.

However, it is not requiring hospitals to participate in specific registries as part of the PRO data collection initiative, noting that previous comments regarding the use of proprietary registries have urged CMS to avoid adoption of policies that require hospitals to join a specific registry.

5. Possible Future Measures

CMS summarizes the responses it received to its request for comments on the three following possible future measure topics that may be appropriate for the CJR model: shared decision-making, use of shared care plans, and use of certified health IT. It will take these into account for future consideration.

6. Display of CJR Model Quality Measures and Public Availability of Information

CMS finalizes that data for CJR model measures for each hospital required to participate will be posted on the Hospital Compare website in an easily understood format. As is the case with other Hospital Compare information, CMS will share a hospital's performance data with the hospital before public display. In addition to the posting, the data on each hospital's performance on the two CJR measures will be available in a downloadable format in a section of the website specific to the CJR model. This will be similar to how measures relevant to the Medicare Readmissions Reduction and HAC Reduction programs are handled. In addition to the two measures, data on whether or not the hospital met the criteria for receiving a reconciliation payment will be posted. With respect to the voluntary reporting of information related to THA/TKA patient-reported outcomes, CMS finalizes that an icon be included on Hospital Compare indicating whether the hospital voluntarily submitted data. The voluntarily submitted data itself will not be publicly reported.

Responding to commenters, CMS clarifies that as in the IQR Program, it will annually deliver confidential reports (via secure QualityNet accounts) and accompanying confidential discharge-level information to CJR participant hospitals. The reports will contain hospital-specific information for the relevant performance period on the THA/TKA complications and HCAHPS measures and whether the hospital successfully submitted the voluntary patient-reported outcome data. Hospitals will have 30 days to review and submit corrections in a manner similar to that used for the IQR Program and other quality reporting programs. The review will not permit hospitals to submit corrections to the claims underlying the THA/TKA complications measure. For that measure, a data extract is taken 90 days following the last date of discharge in the performance period. This is consistent with IQR Program and other programs using claims-based measures.

E. Data Sharing

CMS finalizes its proposal to make historical and ongoing claims data for care furnished during episodes of LEJRs available to hospitals participating in the demonstration. As in the proposed rule, CMS summarizes existing instances where data are being made available to participants in APMs including to participants in MSSP, the Pioneer ACO model, and the BPCI. CMS states

that providing opportunities for hospitals participating in the CJR to request data, specifically certain claims and summary information, can help those participants evaluate their practices, actively manage care and better target care coordination to where it is otherwise lacking, monitor trends and make adjustments in practice patterns.

Beneficiary claims data. CMS will make claims data available in two alternate formats. For hospitals that don't have the capacity to analyze raw claims data, CMS will provide summary data reports on beneficiaries' use of health care services during the baseline and performance periods. For hospitals that request it, summary data will be made available for both a baseline period, and on a quarterly basis during a hospital's performance period. It will include all expenditures and claims for an LEJR episode for all care covered under Medicare Parts A and B within the 90 days after discharge for those beneficiaries whose anchor diagnosis at discharge was either MS DRG 469 or 470. The categories of payment information that will be contained in the summary reports include inpatient hospital, outpatient hospital, physician, LTCH, IRF, SNF, HHA, hospice, ASC, Part B drugs, DME, clinical labs, and ambulance. Data may also include Medicare payments during the anchor hospitalization and the post-acute phase. For physician services, data may include admission and discharge dates from the anchor hospitalization; and the physician for the primary procedure. They will exclude spending related to those MS-DRGs that are proposed to be specifically excluded from the episode of care.

Raw claims data at a beneficiary level and in accordance with privacy and security protections will be made available for hospitals that have the capacity to analyze such data and request it. Raw claims data will include services furnished by the participant and other entities during the episode.

For both formats, beneficiary information that is subject to regulations in 42 CFR part 2 regarding the confidentiality of alcohol and drug abuse patient records will not be included in any beneficiary identifiable claims data shared with a hospital under this proposal. In response to comments requesting that this information be included, CMS declines to do so, but notes that it will continue to consider the feasibility of making such data available in a way that is meaningful and compliant with confidentiality requirements.

Aggregate Regional Data. CMS finalizes its proposal to make data aggregated to the census region in which the participating hospital is located available as a hospital's target price will be calculated based on a blend of its own experience with that of all other hospitals in a region. CMS will provide high-level information on the average episode spending for MS-DRGs 469 and 470 for the region in which the participant hospital is located.

CMS requested, and commenters provided recommendations on the kinds of aggregate data and the frequency of data reports that would be most helpful to hospitals' efforts to coordinate care, improve health, and increase efficiencies. CMS notes that it will consider the range of comments received regarding specific data elements and will provide further guidance or rulemaking on those as warranted.

Timing and Period of Baseline Data, and Frequency and Period of Claims Data Updates. CMS finalizes its intent to make baseline data available to CJR hospitals:

- Before the April 1, 2016 start date.
- Within 60 days of CMS' receipt of a request from a participating hospital and before the April 1, 2016 start date. Three-years of baseline data will be provided.

CMS received comments regarding its proposal to make baseline data available to CJR hospitals no sooner than 60 days after the effective date of the model. Commenters expressed concern that hospitals would need that information sooner and in advance of the model's start date in order to analyze and identify opportunities for care redesign, to formulate processes and protocols to redesign care, to assess performance, and to develop networks and infrastructure. In response CMS points out that changes were made in other parts of the demonstration that should address those concerns: implementation of the demonstration is being delayed until April 1, 2016 and participants' potential risk will be reduced as the stop-loss will be lowered from 10 to 5 percent.

In response to commenters who expressed a need for more frequent data updates, CMS changes its proposal to provide data updates, upon request, "as frequently as" on a quarterly basis. Instead, CMS will provide those data "no less frequently" than on a quarterly basis. CMS notes that this applies to both beneficiary level claim data and aggregate regional data and that since the start date of the demonstration is delayed, during the first year the data would encompass episodes that began on or after April 1, 2016 (rather than January 1, 2016). For subsequent years, the updates would incorporate episodes beginning on or after January 1 of that year. Those updates will include the most recent quarter and up to the previous 6 quarters of cumulative data.

Also in response to comments, CMS clarifies that participants will need to make only one initial request for data at the start of the model which would apply throughout their participation in the model (although they could make changes to the type of data they elect to receive during their participation).

Legal Permission to Share Beneficiary-Identifiable Data. As in the proposed rule, CMS reviews its legal authority to provide individually identifiable health information; and finalizes its proposal to provide advance notice to beneficiaries that their claims data are being shared. CMS does not finalize, however, its proposal to allow for those beneficiaries to "opt-out" from claims data sharing. CMS discusses its decision to drop its proposal allowing beneficiaries to opt-out from data sharing choosing instead to provide participating hospitals with as much complete data on their beneficiaries as possible. CMS also declines the recommendation of some commenters to share data with non-hospital collaborators within the model or others outside of the model.

F. Monitoring and Beneficiary Protection

CMS finalizes safeguards for beneficiaries as the CJR model design could provide incentives for providers to direct beneficiaries into care pathways that save money at the expense of beneficiary outcomes with several additions. One addition would specify that the CJR model

does not restrict beneficiaries' ability to choose their provider or supplier. In addition, §510.405 provides for:

- Required notification for beneficiaries who initiate a CJR episode that explains the model, informs beneficiaries that they retain their freedom to choose providers and services, explains how patients can access care records and claims data, and advises that all standard beneficiary protections remain in place. Such notification would take place at the point of admission to the hospital. For hospitals with sharing arrangements, a condition of that sharing arrangement should be that collaborators provide notice of the sharing arrangement.
- In response to comments, CMS adds additional detail to the content, timing and form of the notification requirements. The final rule incorporates the following changes to the notification requirements:
 - For hospitals, the notice must be provided upon admission or immediately following the decision to schedule surgery. Collaborators who are physicians must provide the notice at the point of the decision to proceed to surgery.
 - CMS adds an additional notification requirement that beneficiaries must be informed, as part of the discharge planning and referral process, of all post-acute care providers in an area and of those with whom a hospital has sharing arrangements. Section §510.405(a)(1) specifies the information that must be included in such notice.
- CMS finalizes its proposals to monitor claims data to ensure access to care, quality of care, and to determine if there are unnecessary delays in care. CMS will track case mix and other data to determine if complex patients are being systematically excluded and will publish such information as part of the model evaluation. CMS will track medical records and claims data to ensure access to medically necessary services and will incorporate a payment adjustment as a deterrent to offset incentives for providers to delay care.
- In response to comments, CMS adds specific consequences for systemic underutilization – it will modify reconciliation payments described at §510.410 to withhold such payments if the payment is found to be based in part on savings resulting from inappropriate and systemic under-delivery of care. In addition, CMS will monitor sharing arrangements and beneficiary provider/supplier comments for evidence of anticompetitive behavior.
- CMS responds to numerous comments recommending additional beneficiary protections, for example, adding second opinion requirements, special appeals rights, discharge planning documentation, and mandatory decision-making approaches. CMS, however, finalizes its proposed monitoring provisions and notes that additional educational

materials to ensure that beneficiaries take advantage of existing avenues for voicing concerns or grievances may be developed in the future.

- As in the proposed rule, CMS will monitor for delayed care – especially care that is pushed to outside of the 90-day post-discharge period. CMS expresses confidence that existing safeguards are likely to be sufficient to ensure this doesn't happen and that experience with other bundled payment initiatives has shown that providers tend to focus on quality first. Nonetheless, CMS notes that as part of the payment definition, there will be certain post-episode adjustments for services provided during the 30-day window subsequent to the end of the 90-day post-discharge period and the data that will need to be collected for such calculations should provide an additional deterrent for delaying care.

IV. Evaluation Approach

CMS finalizes its proposed evaluation approach for CJR. The CJR approach will be like those undertaken with other projects including the BPCI initiative, the Acute Care Episode (ACE) demonstration, and Pioneer ACO models wherein historic patterns of care among the participating providers are compared with patterns after the start of the demonstration to determine if there were changes in response to the model. CMS will compare randomly selected MSAs participating in the demonstration to those MSAs not selected (but were eligible to be selected). A range of analytic methods and statistical methods will be used on measures of interest. CMS plans to examine the model at the geographic unit level, hospital level and the patient level.

In addition to the use of existing secondary sources of data including Medicare FFS claims, CMS is considering:

- Administering a survey of beneficiaries who received an LEJR during the performance period;
- Conducting guided interviews with providers furnishing services to beneficiaries under the CJR model; and
- Employing a contractor to conduct site visits with selected hospitals, PAC providers, and focus groups.

CMS describes the key research areas that their evaluation approach would seek to assess. For each of those areas, CMS lays out specific research questions that would be included in CMS evaluations. The general areas include payment, utilization, outcomes/quality, referral patterns and market impact, and unintended consequences, potential for extrapolation of results, and explanations for variations in impact.

Commenters provided a large number of recommended evaluation topics and specific measures and metrics to include in evaluations. CMS notes that the recommended evaluation topics are consistent with CMS' intended approach and the measures and metrics, including those recommended by MedPAC will be considered for inclusion in the final evaluation plan.

CMS also finalizes its proposed timeline for evaluations: participants in the CJR would have a 5-year performance period. The evaluation period would include those 5 years and up to two additional years. CMS will evaluate the CJR model annually and will provide a final analysis after the end of the 5-year performance period.

V. Collection of Information Requirements.

Collection of information requirements under Chapter 35 of title 44 of the U.S. Code do not apply to testing and evaluation models under section 1115A and are therefore not included in the proposed rule.

VI. Response to Comments

CMS states that it does not respond to comments individually, but will consider all timely comments and respond to them in the preamble to a subsequent regulatory document.

VII. Regulatory Impact Analysis

Using FY 2014 Medicare FFS claims data (October 1, 2013 through September 30, 2014), CMS reports that there were approximately 478,000 discharges for MS-DRGs 469 and 470 nationally. Based on the same data for 2014, it estimates that the participant hospitals had approximately 86,000 LEJR episodes (as defined in the CJR model), about 18 percent of LEJR discharges nationally. The mean estimated 90-day episode payment for LEJR is about \$26,000 based on the FY 2014 claims data, with approximately 55 percent of the spending attributed to hospital inpatient services, 25 percent to post-acute services such as physical therapy (either ambulatory or in a facility) and 20 percent to physician, outpatient hospital and other spending.

The CJR model will apply to 67 MSAs out of the 196 MSAs initially deemed eligible for selection. CMS estimates that the model will apply to about \$1.247 billion in episode spending in 2016 and \$2.980 billion in episode spending in 2020 as shown in Table 33 below.

Data and methodology used in the impact analysis:

CMS simulated the impact of the model on Medicare spending for joint replacement episodes using final action Medicare claims data from January 1, 2012 through March 31, 2015. It used hospital performance from calendar years 2012 through 2014 and the methodology specified in the final rule, including risk stratifying MS-DRG 469 and MS-DRG 470 for hip fracture status, to calculate target prices for all hospitals that would be required to participate in the model.

After calculating risk stratified target prices for MS-DRG 469 and 470 for each hospital appropriate for each performance year, CMS compared these target prices against actual performance in the 2014 calendar year applying the methodology specified in this final rule. 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.

To model the composite quality score, CMS used these data:

- Hospital-level risk-standardized complication rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) measure results reported on Hospital Compare in July 2015 based on the performance period of April 1, 2011 through March 31, 2014.
- HCAHPS survey (NQF #0166) reported on Hospital Compare in October 2015 based on the performance period of January 1, 2014 through December 31, 2014.

To calculate improvement included in the composite quality score, CMS used these data:

- Hospital-level risk-standardized complication rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) measure results reported on Hospital Compare in July 2014 based on the performance period of April 1, 2010 through March 31, 2013.
- HCAHPS survey (NQF #0166) reported on Hospital Compare in December 2014 based on the performance period of January 1, 2013 through December 31, 2013.

CMS calculated composite quality scores, including quality improvement points on the two measures, and hospitals were assigned to a quality category of "below acceptable", "acceptable", "good" or "excellent" based on the assignment rules specified in Tables 19, 20 and 21 of the final rule for the 5 performance years. To model payments, hospitals assigned as 'below acceptable' were not eligible for a reconciliation payment and were subject to a 3 percent effective discount percentage; hospitals assigned as 'acceptable' were eligible for a reconciliation payment and were subject to a 3 percent effective discount percentage; hospitals assigned as 'good' were eligible for a reconciliation payment and were subject to a 2 percent effective discount percentage, and hospitals assigned as 'excellent' were eligible for a reconciliation payment and were subject to a 1.5 percent effective discount percentage.

For performance years 2 and 3 of the model, for the purpose of repayment, the discount percentage is one percentage point lower than the effective discount percentage assigned for reconciliation payment. For the purpose of modeling, CMS assumed that hospitals have the same composite quality score throughout the 5-year performance period of the model.

The impact analysis assumes that no hospitals voluntarily submit patient reported outcome measures because CMS lacks information to determine which hospitals in the model would submit these data. CMS reports that making the assumption that all hospitals in the model voluntarily submit patient reported outcome measures, it estimates that the CJR model would save \$329 million (or 2.7% of total episode spend) over the 5 performance years, compared to projected savings of \$343 million (or 2.8% of total episode spend) under the assumption that no hospitals submit these data.

Results:

CMS estimates that the CJR model would reduce Medicare spending by about \$343 million dollars over the model's 5 performance years (2016 through 2020), out of \$12.299 billion in

total episode spending. Table 33 below summarizes the estimated impact for the CJR model. In making these estimates, CMS made no assumptions about changes in efficiency or utilization over the course of the model.

TABLE 33: ESTIMATES OF RECONCILIATION PAYMENTS*
(\$ in millions)

	Performance Year of the Model					Across all 5 years of the Model
	2016	2017	2018	2019	2020	
Total episode spending	\$1,247	\$2,562	\$2,688	\$2,821	\$2,980	\$12,299
Net reconciliation payments**	\$11	\$(36)	\$(71)	\$(120)	\$(127)	\$(343)
Reconciliation amounts	\$11	\$23	\$30	\$52	\$55	\$170
Repayment amounts	\$-	\$(58)	\$(101)	\$(172)	\$(182)	\$(513)
Net reconciliation as a percentage of total episode spend	0.8%	-1.4%	-2.6%	-4.2%	-4.2%	-2.8%

*Impact for 67 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.

APPENDIX

TABLE 28: SUMMARY OF PROPOSED AND FINALIZED LIMITED RISK VARIABLE AND PATIENT-REPORTED OUTCOME DATA ELEMENTS TO BE SUBMITTED FOR SUCCESSFUL PARTICIPATION IN VOLUNTARY PATIENT-REPORTED OUTCOMES DATA COLLECTION			
Proposed Voluntary PRO* and Risk Variable Data Elements	Finalized PRO and Risk Variable Data Elements	Definition of Finalized PRO and Risk Variable Data Elements	Timing of Collection
Age	N/A	(Will be captured by linking to claims data)	N/A
Date of Birth**	Date of Birth	(MM/DD/YYYY)	-90 to 0 days prior to and 270 to 365 days after THA/TKA procedure (to be used for linking to claims data)
Gender	N/A	(Will be captured by linking to claims data)	N/A
Race and Ethnicity**	Race and Ethnicity	Race: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, White Ethnicity: Hispanic or Latino, Not Hispanic or Latino	-90 to 0 days prior to THA/TKA procedure
THA or TKA Procedure	N/A	(Will be captured as possible by linking to claims data)	N/A
Date of admission to anchor hospitalization**	Date of admission to anchor hospitalization	(MM/DD/YYYY)	270 to 365 days after THA/TKA procedure (to be used for linking to claims data)
Date of discharge from anchor hospitalization	N/A	(Will be captured as possible by linking to claims data)	N/A
Date of eligible THA/TKA procedure**	Date of eligible THA/TKA procedure	(MM/DD/YYYY)	270 to 365 days after THA/TKA procedure
Medicare Health Insurance Claim Number**	Unique Identifier	Medicare Health Insurance Claim Number	-90 to 0 days prior to and 270 to 365 days after THA/TKA procedure (to be used for linking to claims data)
PROMIS Global (all items)	Generic PROM Instrument for THA and TKA Procedures	VR-12 OR PROMIS-Global	-90 to 0 days prior to and 270 to 365 days after THA/TKA procedure
VR-12 (all items.)	Generic PROM Instrument for THA	VR-12 OR PROMIS-Global	-90 to 0 days prior to and 270 to 365 days

TABLE 28: SUMMARY OF PROPOSED AND FINALIZED LIMITED RISK VARIABLE AND PATIENT-REPORTED OUTCOME DATA ELEMENTS TO BE SUBMITTED FOR SUCCESSFUL PARTICIPATION IN VOLUNTARY PATIENT-REPORTED OUTCOMES DATA COLLECTION			
Proposed Voluntary PRO* and Risk Variable Data Elements	Finalized PRO and Risk Variable Data Elements	Definition of Finalized PRO and Risk Variable Data Elements	Timing of Collection
	and TKA Procedures		after THA/TKA procedure
For TKA patients Knee injury and Osteoarthritis Outcome Score (KOOS) (all items)	Knee-Specific PROM Instrument for TKA Procedures	KOOS Jr. Only OR KOOS Stiffness Subscale AND KOOS Pain Subscale AND KOOS Function, Daily Living Subscale	-90 to 0 days prior to and 270 to 365 days after TKA procedure
For THA patients Hip disability and Osteoarthritis Outcome Score (HOOS) (all items)	Hip-Specific PROM Instrument for THA Procedures	HOOS Jr. Only OR HOOS Pain Subscale AND HOOS Function, Daily Living Subscale	-90 to 0 days prior to and 270 to 365 days after TKA procedure
Body Mass Index**	Body Mass Index (or height in cm and weight in kg)	Body Mass Index (or height in cm and weight in kg)	-90 to 0 days prior to THA/TKA procedure
Presence of live-in home support, including spouse	N/A	(Will be captured by linking to claims data)	N/A
Use of chronic (≥ 90 day) narcotics**	Pre-operative use of narcotics	Provider-reported yes/no	-90 to 0 days prior to THA/TKA procedure
American Society of Anesthesiologists (ASA) physical status classification	N/A	N/A	N/A
Charnley Classification	N/A	N/A	N/A
Presence of retained hardware	N/A	(Will be captured by linking to claims data)	N/A
Total painful joint count**	Patient-Reported Pain in Non-operative Lower Extremity Joint	"What amount of pain have you experienced in the last week in your other knee/hip?" (none, mild, moderate, severe, extreme)	-90 to 0 days prior to THA/TKA procedure
Quantified spinal pain**	Patient-Reported Back Pain (Oswestry Index question)	"My BACK PAIN at the moment is" (none, very mild, moderate, fairly severe, very severe, worst imaginable)	-90 to 0 days prior to THA/TKA procedure
Joint range of motion in degrees (specify hip or knee)	N/A	N/A	N/A
Use of gait aides	N/A	N/A	N/A
For THA patients abductor muscles strength	N/A	N/A	N/A
For THA patients presence of Trendelenberg gait	N/A	N/A	N/A

TABLE 28: SUMMARY OF PROPOSED AND FINALIZED LIMITED RISK VARIABLE AND PATIENT-REPORTED OUTCOME DATA ELEMENTS TO BE SUBMITTED FOR SUCCESSFUL PARTICIPATION IN VOLUNTARY PATIENT-REPORTED OUTCOMES DATA COLLECTION			
Proposed Voluntary PRO* and Risk Variable Data Elements	Finalized PRO and Risk Variable Data Elements	Definition of Finalized PRO and Risk Variable Data Elements	Timing of Collection
For THA patients history of congenital hip dysplasia or other congenital hip disease	N/A	(Will be captured as possible by linking to claims data)	N/A
For THA patients presence of angular, translational, or rotational deformities of the proximal femur (in degrees)	N/A	(Will be captured as possible by linking to claims data)	N/A
For TKA patients anatomic angle (femoro-tibial angle) in degrees with varus/valgus	N/A	N/A	N/A
For TKA patients knee extensor strength	N/A	N/A	N/A
Single Item Health Literacy Screening (SILS2) questionnaire.**	Patient-Reported Health Literacy	"How comfortable are you filling out medical forms by yourself?" (extremely, quite a bit, somewhat, a little bit, or not at all)	-90 to 0 days prior to THA/TKA procedure
<p>* PRO: Patient-reported outcome survey instrument. See National Quality Forum. Patient reported outcomes (PROs) in Performance Measurement. January 10, 2013. Available at: http://www.qualityforum.org/docs/measure_evaluation_criteria.aspx</p> <p>** Risk variable data element.</p> <p>Note: Table 28 in final rule includes some footnoted literature citations not shown here.</p>			

TABLE 30: FINALIZED PERFORMANCE PERIODS FOR PRE- AND POST-OPERATIVE THA/TKA VOLUNTARY DATA SUBMISSION				
Model	Performance Period	Duration of the Performance Period	Patient Population Eligible for THA/TKA Voluntary Data Submission	Requirements for Successful THA/TKA Voluntary Data Submission
2016	July 1, 2016 through August 31, 2016	2 months	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2016 and August 31, 2016.	Submit PRE-operative data on primary elective THA/TKA procedures for $\geq 50\%$ or ≥ 50 eligible procedures performed between July 1, 2016 and August 31, 2016.
2017	July 1, 2016 through August 31, 2016	13 months	All patients undergoing elective primary THA/TKA procedures performed between July 1, 2016 through August 31, 2016.	Submit POST-operative data on primary elective THA/TKA procedures for $\geq 50\%$ or ≥ 50 eligible procedures performed between July 1, 2016 through August 31, 2016.
2017	September 1, 2016 through June 30, 2017		All patients undergoing elective primary THA/TKA procedures performed between September 1, 2016 through June 30, 2017.	Submit PRE-operative data on primary elective THA/TKA procedures for $\geq 60\%$ or ≥ 75 procedures performed between September 1, 2016 through June 30, 2017.
2018	September 1, 2016 through June 30, 2017	22 months	All patients undergoing elective primary THA/TKA procedures performed between September 1, 2016 and June 30, 2017.	Submit POST-operative data on primary elective THA/TKA procedures for $\geq 60\%$ or ≥ 75 procedures performed between September 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 $\geq 70\%$ or ≥ 100 procedures performed between July 1, 2017 and June 30, 2018.
2019	July 1, 2017 through June 30, 2018	24 months	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 $\geq 70\%$ or ≥ 100 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 $\geq 80\%$ or ≥ 200 procedures performed between July 1, 2018 and June 30, 2019.

TABLE 30: FINALIZED PERFORMANCE PERIODS FOR PRE- AND POST-OPERATIVE THA/TKA VOLUNTARY DATA SUBMISSION				
Model	Performance Period	Duration of the Performance Period	Patient Population Eligible for THA/TKA Voluntary Data Submission	Requirements for Successful THA/TKA Voluntary Data Submission
2020	July 1, 2018 through June 30, 2019	24 months	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 $\geq 80\%$ or ≥ 200 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 $\geq 80\%$ or ≥ 200 procedures performed between July 1, 2019 and June 30, 2020.