

July 28, 2015

## PROPOSED BUNDLED PAYMENT PROGRAM FOR HIP AND KNEE REPLACEMENTS

### *AT A GLANCE*

#### ***At Issue:***

The Centers for Medicare & Medicaid Services (CMS) on July 9 proposed a new payment model that would bundle payment to acute care hospitals for hip and knee replacement surgery. Under this [Comprehensive Care for Joint Replacement](#) (CCJR) model, the hospital in which the lower extremity joint replacement takes place would be held financially accountable for quality and costs for the entire episode of care, from the date of surgery through 90 days post-discharge. According to CMS, the model would be implemented in 75 geographic areas across the country and mandatory for most hospitals in those areas.

**Episode of Care:** CMS proposes to test the CCJR model for five years, beginning Jan. 1, 2016 and ending Dec. 31, 2020. An episode would begin with a beneficiary's admission to an inpatient prospective payment system (PPS) hospital for a procedure assigned to one of the two "Major Joint Replacement" Medicare-severity diagnosis-related groups. The episode would end 90 days after discharge from the hospital. It would include the surgical procedure and inpatient stay, as well as all related care covered under Medicare Parts A and B within 90 days of discharge, including inpatient and outpatient, readmission, physician, inpatient rehabilitation, skilled-nursing and home health (HH) services. Unrelated services would be excluded from the episode.

**Payment:** CMS proposes to use a retrospective payment methodology with one-sided risk in the first year of the program (meaning, no hospital would be penalized in year 1) and two-sided risk in subsequent years. Under the rule, all providers would continue to receive payment under fee-for-service (FFS) Medicare in the same manner as would otherwise be made. After the completion of a performance year, services furnished to beneficiaries in that year's episodes would be grouped into episodes and aggregated. CMS would compare the participating hospitals' total episode payments to their "target price," which would generally reflect a hospital's hospital-specific and regional blended historical payments, minus 2 percent. If total episode payments were below the target price, Medicare would pay the hospital the difference in the form of a "reconciliation payment." If spending was in excess of the target price, the hospital would pay Medicare the difference.

**Quality:** CMS proposes that, in order for a participating hospital to be eligible for a reconciliation payment, it must meet or exceed performance thresholds on three quality measures currently reported in the Hospital Inpatient Quality Reporting Program: the 30-day hospital readmissions for total hip and total knee replacements; complications (such as infections or blood clots in the lungs) within 90 days of hospitalization for elective total hip and total knee replacements; and the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. Hospitals would be required to achieve these performance thresholds for all three measures to receive reconciliation payments.

**Waivers:** CMS proposes to waive the “incident to” rule (to allow a beneficiary who does not qualify for HH services to receive post-discharge visits in his or her home), the geographic site requirements for telehealth payment and the skilled-nursing facility (SNF) 3-day rule (for years 2 through 5, and only if the SNF is rated an overall of three stars or better in the Five-Star Quality Rating System for SNFs on the *Nursing Home Compare* website). It also would allow participating hospitals to share payments received from Medicare as a result of reduced episode spending and hospital internal cost savings with collaborating providers and suppliers.

However, CMS does not propose any waivers of the Civil Monetary Penalty (CMP), federal Anti-kickback or physician self-referral laws, although it states that it will consider the need for or scope of waivers of these laws when it is reviewing comments on this rule. In addition, CMS notes that the model does not limit the ability of beneficiaries to choose among Medicare providers, or the range of services available to the beneficiary. The proposed model would allow participant hospitals to recommend preferred providers, but only within the constraints of current law.

### **Our Take:**

America’s hospitals are in the process of redesigning delivery systems to increase value and better serve patients. **CMS’s proposal could help further these reforms, but it also raises important questions as to how to appropriately design a program that will be required for hospitals of many different sizes and at very different points in the “re-design” process.** For example, even recognizing that there would be no downside risk in the first year of the program, we are concerned that the proposed Jan. 1, 2016 start date provides a very short amount of time for hospitals to put in place the care processes and procedures necessary to achieve success in the program.

**In addition, we are very concerned that the Department of Health and Human Services (HHS) has failed to provide hospitals the legal protections necessary to achieve the goals of this initiative.** While this program relies on hospitals to drive care redesign across the continuum by forming financial relationships with other providers, it does not provide any waivers of the CMP, federal Anti-kickback or physician self-referral laws that would allow them to do so. Further, the scope of the payment waivers proposed is too limited, particularly the failure to propose waivers to hospital discharge planning requirements that prohibit hospitals from specifying or otherwise limiting the providers who may provide post-hospital services. If hospitals will be held financially accountable for the quality and costs of an entire episode of care, HHS must assure that impediments created by all of the relevant regulations are removed to allow hospitals to effectively coordinate and manage patients’ care. **As such, the AHA will strongly advocate that all of the needed waivers be established well in advance of any required implementation of the program.**

### **What You Can Do:**

- ✓ Determine whether your hospital would be required to participate in this program under the proposed rule.
- ✓ Share this advisory with your senior management team and ask your chief financial officer to examine the impact of the proposed payment changes on your hospital.
- ✓ Listen to AHA’s member call on the proposed rule. The presentation and audio recording are available at [www.aha.org/150729bundlingcall](http://www.aha.org/150729bundlingcall).
- ✓ Submit comments to CMS with your specific concerns by Sept. 8 at [www.regulations.gov](http://www.regulations.gov).

### **Further Questions:**

For additional questions, please contact Joanna Hiatt Kim, vice president of payment policy, at (202) 626-2340 or [jkim@aha.org](mailto:jkim@aha.org).



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## **BACKGROUND**

On July 9, the Centers for Medicare & Medicaid Services (CMS) proposed a new payment model that would bundle payment to acute care hospitals for hip and knee replacement surgery – the [Comprehensive Care for Joint Replacement](#) (CCJR) model. Under this model, the hospital in which the lower extremity joint replacement (LEJR) takes place would be held financially accountable for quality and costs for the entire episode of care, from the date of surgery through 90 days post-discharge. According to CMS, the model would be implemented in 75 geographic areas across the country (see Appendix A) and mandatory for most hospitals in those areas. CMS proposes to make the program effective on Jan. 1. As such, we anticipate the agency will issue a final rule by Nov. 1. A detailed summary of the proposed rule follows.

## **SUMMARY**

### ***Participation in the CCJR Model***

Under the CCJR model, CMS proposes that hospitals would be the only episode initiators. That is, a LEJR episode would only be included in the CCJR model if the surgery took place at a participating hospital. As the episode initiators, only hospitals would be financially responsible for the episode of care – the agency would not allow conveners to participate as participants in CCJR. CMS states it believes that utilizing the hospital as the episode initiator is a straightforward approach because the hospital furnishes the LEJR procedure.

The agency proposes to define “participating hospital” as an acute care hospital paid under the inpatient prospective payment system (PPS). Therefore, critical access hospitals (CAHs) would be excluded from the CCJR model, as would Maryland hospitals. CMS also proposes to exclude certain inpatient PPS hospitals participating in the Bundled Payment for Care Improvement (BPCI) program. Specifically, it would exclude (during the time that their qualifying episodes are included in one of the BPCI models) Model 1 BPCI participant hospitals that were active as of July 1, 2015, as well as episode initiators for LEJR episodes in the risk-bearing phase of Model 2 or 4 of BPCI as of July 1, 2015.

CMS also proposes to limit participation to inpatient PPS hospitals in certain geographic regions. Specifically, it proposes that inpatient PPS hospitals physically located in one of 75 specific metropolitan statistical areas (MSAs) be included in the CCJR model (see Appendix A). There are about 900 hospitals that would be included and the agency estimates that they account for about 25 percent of LEJR episodes nationwide.

In selecting participating MSAs, CMS determined that a sample size of 75 MSAs was necessary to be able to be confident in the results and generalize to the larger national context. It then examined all MSAs and excluded those that had a very low volume of LEJR episodes and those with a large amount of BPCI participation. The agency

stratified the remaining MSAs by their average wage-adjusted historical LEJR episode payments and by population size. It then randomly selected 75 MSAs from the strata, “oversampling” from the MSAs with higher payments and “undersampling” from the MSAs with lower payments. CMS stated that it believes this approach was appropriate because MSAs with the lowest expenditures are already performing relatively efficiently.

Although MSAs are revised periodically, CMS proposes to generally maintain the same cohort of selected hospitals throughout the CCJR model. Therefore, it would neither add hospitals if new counties are added to a selected MSA after the program begins, nor remove hospitals if counties are removed from a selected MSA after the program begins. The agency does state, however, that it retains the possibility of adding a new hospital that is opened or incorporated within a selected MSA after the program begins.

### ***Episode of Care***

CMS proposes to test the CCJR model for five years, beginning Jan. 1, 2016 and ending Dec. 31, 2020. CMS proposes that an episode of care in the CCJR model would begin upon admission to an inpatient PPS hospital for a stay paid under either Medicare-severity diagnosis-related group (MS-DRG) 469 or 470.<sup>1</sup> This triggering hospitalization is referred to as the “anchor hospitalization.” Episodes would end 90 days after discharge from the hospital. Although the episode would begin upon admission, CMS notes that all services that are already included in the inpatient PPS payment, but which may be furnished prior to admission, would also be included in the episode. Such services would include, for example, diagnostic services related to the admission that are provided by the admitting hospital or by an entity wholly owned or operated by the admitting hospital within three days prior to and including the date of admission.

Included Beneficiaries. Under the rule, CMS would not include all Medicare beneficiaries in the CCJR. Specifically, it proposes to include only those episodes that are triggered by Medicare beneficiaries who:

- Are enrolled in Medicare Parts A and B throughout the duration of the episode;
- Are not eligible for Medicare on the basis of end-stage renal disease;
- Are not enrolled in any managed care plan (such as Medicare Advantage);
- Are not covered under a United Mine Workers of American health plan; and
- Have Medicare as their primary payer.

Included and Excluded Services. CMS proposes that episodes would include the surgical procedure and inpatient stay, as well as all related care covered under Medicare Parts A and B within 90 days of discharge, including inpatient and outpatient, readmission, physician, inpatient rehabilitation, skilled-nursing and home health (HH) services. Unrelated services would be excluded, including:

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<sup>1</sup> MS-DRG 469 is Major Joint Replacement or Reattachment of Lower Extremity with Major Complications or Comorbidities (MCC) and MS-DRG 470 is Major Joint Replacement or Reattachment of Lower Extremity without MCC.

- Unrelated hospital readmissions, as identified by MS-DRG;
- Unrelated Part B services based on ICD-9-CM/ICD-10-CM code;
- Drugs paid outside of the MS-DRG (hemophilia clotting factors); and
- Inpatient PPS new-technology payments.

CMS has included a complete list of its proposed exclusions on its [website](#). It states that its list of excluded readmissions and Part B services is consistent with the LEJR episode definition currently being used in BPCI Model 2.

**Cancelled Episodes.** Once an episode begins, CMS proposes that it continue to the end unless the beneficiary no longer meets the inclusion criteria, in which case the episode would be cancelled. When an episode is cancelled, the services furnished to the beneficiary prior to and following cancellation would continue to be paid as usual, but would not be included in evaluating hospital performance and spending under the CCJR model. The agency proposes to cancel an episode if:

- A beneficiary is readmitted to an acute care hospital during the episode and discharged under MS-DRG 469 or 470 (in this case, the first episode would be cancelled and a new one would begin);
- The beneficiary dies during the anchor hospitalization; or
- The beneficiary is admitted for an LEJR episode under a non-hospital BPCI initiator, such as a physician group practice. Such cancellation would apply to non-hospital initiators participating in any of the four BPCI.

### **Retrospective Payment Methodology**

CMS proposes to apply a retrospective payment methodology to each of the five performance years for the CCJR model. The performance years correspond to the five calendar years for which the program would run, with the episode end date generally determining the year to which the episode was assigned, as shown in Table 1 below.

**Table 1: Performance Years for CCJR Model**

| <b>Performance Year</b> | <b>Calendar Year</b> | <b>Episodes Included</b>  |
|-------------------------|----------------------|---|
| 1                       | 2016                 | Episodes that begin on or after Jan. 1, 2016 and end on or before Dec. 31, 2016 |
| 2                       | 2017                 | Episodes that end from Jan. 1, 2017 through Dec. 31, 2017                       |
| 3                       | 2018                 | Episodes that end from Jan. 1, 2018 through Dec. 31, 2018                       |
| 4                       | 2019                 | Episodes that end from Jan. 1, 2019 through Dec. 31, 2019                       |
| 5                       | 2020                 | Episodes that end from Jan. 1, 2020 through Dec. 31, 2020                       |

During a performance year, CMS proposes to pay all providers and suppliers involved in CCJR episodes their usual FFS payments as calculated under the appropriate payment system. After the completion of a performance year, payments for services furnished to beneficiaries in that year's episodes would be grouped into episodes and aggregated. CMS would compare a participating hospital's actual episode payments to its "target price." If actual episode payments were below the target price, Medicare would pay the hospital the difference in the form of a "reconciliation payment," so long as it achieved the appropriate quality outcomes (see "Use of Quality Measures in Payment Determination" below for more details). If spending was in excess of the target price, the hospital would repay Medicare the difference, but only in years 2 through 5. No hospital would be penalized in year 1 of the program.

### Calculating the Target Price.

*Historical Data Used.* To set target prices, CMS proposes to utilize three years of historical Medicare payment data grouped into episodes of care. The set of years used would be updated every other performance year. Specifically, CMS proposes to use episodes that start between Jan. 1, 2012 and Dec. 31, 2014 for performance years 1 and 2. It would use episodes that start between Jan. 1, 2014 and Dec. 31, 2016 for performance years 3 and 4, and episodes that start between Jan. 1, 2016 and Dec. 31, 2018 for performance year 5. CMS would apply updates to translate these data into "current dollars."

The agency states that, in FY 2014, about 55 percent of LEJR episode spending was attributable to hospital inpatient services, about 25 percent to post-acute care services, and about 20 percent to physician, outpatient hospital and other services.

*Adjustments to Historical Data.* CMS proposes several adjustments to historical data when calculating target prices. These same adjustments would apply when calculating actual episode payments. First, CMS proposes to exclude special payment provisions that are intended to improve quality and efficiency in service delivery, such as under the hospital value-based purchasing program, the various quality reporting programs, and indirect medical education payments. See Appendix B for a list of exclusions. It also would exclude the effects of sequestration.

The agency also proposes to adjust for services that begin during an episode but conclude after the end of the episode, and for which Medicare makes a single payment, such as the case-mix group payment made for services payable under the inpatient rehabilitation facility PPS. It would prorate the payments for such services so only the portion attributable to care during the episode is included when calculating actual Medicare payments for the episode.

Lastly, CMS also proposes to make adjustments for high-payment episodes in order to provide hospitals with some protection "where the clinical scenarios for these cases each year may differ significantly and unpredictably." Specifically, CMS would cap the amount of spending for a given episode at two standard deviations above the mean, as

calculated by region. In other words, if the payment for an episode exceeds this ceiling amount, CMS would use the ceiling amount, rather than the actual amount, in its calculations.

CMS would not include any reconciliation or repayments made under the CCJR model in hospitals' target prices.

*Hospital-specific and Regional Data.* In calculating the target price, CMS proposes to blend together hospital-specific and regional historical episode payments, transitioning from primarily hospital-specific to completely regional pricing over the course of the five performance years. Regions would be defined as each of the nine [U.S. Census divisions](#). Specifically, in performance years 1 and 2, the target price would be a blend of two-thirds of the hospital-specific episode payments and one-third of the regional episode payments. In performance years 3 and 4, the target price would be a blend of one-third of the hospital-specific episode payments and two-thirds of the regional episode payments. Finally, in year 5, the target price would be fully based on regional episode payments. Using regional payments will help avoid penalizing hospitals that achieve, or have already achieved, cost efficiencies by making future efficiencies more difficult to achieve.

CMS proposes an exception to the blended target pricing approach for hospitals with low historical CCJR volume – those hospitals with less than 20 CCJR episodes across their three years of historical data. For these hospitals, CMS would calculate target prices based fully on regional episode payments in all performance years.

CMS also proposes an exception for hospitals receiving a new CMS Certification Number (CCN) during the 24 months prior to, or during, the performance period for which target prices are being calculated. If the new CCN is due to a merger between or split from previously existing hospitals, CMS would calculate hospital-specific historical payments using episodes attributed to the previously existing hospitals. If the new CCN is due to a newly opening hospital, CMS proposes to calculate target prices based fully on regional episode payments in all performance years.

*Wage Adjustments.* CMS notes that some variation in historical CCJR episode payments in a region may be due to wage adjustment differences in Medicare's payments. Therefore, CMS proposes to normalize for wage index differences in historical episode payments when calculating and blending the regional and hospital-specific components of the target prices. After this is complete, CMS would reapply wage adjustments when determining hospital-specific target prices, using the wage index that applies to the hospital during the performance year for which the target prices are being calculated (for example, it would apply the FY 2016 wage index for the Jan. 1 through Sept. 30, 2016 performance year target prices).

*Pooling of MS-DRG 469 and 470 Episodes.* As a next step, CMS proposes to pool together CCJR episodes anchored by MS DRGs 469 and 470 to use a greater historical CCJR episode volume. The agency states that doing so would result in more stable

prices because there may be too few MS-DRG 469 episodes to calculate an accurate target price for each hospital for that DRG.

*Discount Factor.* In the first year of the program, in order to determine reconciliation payments, CMS proposes to set a target price equal to a hospital’s hospital-specific and regional blended historical payments minus a 2 percent discount (see Table 2 below). (This discount would be slightly less for hospitals that successfully submit data on the proposed voluntary patient-reported outcome (PRO) measure (see “Use of Quality Measures in Payment Determination” below for more details).) Thus, hospitals would keep any savings they achieve in excess of 2 percent. In year 2, CMS would maintain this 2 percent discount for purposes of calculating reconciliation payments. However, in order to determine repayments to Medicare, CMS would set a target price equal to a hospital’s hospital-specific and regional blended historical payments, minus 1 percent. In other words, in year 2 of the program, hospitals would only bear risk for spending above a 1 percent discount. Finally, in years 3 through 5, the 2 percent discount would apply to both reconciliation payments to hospitals and repayments to Medicare.

**Table 2: Applicable CCJR Discount by Performance Year**

| <b>Performance Year</b> | <b>Discount for Purposes of Calculating Reconciliation Payments</b> | <b>Discount for Purposes of Calculating Repayments to Medicare</b> |
|-------------------------|---|--|
| 1                       | 2%  | No repayments required   |
| 2                       | 2%  | 1%   |
| 3                       | 2%  | 2%   |
| 4                       | 2%  | 2%   |
| 5                       | 2%  | 2%   |

After applying the discount factor, CMS would “unpool” target prices so that it has separate target prices for MS-DRG 469 and 470. It proposes to apply the target price it obtains immediately after applying the discount factor to MS-DRG 470, as it accounts for more than 10 times as many episodes as MS-DRG 469. To obtain the target price for MS-DRG 469, it would multiply the MS-DRG 470 target price by the percent by which national average historical MS-DRG 469 payments exceeded national average historical MS-DRG 470 payments.<sup>2</sup>

*Resulting Target Prices.* As described above, for each performance year, CMS would set a target price for MS-DRG 469 episodes, as well as MS-DRG 470 episodes. Because different Medicare payment system updates become effective at two different times of the year, each MS-DRG would have one target price Jan. 1 through Sept. 30 and another for Oct. 1 through Dec. 31. In addition, each of those target prices would reflect whether the hospital successfully submits data on the voluntary PRO measure or

<sup>2</sup> In the proposed rule, CMS discusses two different methodologies for calculating the “unpooled” target price for MS-DRG 469. We have asked for clarification, but believe this is the correct version of the methodology.

not (see “Use of Quality Measures in Payment Determination” below for more details). As a result, there would be eight different target amounts per hospital (see Table 3). Target prices would be applied based when the episode begins, even though the performance year to which an episode applies is based on when the episode ends. For example, an episode beginning in November 2016 and ending in February 2017, would have the Oct. 1, 2016 through Dec. 31, 2016 target price applied, but would be captured in the second performance year.

**Table 3: Target Prices during a Performance Year**

|                          | <b>MS-DRG 469</b>   | <b>MS-DRG 469</b>   |
|--------------------------|---------------------|---------------------|
| <b>Jan. 1 – Sept. 30</b> | Reports PRO         | Reports PRO         |
|                          | Does not report PRO | Does not report PRO |
| <b>Oct. 1 – Dec. 31</b>  | Reports PRO         | Reports PRO         |
|                          | Does not report PRO | Does not report PRO |

However, for year 2, CMS would actually calculate 16 different target amounts. Because the agency proposes to use a 2 percent discount for purposes of reconciliation payments, but a 1 percent discount for purposes of repayments in this year, it would need separate targets for reconciliation versus repayment.

CMS intends to calculate and communicate target prices to hospitals prior to the time period to which they apply (i.e., prior to Jan. 1 for target prices covering Jan. 1 through Sept. 30 and prior to Oct. 1 for target prices covering Oct. 1 through Dec. 31). It does not state how far in advance it intends to convey this information, however.

The agency does not propose to make any additional risk-adjustments, such as for patient-specific clinical indicators or Hierarchical Condition Categories, beyond the fact that it is setting separate target prices for MS-DRGs 469 and 470.

*Payment Reconciliation.* After completion of a performance year, CMS proposes to retrospectively calculate a participant hospital’s actual episode performance. In doing so, CMS would make adjustments in the same manner that they were made to historical spending in setting the target price. CMS would then compare each participant hospital’s actual episode payments to its target price, calculating a resulting “raw Net Payment Reconciliation Amount” (NPRA). The NPRA would then be adjusted to account for post-episode payment increases and for stop-loss and stop-gain limits, as applicable (see below sections below for more information).

CMS would 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, when applicable, in the second quarter of that calendar year. CMS also proposes that, during the following performance year’s reconciliation process, it would calculate the prior performance year’s episode spending a second time to account for final claims run-out (i.e., calendar year claims submitted after March 1), as well as overlap with

other models. This would occur approximately 14 months after the end of the prior performance year. If the re-calculation produces a result other than zero, CMS would apply this amount to the NPRA for the most recent performance year.

*Hospital Responsibility for Increased Post-episode Payments.* In order to address a hospital's potential incentive to withhold or delay medically necessary care until after an episode ends, consistent with BPCI Model 2, CMS proposes to examine post-episode payments to hospitals. Specifically, CMS proposes to calculate for each performance year the total Medicare Part 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.

CMS would then 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 for episodes attributed to all CCJR eligible hospitals in the same region. If the hospital's average post-episode spending exceeds this threshold, CMS proposes that the participant hospital would repay Medicare for the amount that exceeds such threshold, subject to the stop-loss limits proposed by CMS in this proposed rule.

*Proposed Stop-loss Limits on Payment Amounts.* Beginning in year two of CCJR, participant hospitals would be required to repay Medicare for episode expenditures that are greater than the applicable target price. However, to limit a hospital's overall repayment responsibility, CMS proposes a stop-loss limit in performance year 2 of 10 percent of a hospital's target price multiplied by its number of episodes. CMS proposes a stop-loss limit in performance years 3 through 5 of 20 percent of a hospital's target price multiplied by its number of episodes, which is consistent with the stop-loss limit for the BPCI Model 2 policy. For example, if a hospital's target price is \$50,000 and it had 20 episodes, its repayment risk to Medicare in performance year 2 would be capped at 10 percent of \$50,000 x 20, or \$100,000. In years 3 through 5 of the program, its repayment risk to Medicare would be capped at 20 percent of \$50,000 x 20, or \$200,000.

CMS estimates that the 10 percent stop-loss limit would impact about 11 percent of hospitals. For performance year 3, it estimates that the 20 percent limit would affect about 3 percent of hospitals.

*Proposed Stop-gain Limits on Reconciliation Payments.* CMS also proposes a parallel limit on the amount it would pay to a hospital as a reconciliation payment. For all five performance years, the agency proposes to set a stop-gain limit equal to 20 percent of a hospital's target price multiplied by its number of episodes. For example, if a hospital's target price is \$50,000 and it had 20 episodes, its reconciliation payments from Medicare would be capped at 20 percent of \$50,000 x 20, or \$200,000.

CMS indicates that this stop-gain limit of 20 percent is consistent with the stop-gain limit for the BPCI Model 2 policy; and that it is necessary to protect CMS resources and beneficiaries from harm due to potentially excessive reductions in utilization under the CCJR model. Despite this, CMS estimates that the 20 percent stop gain limit would impact the reconciliation payment amount for almost no hospitals.

*Additional Proposals to Limit Repayment Responsibility for Certain Hospitals.* CMS proposes additional protections for certain groups of hospitals that may have a lower risk tolerance and less infrastructure and support to achieve efficiencies for high payment episodes. Specifically, CMS proposes a stop-loss limit of 3 percent of episode payments for these categories of hospitals in performance year 2 and a stop-loss limit of 5 percent for performances years 3 through 5. This proposal does not impact the stop-gain policy for these categories of hospitals.

The additional protections would apply to sole community hospitals, Medicare-dependent hospitals and rural referral centers. The protections also would apply to rural hospitals, which, for purposes of this policy would be defined as inpatient PPS hospitals that are either located in a rural area in accordance with Section 412.64(b), in a rural census tract within an MSA defined at Section 412.103(a)(1), or has reclassified to rural in accordance with Section 412.103.

### ***Use of Quality Measures in Payment Determination***

As with existing payment programs where quality metrics determine whether an organization receives a reward or financial penalty, CMS proposes to require that achievement on quality metrics would be essential for hospitals to earn rewards in this CCJR program. CMS specifically proposes that hospitals must meet or exceed a performance threshold (described in the next section) for three measures currently used in the hospital inpatient quality reporting (IQR) program in order to receive reconciliation payments:

- hip and knee replacement readmissions
- hip and knee replacement complication rates
- Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey results (Note: These are the same survey results reported in the IQR program -- a sampling of all hospital patients -- and not surveys just from lower extremity joint replacement patients).

CMS hypothesizes that in addition to assuring patients continued attention to quality of care throughout the duration of this program, these measures can be used to help promote collaboration among the parties involved in the CCJR program with the hospital. The agency acknowledges that current public reporting and pay-for-performance efforts have shown a decrease in hip and knee replacement patients being readmitted (from 5.4 percent to 4.8 percent in two years) and in complications (from 3.4 percent to 3.1 percent in one year). Nevertheless, CMS suggests there continues to be

substantial variation in readmissions and complication rates among hospitals and sees this as evidence of the opportunity for further improvement.

Quality Performance Thresholds. CMS proposes that, to be eligible for a reconciliation payment, a hospital must score at or above the 30<sup>th</sup> percentile on each of the three measures in years 1 through 3. In years 4 and 5, the hospital's performance on quality metrics would have to be better than or equal to the 40<sup>th</sup> percentile on each of the three measures. If a hospital had too few applicable cases for a reliable score on any of the required measures, it would be deemed to have scored at the threshold level for purposes of determining if it is eligible for a reconciliation payment. To determine whether a hospital met these quality thresholds, CMS proposes to compare the results obtained by each hospital participating in the CCJR program with the national performance results in the hospital IQR on each of these three measures. Details on how each measure is scored and the performance periods CMS will use are detailed in the next two sections of this advisory.

**To be clear, achieving the quality performance thresholds does not guarantee that a hospital would receive a reconciliation payment. Hospitals with costs above the target price would not receive reconciliation payments, even if they achieve the quality performance thresholds. Hospitals with costs below their target price would be eligible for reconciliation payments only if they also meet the quality performance thresholds.**

#### Measure Details.

*Hip/Knee Readmissions.* The hip/knee readmissions measure assesses the percentage of Medicare fee-for-service (FFS) patients discharged from the hospital following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) who are readmitted to the hospital with 30 days. The measure is calculated using Medicare claims data and utilizes an algorithm to exclude readmissions for certain planned procedures (e.g., hernia repair) or conditions (e.g., most cancer patients). Measure results also are risk-adjusted for certain clinical factors associated with a higher likelihood for readmissions (e.g., age, gender, co-morbid conditions). However, the risk-adjustment approach does not account for sociodemographic factors such as poverty or dual-eligibility for Medicare and Medicaid.

*Hip/Knee Complications.* This measure uses Medicare claims data to yield a hospital-level, risk-adjusted complication rate within 90 days of an admission to a hospital for elective primary THA and TKA procedures. The measure includes a number of different complications that range among several different post-admission periods, including:

- Seven days post-admission: heart attack, pneumonia or sepsis/septicemia;
- 30 days post-admission: surgical site bleeding, pulmonary embolism or death; and
- 90 days post-admission: mechanical complications, periprosthetic joint infection or wound infection.

Similar to the readmission measure, the complications measure is risk-adjusted for certain clinical factors beyond the control of hospitals that are associated with a higher risk of complications. The measure also does not include adjustment for sociodemographic factors.

*HCAHPS.* The collection of the HCAHPS survey has been a requirement of the hospital IQR program for many years. The survey includes 21 core items assessing aspects of a patient's experience of care in the hospital, and is administered to a random sample of a hospital's adult (i.e., 18 years of age and older) inpatients. CMS uses the survey results to calculate and report publicly a total of 11 HCAHPS measures. Seven of these measures are "composites" constructed by combining the results of two or three survey questions. For example, there are composites reflecting how well nurses, doctors and hospital staff communicate with patients. There also are two individual measures reflecting survey results on cleanliness and quietness of patient rooms, as well as two "global" items reporting a patient's overall rating of the hospital and whether they would recommend the hospital to friends and family.

HCAHPS survey items have different response options. Some are "yes" or "no" questions, while others call for responses of "never, sometimes, usually, or always." To be able to compare a single hospital performance score to a national average hospital performance score, CMS proposes to use a complex approach to create a single performance score for each hospital out of the various ratings on different HCAHPS questions. The approach would first convert the results of each of the 11 HCAHPS measures into a "linear score" of 0-100 points, with 100 being best. Each score would then be adjusted for patient mix, survey mode (e.g., mailed surveys, telephonic surveys), and quarterly volumes. Lastly, CMS would calculate a weighted average of the 11 adjusted linear scores – called an HCAHPS Linear Mean Rollup (HLMR) score – using a weight of 1.0 for the seven composite scores, and 0.5 for the individual and global items. This approach incorporates aspects of the [methodology](#) used to calculate HCAHPS star ratings on CMS's *Hospital Compare* website.

Measure Performance Periods. CMS proposes to compare each CCJR hospital's measure results during specified performance periods to the national quality performance threshold (i.e., the 30<sup>th</sup> or 40<sup>th</sup> percentile). The measure performance periods for each performance year (PY) of the CCJR are outlined Table 4. For the readmissions and complications measures, CMS proposes to use the same three-year rolling time period for calculating performance that is used in the hospital IQR program because the time period provides more reliable and valid measurement and because using the same data as those that are publicly reported will reduce confusion.

For HCAHPS, CMS proposes to align the performance periods for this program with the reporting used in the hospital IQR program. HCAHPS scores contain four consecutive quarters of survey data.

**Table 4: Proposed CCJR Measure Performance Periods**

| <b>Measure</b>           | <b>PY 1<br/>(CY 2016)</b>       | <b>PY 2<br/>(CY 2017)</b>       | <b>PY 3<br/>(CY 2018)</b>       | <b>PY 4<br/>(CY 2019)</b>       | <b>PY 5<br/>(CY 2020)</b>       |
|--------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|
| THA/TKA<br>Complications | Apr. 1, 2013 –<br>Mar. 31, 2016 | Apr. 1, 2014 –<br>Mar. 31, 2017 | Apr. 1, 2015 –<br>Mar. 31, 2018 | Apr. 1, 2016 –<br>Mar. 31, 2019 | Apr. 1, 2017 –<br>Mar. 31, 2020 |
| THA/TKA<br>Readmissions  | Jul. 1, 2013 –<br>Jun. 30, 2016 | Jul. 1, 2014 –<br>Jun. 30, 2017 | Jul. 1, 2015 –<br>Jun. 30, 2018 | Jul. 1, 2016 –<br>Jun. 30, 2019 | Jul. 1, 2017 –<br>Jun. 30, 2020 |
| HCAHPS                   | Jul. 1, 2015 –<br>Jun. 30, 2016 | Jul. 1, 2016 –<br>Jun. 30, 2017 | Jul. 1, 2017 –<br>Jun. 30, 2018 | Jul. 1, 2018 –<br>Jun. 30, 2019 | Jul. 1, 2019 –<br>Jun. 30, 2020 |

Voluntary Reporting of PRO Measure. In addition to the required performance measures, hospitals would be encouraged, but not required, to collect and submit information on patient-reported outcomes. In general, these outcomes reflect the extent to which patients report they have recovered daily functions (e.g., mobility) or have reduced symptom burden (e.g., reduced pain). Such information has been of keen interest to many as patient-centered quality measures, but few such measures exist. As such, CMS proposes to provide a financial incentive for hospitals that report the specified PRO measure successfully by reducing their discount factor from 2.0 percent to 1.7 percent. Thus, hospitals that report the PRO measure would have a higher target price, meaning it is easier to meet and would result in them keeping more of the savings they achieve.

*Data Collection Details.* The proposed voluntary PRO measure requires the collection of detailed data on elective THA and TKA patients in both the pre-and-post operative time period. In Table 12 of the proposed rule, CMS proposes a series of data collection periods for pre-operative and post-operative data that correspond to a particular CCJR year. Participating hospitals would have 60 days following the end of a data collection period to submit data to CMS. Hospitals would be expected to collect pre-operative data on THA and TKA patients that are 0 to 90 days from having a procedure, and post-operative data on THA and TKA patients that are at least 366 days out from their TKA or THA procedure. The specific data elements CMS would ask hospitals to collect are listed in Appendix C.

To qualify for a reduced discount factor, CMS proposes that hospitals submit PRO measure data on 80 percent or more of their eligible elective total hip or knee replacement patients.<sup>3</sup> CMS estimates that on average, for hospitals that choose to submit these data, the discount will equate to approximately \$75 per case, which CMS believes will cover the cost of the data collection. The data collection will include both abstraction of data from the patient’s medical record and the collection of patient reported information via a phone survey. These patient reported outcome data will be reviewed by CMS and used to further develop a measure of quality and test the feasibility, reliability and usefulness of the measure, but will not be publicly reported

<sup>3</sup> In the proposed rule, CMS includes both an 80-percent and a 70-percent threshold. However, the agency confirmed with us that the 80-percent threshold is correct and the references to a 70-percent threshold were in error.

during the five years of this program. CMS anticipates this discount will be available during the entire five years, but does note that if they have acquired sufficient data for their measure development and testing purposes, they will notify the participants that the data are no longer needed and the discount will no longer be provided.

Alternative Methodologies. For both the calculation of whether a hospital's care is of high enough quality to be eligible for a reconciliation payment and to determine if a hospital has successfully submitted the voluntary data on patient-reported outcomes, CMS considered alternate methods. For example, the agency considered calculating a composite quality score that would be used to create a sliding scale of reconciliation payments based on the level of quality performance. However, the agency proposes the methods it considers superior, and invites comments on both the methods it has proposed and on alternative methodologies.

### ***Waivers of Medicare Program Rules***

These waivers would apply to care of beneficiaries in CCJR episodes at the time the waiver is used to bill for a service furnished to the beneficiary, even if the episode is later cancelled. If a service is found to have been billed and paid by Medicare outside of these circumstances, CMS would recoup payment for that service from the provider or supplier who was paid, and require that provider and supplier to repay the beneficiary for any coinsurance previously collected.

Skilled Nursing Facility (SNF) Three-day Rule. CMS proposes to waive, in certain instances, the SNF three-day rule for coverage of a SNF stay following a CCJR anchor hospitalization. Specifically, it would waive this rule for performance years 2-5 only, and only for discharges to SNFs with at least a three star rating in the Five-Star Quality Rating System for SNFs on the *Nursing Home Compare* website.

Post-discharge Home Visits. CMS does not propose to waive the requirement that a beneficiary is "home-bound" in order to receive home health (HH) services and states several reasons for its decisions. For example, the agency believes that many beneficiaries would be home-bound after an LEJR procedure anyway, so they would already be able to receive HH services under existing rules. In addition, CMS notes that it has not waived the homebound requirement in other CMS episode payment models, such as BPCI.

However, CMS does propose to waive the "incident to" rule, which would allow a CCJR beneficiary to receive post-discharge visits in his or her home or place of residence any time during the episode. The waiver would not apply for beneficiaries who would qualify for Medicare HH services. CMS proposes to allow up to nine post-discharge home visits to be billed and paid under the Physician Fee Schedule (PFS) during each CCJR episode. Licensed clinicians, such as nurses, either employed by a hospital or not, would be able to furnish the service under the general supervision of a physician, who may be either an employee or a contractor of the hospital.

Telehealth Services. CMS proposes to waive the geographic site requirements that limit telehealth payment to services furnished within specific types of geographic areas or in an entity participating in a federal telemedicine demonstration project approved as of Dec. 31, 2000. Waiver of this requirement would allow beneficiaries located in any region to receive services related to the episode via telehealth, as long as all other Medicare requirements for telehealth services are met. Any service on the list of Medicare-approved telehealth services and reported on a claim with a CCJR-eligible principal diagnosis could be furnished to a CCJR beneficiary, regardless of the beneficiary's geographic location.

In addition, CMS proposes to waive the originating site requirements that specify the particular sites at which the eligible telehealth individual must be located at the time the service is furnished via a telecommunications system, but only when telehealth services are being furnished in the CCJR beneficiary's home or place of residence during the episode.

### ***Financial Arrangements and Beneficiary Incentives***

Financial Arrangements. CMS notes that it expects that CCJR hospitals will identify key providers and suppliers for CCJR beneficiaries and establish close partnerships with those providers and suppliers (which CMS calls “CCJR collaborators”) to assist the hospital in redesigning care for LEJR episodes. As part of these partnerships, the agency believes participant hospitals may want to create financial arrangements with those providers and suppliers to share reconciliation payments or hospital internal cost savings, or both (known as a “gainsharing payment”), as well as responsibility for repaying Medicare for excess spending (known as an “alignment payment”). CMS proposes requirements for such arrangements, which it refers to as “CCJR Sharing Arrangements.” Specifically, it proposes that:

- CCJR Sharing Arrangements must be solely related to contributions of CCJR collaborators to care redesign that achieve quality and efficiency improvements;
- CCJR collaborators must furnish services included in the episode to the CCJR beneficiary to be eligible for gainsharing or alignment payments; and
- Gainsharing and alignment payments must be proportionally related to CCJR beneficiary care.

The agency also proposes extensive technical requirements related to sharing arrangements, participant agreements with CCJR collaborators, and gainsharing and alignment payments.

Records Retention. CMS proposes to require that participant hospitals and CCJR collaborators comply with audit and document retention requirements similar to those under the BPCI Model 2. In addition, participating hospitals and CCJR collaborators must maintain books and records for a 10-year period that begins on the last day of participation under the model; that requirement would be extended an additional 6 years in the case of a dispute or allegation of fraud.

Beneficiary Incentives. CMS proposes to permit participating hospitals to provide “in-kind patient engagement incentives” to beneficiaries in CCJR episodes for free or below fair market value. The incentives must meet the following conditions:

- The incentive must be provided to the beneficiary during a CCJR episode of care;
- The item or service provided must be reasonably connected to the beneficiary's medical care and engage the beneficiary in better managing his or her own health; and
- The item or service must be a preventive care item or service or an item or service that advances clinical goals.

Participant hospitals would have to document beneficiary incentives that exceed \$10, including the date the incentive is provided and the identity of the beneficiary to whom it was provided. CMS also proposes 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 CCJR episode. The hospital also would be required to retain ownership of the technology where its cost exceeds \$50. The hospital would have to retrieve the technology from the beneficiary at the end of the CCJR episode and maintain documentation of the date of retrieval.

### ***Compliance with Fraud and Abuse Laws***

Section 1115A of the Social Security Act provides the Secretary of HHS with authority to waive specified fraud and abuse laws as necessary to test payment models. **However, the proposed rule does not include proposed waivers of any provisions of the civil monetary penalty, federal anti-kickback or physician self-referral laws. Therefore, any arrangement or agreement under the model that implicates these laws would not be protected unless it falls under an existing exception or safe harbor.** The proposed rule notes that HHS will determine whether waivers are required as the model develops, and that any waivers would be promulgated separately by the Office of Inspector General and CMS.

### ***Beneficiary Considerations***

Beneficiary Choice. Beneficiaries would not be able to opt-out of the CCJR model. However, CMS notes that the model does not limit the ability of beneficiaries to choose among Medicare providers, or the range of services available to the beneficiary. The proposed model would allow participant hospitals to enter into a CCJR Sharing arrangement with certain providers and these preferred providers may be recommended to beneficiaries, such recommendations must be made within the constraints of current law. **Hospitals may not restrict beneficiaries to any list of preferred or recommended providers in a way that exceeds restrictions in current statute and regulations.**

Beneficiary Notification. CMS proposes that participating hospitals must require all providers and suppliers who execute a CCJR Sharing Arrangement with a participant hospital to share certain notification materials, to be developed or approved by CMS that detail the CCJR model before they order an admission for joint replacement for a beneficiary who would be included under the model. Where a participant hospital does not have CCJR Sharing Arrangements with providers or suppliers that furnish services to beneficiaries during a CCJR episode of care, or where the admission for joint replacement was ordered by a physician who does not have a CCJR Sharing Arrangement, the beneficiary notification materials must be provided to the beneficiary by the participant hospital.

Monitoring Access and Quality. CMS states that it intends to monitor claims data from participant hospitals to, for example, compare a hospital's case mix to a pre-model historical baseline to determine whether complex patients are being systematically excluded. They proposed to publish these data and also continue to review and audit hospitals if they have reason to believe that hospitals are compromising beneficiary access to care.

In addition, to enhance safeguards against directing beneficiaries away from more costly services at the expense of outcomes and quality, CMS proposes to require participant hospitals to, as part of discharge planning, provide beneficiaries with a complete list of all available post-acute care options in the service area consistent with medical need. This list would include beneficiary cost-sharing and quality information (where available and when applicable). These proposed requirements for CCJR participant hospitals would supplement the existing discharge planning requirements under the hospital Conditions of Participation.

### ***Data Sharing***

Beneficiary Claims Data. CMS proposes to provide participants with beneficiary-level claims data for the historical period used to calculate a participant's target price, as well as ongoing quarterly beneficiary-identifiable claims data in response to a participant's request for such data.

CMS proposes to make these data available in two formats. First, for participants that lack the capacity to analyze raw claims data, CMS proposes to provide summary beneficiary-level reports using data from the historical and performance periods. These data would include total expenditures and payment information for the procedure, inpatient stay, and all related care covered under Medicare Parts A and B for the 90 days after discharge for hospital beneficiaries whose anchor discharge diagnosis was MS-DRG 469 or 470. Data on services excluded from the episode would not be included.

Second, for hospitals with a capacity to analyze raw claims data, CMS proposes to provide participants with an opportunity to request line-level claims data for the historical

period that is used to set the target price and for each episode that is included in the relevant performance year.

Aggregate Regional Data. CMS also proposes to provide CCJR hospitals with aggregate data on the average total expenditures for relevant episodes in their census division. These data would not include beneficiary-identifiable claims data.

Timing and Period of Baseline Data. CMS proposes to begin making historical data for the period used to set the hospital's target price available to CCJR hospitals within 60 days of CMS's receipt of the request for such data, but requests will not be accepted until Jan. 1, 2016, the effective date of the model. CMS will announce the form, time and manner of such requests at a later date.

CMS is proposing to make baseline data available for up to a three-year period aligning with the baseline period utilized to establish target prices.

Frequency and Period of Claims Data Updates for Sharing Beneficiary-identifiable Claims Data during the Performance Period. CMS proposes to make data available on a quarterly basis upon request provided that the request meets the requirements of the HIPAA privacy rule. This data would include up to six quarters of information on a running quarterly basis.

Legal Permission to Share Beneficiary-identifiable Data. CMS proposes to provide beneficiaries with the opportunity to opt out of claims data sharing through 1-800-Medicare. CMS would provide advance notification to all Medicare beneficiaries about this opportunity. The decision to opt out does not otherwise limit whether the beneficiary is included in an episode, is included in quality measures or is included in the data for baseline or reconciliation calculations.

### ***Adjustments for Overlaps with Other CMMI Models and CMS Programs***

Interaction with BPCI. CMS proposes to exclude from the CCJR certain hospitals that participate in BPCI (see "Participation in the CCJR Model" above for more information). However, the agency acknowledges that there still may be situations where a CCJR hospital provides an LEJR to a BPCI beneficiary, such as if there is a non-hospital BPCI episode initiator. CMS proposes that in those situations, the BPCI LEJR episode would take precedence, and CMS would cancel the CCJR episode. Thus, CMS would exclude the episode from the hospital's reconciliation calculations.

Accounting for CCJR Reconciliation Payments and Repayments in Other Models and Programs. CMS notes that it is necessary to have beneficiary-specific information on CCJR-related reconciliation payments and repayments available to other models and programs in which providers are accountable for the total cost of care. Thus, it proposes to calculate beneficiary-specific reconciliation payment or repayment amounts for CCJR episodes to allow those other programs and models to determine the total cost of care for overlapping beneficiaries.

Accounting for Per-beneficiary Per-month (PBPM) Payments in the Episode Definition. Currently, five CMS models pay PBPM payments to providers to improve care coordination services. Those models are:

- Comprehensive Primary Care Initiative;
- Multi-payer Advanced Primary Care Practice;
- Oncology Care Model;
- Million Hearts; and
- Medical Care Choices Model.

CMS proposes to include or exclude services paid by PBPM in the CCJR episode based on their funding source and clinical relationship to CCJR episodes. Specifically, if services paid by PBPM payments are not clinically related to the CCJR episode, they would be excluded from target prices and actual episode payments. For clinically related services, if the PBPM payment is funded through the Medicare Part A or Part B trust fund, CMS would include the services paid by the PBPM payment in the episode if they would not otherwise be excluded from the episode definition. PBPM payments funded through CMMI's appropriation would always be excluded, regardless of whether they are clinically related to the episode.

CMS states that only one of the current models with PBPM payments – the Multi-payer Advanced Primary Care Practice model – would not be excluded from CCJR episodes based its proposed criteria. As new models that include PBPM payments emerge, CMS will make a determination on inclusion or exclusion of each through subregulatory guidance, generally using these proposed criteria.

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

CMS identifies several programs and models that hold providers accountable for total cost of care during a defined episode or performance period, some of which include shared savings. It lists these models in Table 15 of the proposed rule. CMS proposes to allow beneficiaries who receive an LEJR procedure at a CCJR hospital to be in a CCJR episode and also be attributed to a provider participating in one of these models. To address overlap between the programs and ensure that the full CCJR model savings to Medicare is realized, CMS proposes the following approach:

- *Non-ACO Total Cost of Care Models:* CMS would adjust the total cost of care calculations to ensure that the CCJR discount factor is not paid out as savings or other performance-based payment to the other model participants.
- *MSSP and Other ACO Models When the CCJR Hospital Participates in the ACO to which the Beneficiary is Aligned:* CMS would allow the CCJR discount factor to be included when determining and paying shared savings through the MSSP and other ACO models. It would then adjust the CCJR reconciliation to recoup the discount. The agency states this is necessary to ensure that the discount under CCJR is not reduced because a portion of it is paid out in shared savings to the ACO and thus, indirectly, to the hospital.

- *MSSP and Other ACO Models when the CCJR Hospital Does Not Participate in the ACO to which the Beneficiary is Aligned:* CMS would allow the CCJR discount to be included when determining and paying shared savings through the MSSP and other ACO models. However, it would not make a corresponding adjustment to the CCJR reconciliation to recoup the discount. The agency acknowledges that this would allow an ACO that is unrelated to the CCJR hospital to receive full credit for the Medicare savings achieved by the CCJR hospital. However, CMS states that it would be operationally infeasible to adjust the ACO's reconciliation process to adjust for the CCJR discount factor, and would be inappropriate to hold the CCJR hospital responsible for repayment of the discount.

### **Appeal Procedures**

CMS proposes to institute a two-step appeals process under this model that would allow participant hospitals to appeal matters related to reconciliation and payment, as well as non-payment related issues, such as enforcement matters.

Payment. Payment to the hospital or repayment to CMS would be set forth in the participant hospital's CCJR Reconciliation Report each year. Generally, payment and repayments would be required to be made within 30 calendar days from issuance of the CCJR Reconciliation Report. If a participant hospital fails to pay CMS the amount owed within that 30 days, CMS will issue a demand letter requiring that payment be made immediately. If the participant fails again to pay CMS the amount owed, CMS indicates it would involve all legal means to collect the debt, including referral of the remaining debt to the U.S. Department of the Treasury.

Calculation Error. After reviewing their CCJR Reconciliation Report, participant hospitals would be required to provide written notice of any error. This notice would be provided on a "calculation error form" that would have to be submitted in a form and manner specified by CMS. If the participant hospital provides such notice, CMS would respond in writing within 30 days to either confirm or refute the calculation (CMS reserves the right to extend this period, upon written notice to the hospital).

Unless the participant hospital provides notice on the calculation error form, the reconciliation report would be deemed final within 30 calendar days after it is issued, and CMS would proceed with payment or repayment. If a participant hospital does not submit timely notice of a calculation error, it would be precluded from later contesting the following items contained in the CCJR Reconciliation Report for that performance year:

- Any matter involving the calculation of the participant hospital's reconciliation amount or repayment amount;
- Any matter involving the calculation of NPRA;
- The calculation of the percentiles of quality measure performance to determine eligibility to receive a reconciliation payment; and

- The successful reporting of the voluntary PRO measure to adjust the reconciliation payment.

Dispute Resolution. Currently, in accordance with Section 1115A(d) of the Social Security Act (the Act), there is no administrative or judicial review for the following:

- The selection of models for testing or expansion under Section 1115A of the Act;
- The selection of organizations, sites or participants to test those models selected;
- The elements, parameters, scope and duration of such models for testing or dissemination;
- Determinations regarding budget neutrality;
- The termination or modification of the design and implementation of the model; and
- Decisions about expansion of the duration and scope of a model under subsection 1115A(c).

CMS does, however, propose a dispute resolution process that may be used by participant hospitals for issues where administrative and judicial review is not precluded. For payment matters, the participant hospital must have submitted a timely calculation error form with respect to a CCJR Reconciliation Report in order to participate in the dispute resolution process. If a participant hospital is then dissatisfied with CMS's response to its calculation error form, it may submit a request for reconsideration review by a CMS official. This request would include a detailed explanation of the basis for the dispute and include supporting documentation with respect to payment matters. Reconsideration review would be on-the-record and limited to review of briefs and evidence. The CMS reconsideration official would "make reasonable efforts" to send the hospital a Scheduling Notice within 15 days of receipt of the review request and to issue a written determination within 30 days of review. The reconsideration determination would be final and binding.

For reconsideration review requests that are not related to payment matters, CMS proposes to require a timely submitted request for review, but does not elaborate on what "timely" means for this purpose. The procedures for the Scheduling Notice and written determination would be the same as described above.

### ***Enforcement Mechanisms***

CMS proposes several enforcement mechanisms for use if participant hospitals:

- do not comply with the CCJR model requirements;
- are identified as noncompliant via CMS's monitoring of the model;
- take any action that threatens the health or safety of patients;
- avoid at-risk Medicare beneficiaries;
- avoid patients on the basis of payer status;

- are subject to sanctions or final actions of an accrediting organization or federal, state or local government agency that could lead to the inability to comply with the requirements and provisions of the model;
- take or fail to take any action that CMS determines for program integrity reasons is not in the best interests of the model; or
- are subject to action by the Department of Health and Human Services (including the Office of Inspector General and CMS) or the Department of Justice to redress an allegation of fraud or significant misconduct, including intervening in a False Claims Act *qui tam* matter, issuing a pre-demand or demand letter under a civil sanction authority, or similar actions.

The specific mechanisms, which could be applied in any order, are:

- Issuing a warning letter to inform participant hospitals of behavior that may warrant additional action by CMS;
- Requesting a corrective action plan for CMS approval by a specified deadline;
- Making a reduction in or eliminating the reconciliation amount;
- Increasing the repayment amount by 25 percent; and
- Terminating the hospital’s participation in the model

CMS also seeks comment on additional enforcement mechanisms that would contribute to the its ability to operate or monitor the program, appropriately engage and encourage all providers to comply with CCJR requirements and provisions and preserve the rights of Medicare beneficiaries to receive safe, medically necessary care and to be able to choose from whom they receive care.

## **NEXT STEPS**

Given the major changes included in this proposed rule, the AHA encourages hospital leaders to estimate the impact of the provisions on their facilities. We have reached out to affected hospitals and will continue to gather input from the field for our comment letter to CMS. All comments are due to CMS by Sept. 8 and may be submitted electronically at [www.regulations.gov](http://www.regulations.gov). Follow the instructions for “Submit a Comment” and enter the file code CMS-5516-P to submit comments on this proposed rule.

You also may submit written comments to CMS.

Via regular mail:

Centers for Medicare & Medicaid Services  
 Department of Health and Human Services  
 Attention CMS-5516-P  
 P.O. Box 8013  
 Baltimore, MD 21244-1850

Via overnight or express mail:

Centers for Medicare & Medicaid Services  
 Department of Health and Human Services  
 Attention: CMS-5516-P  
 Mailstop: C4-26-05  
 7500 Security Boulevard  
 Baltimore, MD 21244-1850

You may also, listen to AHA's member call on the proposed rule for more information. The presentation and audio recording are available at [www.aha.org/150729bundlingcall](http://www.aha.org/150729bundlingcall).

### **FURTHER QUESTIONS**

For additional questions, please contact Joanna Hiatt Kim, vice president of payment policy, at (202) 626-2340 or [jkim@aha.org](mailto:jkim@aha.org).

## Appendix A: MSAs Proposed for Inclusion in the CCJR Model

Akron, OH  
Albuquerque, NM  
Asheville, NC  
Athens-Clarke County, GA  
Austin-Round Rock, TX  
Beaumont-Port Arthur, TX  
Bismarck, ND  
Boulder, CO  
Buffalo-Cheektowaga-Niagara Falls, NY  
Cape Girardeau, MO-IL  
Carson City, NV  
Charlotte-Concord-Gastonia, NC-SC  
Cincinnati, OH-KY-IN  
Colorado Springs, CO  
Columbia, MO  
Corpus Christi, TX  
Decatur, IL  
Denver-Aurora-Lakewood, CO  
Dothan, AL  
Durham-Chapel Hill, NC  
Evansville, IN-KY  
Flint, MI  
Florence, SC  
Fort Collins, CO  
Gainesville, FL  
Gainesville, GA  
Greenville, NC  
Harrisburg-Carlisle, PA  
Hot Springs, AR  
Indianapolis-Carmel-Anderson, IN  
Kansas City, MO-KS  
Killeen-Temple, TX  
Las Vegas-Henderson-Paradise, NV  
Lincoln, NE  
Los Angeles-Long Beach-Anaheim, CA  
Lubbock, TX  
Madison, WI  
Medford, OR  
Memphis, TN-MS-AR  
Miami-Fort Lauderdale-West Palm Beach, FL  
Milwaukee-Waukesha-West Allis, WI  
Modesto, CA  
Monroe, LA  
Montgomery, AL  
Naples-Immokalee-Marco Island, FL  
Nashville-Davidson-Murfreesboro-Franklin, TN  
New Haven-Milford, CT  
New Orleans-Metairie, LA  
New York-Newark-Jersey City, NY-NJ-PA  
Norwich-New London, CT  
Ogden-Clearfield, UT  
Oklahoma City, OK  
Orlando-Kissimmee-Sanford, FL  
Pensacola-Ferry Pass-Brent, FL  
Pittsburgh, PA  
Port St. Lucie, FL  
Portland-Vancouver-Hillsboro, OR-WA  
Provo-Orem, UT  
Reading, PA  
Richmond, VA  
Rockford, IL  
Saginaw, MI  
San Francisco-Oakland-Hayward, CA  
Seattle-Tacoma-Bellevue, WA  
Sebastian-Vero Beach, FL  
South Bend-Mishawaka, IN-MI  
St. Louis, MO-IL  
Staunton-Waynesboro, VA  
Tampa-St. Petersburg-Clearwater, FL  
Toledo, OH  
Topeka, KS  
Tuscaloosa, AL  
Tyler, TX  
Virginia Beach-Norfolk-Newport News, VA-NC  
Wichita, KS

## **Appendix B: Special Payment Provisions Excluded When Calculating Target Prices and Actual Episode Payments**

### Inpatient and Outpatient PPSs

- Hospital Readmissions Reduction Program
- Value-based Purchasing Program
- Hospital-acquired Condition Program
- Inpatient Quality Reporting Program (QRP)
- Outpatient QRP
- Electronic Health Record (EHR) Incentive Program
- Disproportionate Share Hospital Payments
- Indirect Medical Education Payments
- Low-volume payments
- New-technology Add-on Payments
- Sole-community Hospital Program
- Medicare-dependent Hospital Program

### Critical Access Hospitals

- EHR Incentive Program

### Long-term Care Hospital (LTCH) PPS

- LTCH QRP

### Inpatient Rehabilitation Facility (IRF) PPS

- IRF QRP
- Rural Add-on Payments
- Low-income Percentage Payments
- Teaching IRF Payments

### Inpatient Psychiatric Facility (IPF) PPS

- IPF QRP

### Skilled-nursing Facility (SNF) PPS

- SNF QRP
- Human Immunodeficiency Virus Payments

### Home Health (HH) PPS

- HH QRP
- Rural Add-on Payments

### Physician Fee Schedule

- EHR Incentive Program
- Physician Quality Reporting System
- Value-based Modifier Program

Hospice PPS

- Hospice QRP

Ambulatory Surgical Center (ASC) Payment System

- ASC QRP

## Appendix C: Proposed Data Elements for Successful Reporting of PRO Measure

### Pre-operative Data (For Patients 0 to 90 Days before Surgery)

For both TKA and THA patients:

- Age
- Date of birth
- Gender
- Ethnicity
- Whether the procedure is TKA or THA
- Date of admission to anchor hospitalization
- Date of discharge from anchor hospitalization
- Date of eligible THA/TKA procedure
- Medicare Health Insurance Claim Number
- The Patient Reported Outcomes Measurement Information System (PROMIS) Global Health assessment, a 10-item questionnaire asking patients to rate their general physical and behavioral health, ability to perform every day physical activities (e.g., walking, climbing stairs), and general level of pain. The questionnaire can be accessed via the PROMIS [website](#).
- The Veterans-Rand 12-item health status [survey](#) (VR-12), which includes general questions about physical and behavioral health
- Body Mass Index
- Presence of in-home support, including spouse
- Use of chronic (90 days or more) narcotics
- American Society of Anesthesiologists (ASA) physical status classification
- Charnley Classification
- Presence of retained hardware
- Total painful joint count
- Quantified spinal pain
- Joint (hip or knee) range of motion in degrees
- Use of gait aides (e.g., walker)
- Single Item Health Literacy Screening (SILS2) questionnaire

Specific to TKA Patients:

- Knee injury and osteoarthritis outcome score (KOOS), a 42-item questionnaire asking about knee function and pain levels. The survey questionnaire is available [here](#).
- Anatomic angle (femoro-tibial) angle in degrees
- Knee extensor strength

Specific to THA patients:

- Hip injury and osteoarthritis outcome score (HOOS), a 40-item survey which asks several questions about hip function, mobility and pain. The survey questionnaire is available [here](#).
- Abductor muscle strength
- Presence of Trendelenberg gait
- History of congenital hip dysplasia or other congenital hip disease
- Presence of angular, translational or rotational deformities of the proximal femur

Post-Operative Data Collection (for Patients At Least 366 Out From Surgery)

For both TKA and THA patients:

- Age
- Date of birth
- Gender
- Date of admission to anchor hospitalization
- Date of discharge from anchor hospitalization
- Date of eligible THA/TKA procedure
- Medicare Health Insurance Claim Number
- PROMIS Global Assessment
- VR-12

For TKA Patients:

- KOOS

For THA Patients:

- HOOS