Medicare Program: Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing; Medicare and Medicaid Programs; Policies and Regulatory Revisions in Response to the COVID-19 Public Health Emergency - CMS-5529-F
Final Rule Summary

On May 03, 2021, the Centers for Medicare & Medicaid Services (CMS) published in the Federal Register a final rule that would extend the Comprehensive Care for Joint Replacement (CJR) model for an additional 3 performance years, among other policy and technical changes (83 FR 23496-23576).

The CJR model, which began in April 2016, is an episode bundled payment model that is designed to support higher quality and more cost-effective care for beneficiaries undergoing hip and knee replacements, or other lower extremity joint replacements (LEJRs). The final rule provides a three-year extension to the CJR model, through December 31, 2024, for certain participant hospitals. This extension would apply to participant hospitals in the 34 metropolitan statistical areas (MSAs) where participation is mandatory, excluding hospitals that are "low-volume", designated as "rural", or that had voluntarily elected to participate in performance years (PYs) 3 through 5. CMS also finalizes key changes to the episode of care definition, the target price calculation, the reconciliation process, the beneficiary notice requirements, and the appeals process that would apply beginning in PY 6.

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I. Highlights of the Final Rule

Initial evaluation results for the first and second year of the CJR model have shown a positive impact on lowering episode costs when CJR participant hospitals are compared to non-CJR hospitals. Changes to program payment policy and national care delivery patterns, however, have occurred since the CJR model began, and evaluating the impact of these changes is one of the reasons cited by CMS for changing and extending the CJR model for an additional three years. In particular, CMS' previous decisions to remove total knee arthroplasty (TKA) and total hip arthroplasty (THA) procedure codes from the inpatient-only (IPO) list—a annual list published in the Outpatient Prospective Payment System (OPPS) rule that contains procedure codes that Medicare will only reimburse when performed in the inpatient setting – has significant implications on treatment patterns and resulting costs of providing these services as these services can now be paid by Medicare when provided in an hospital outpatient setting.[1]

Recent analysis by CMS shows that national expenditures for LEJR procedures and associated post-acute care services has been decreasing since 2014, 2 years prior to CJR's implementation in 2016. Excluding CJR participant hospitals, for example, national per episode costs dropped by about 8 percent from 2014 to 2017, largely due to reductions in the utilization of post-acute services. Initial reports from the Center for Medicare and Medicaid Innovation (CMMI) Center evaluation contractor as well as an independent study in the New England Journal of Medicine indicate that the model in PYs 1 and 2 resulted in modest cost reductions with quality of care maintained and no increases in case complication.[2] The CMMI evaluation contractor found that CJR was still effective in reducing costs (beyond the declining trend already observed) – average episode payments decreased by almost $1,000 more for CJR episodes than for control group episodes from the baseline to the intervention period.[3] CMS notes that the downward trend in spending for these services has not been captured adequately by its target pricing methodology.

Consistent with its goal of site neutrality, CMS does not want to create separate prices for inpatient and outpatient CJR episodes. However, based on historical spending for the two episode types blended together, CMS recognizes that a single blended target price could potentially underestimate spending on some inpatient episodes and, likewise, overestimate spending on some outpatient episodes.

CMS finalized a series of policies in this final rule that are intended to complement the three-year extension of the program and take into account its decision to pay for TKA and THA in the hospital outpatient setting. These policies address CJR participation, episode of care definition, target price calculation, the reconciliation process, beneficiary notification requirements, quality measures, gainsharing payments, the appeals process, and waivers. These policies are

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[1]The calendar year (CY) 2018 OPPS rule (65 FR 18455) removed the TKA procedure code (27447) from the IPO list and CY 2020 OPPS rule (84 FR 61353) removed the THA procedure code (27130) from the IPO list. Since the publication of the February 24, 2020 proposed rule, CMS finalized phasing out the IPO list entirely over a 3-year period in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85866 through 86305).

[2] Barnett, Wilcock, McWilliams, Epstein, et al. "Two-Year Evaluation of Mandatory Bundled Payments for Joint Replacement" see https://www.nejm.org/doi/10.1056/NEJMsa1809010

[3] For the CJR second annual evaluation at a glance and full report see https://innovation.cms.gov/Files/reports/cjr-fgsecondannrpt.pdf and https://innovation.cms.gov/Files/reports/cjr-secondannrpt.pdf

summarized in the table below and discussed in more detail in subsequent sections.

Category	Policy
Extension	Extend the CJR model for an additional 3 years, PYs 6 through 8 through December 31, 2024. PY 6 begins October 1, 2021.
Participants	Include participant hospitals located in the 34 mandatory MSAs, and exclude rural hospitals, low-volume hospitals, and those who elected to voluntarily participate in PYs 3 through 5.
Episode of care definition	Modify definitions and MS-DRG groupings used for target price settings to include outpatient procedures
Target price calculation	Use one year of claims data instead of the current 3 years. Remove the national update factor and twice yearly fee schedule updates. Remove anchor factors and weights. Modify the high episode spending cap calculation methodology.
Reconciliation process	Move from two reconciliation periods (conducted 2 and 14 months after the close of each PY) to one reconciliation 6 months after the close of the PY. Add an additional episode-level risk adjustment beyond fracture status (i.e., adjust for dual eligibility status, age, and number of clinical conditions). Modify the high episode spending cap calculation methodology. Add a retrospective market trend factor. Increase the quality discount factors applicable to participants with excellent and good quality scores.
Beneficiary notification requirements	Extend notification requirements to include outpatient procedures.
Quality measures	Update measure performance periods to align with revised model timeline for PYs 6 through 8. Increase the PRO measure's required data submission threshold for earning bonus points.
Financial arrangements	Eliminate the 50 percent cap on gainsharing payments, distribution payments, and downstream distribution payments when the recipient is a physician, non-physician practitioner, physician group practice, or non-physician practitioner group practice.
Appeals process	Clarify the reconsideration review (second level appeal) process.
Waivers	Extend the waiver of the skilled nursing facility (SNF) 3-day rule Extend the waiver allowing post-discharge visits to be provided to beneficiaries in their homes after outpatient LEJR procedures under the general level of physician supervision.

This rule also finalizes policies from two interim final rules with comment (IFCs).[4] Specifically, the April 2020 IFC implemented a 3-month extension to CJR PY 5 such that the model would end on March 31, 2021, rather than ending on December 31, 2020, and provided an adjustment to the extreme and uncontrollable circumstances policy to account for the COVID-19 pandemic. The November 2020 IFC further extended PY 5 through September 30, 2021, created an episode-based extreme and uncontrollable circumstances COVID-19 policy, provided two reconciliation periods for PY 5, and added Medicare Severity- Diagnostic Related Groupings

[4] 85 FR 19230 and 85 FR 71142

(MS-DRGs) 521 and 522 for hip and knee procedures.

II. Provisions of the Proposed Rule, Summary and Reponses to Public Comments and Provision of the Final Regulations

In response to the proposed rule, CMS receive 66 timely pieces of correspondence with about 810 discrete comments. These comments covered the extension of the CJR model by 3 years, the CJR model episode of care definition, the target price calculation, the reconciliation process, the elimination of the 50 percent cap on gainsharing, the beneficiary notice requirements and discharge planning notice, program waivers, the appeals process, evaluation, and regulatory impact. CMS also received comments on new LEJR focused models that would include ASCs.

Comments were mixed about general agreement with the proposed rule and the extension of the model. Some commenters raised concerns about CMS' authority to implement a mandatory model contending that it unfairly targets one-fifth of hospitals and one type of procedures and medical specialty. Others expressed concern about the significant administrative and management burden associated with participating in multiple bundle payment initiatives simultaneously (e.g., those that participate in BPCI Advanced and CJR model at the same time).

In its reply, CMS emphasizes that it continues to believe that section 1115A of the Act and the Health and Human Services (HHS) Secretary's existing authority to operate the Medicare program allow it to authorize the CJR model, including an extension of its duration as well as its mandatory nature. The authorizing statute does not require that models be voluntary, but rather gives the Secretary broad discretion to design and test models that meet certain requirements as to spending and quality. CMS also disagrees with commenters that participation in BPCI Advanced and CJR at the same time creates too much burden on participant hospitals. Details about each of the specific topic areas, such as episode definition, the target price calculation, and reconciliation, is discussed below including analysis of comments and the CMS response.

A. Updating the CJR Episode Definition

1. Definitions: Anchor Procedure, Anchor Hospitalization, and Episode of Care

CMS proposed to adopt total knee arthroplasty (TKA) and total hip arthroplasty (THA) into the CJR model through a series of changes to model definitions and episode parameters (§§510.2, 510.200 and 510.210). Commenters generally were supportive; in response to their input, CMS finalizes its proposals with modifications, including changes to address the potential scenario in which a planned outpatient operation is completed but the beneficiary's condition necessitates an unplanned inpatient admission shortly after the operation ends.

- The term *anchor procedure* is added and defined: a TKA or THA procedure that is permitted and paid for by Medicare when performed in a hospital outpatient department and billed through the hospital Outpatient Prospective Payment System, except when the beneficiary is admitted to an inpatient hospital stay within 3 days after the TKA or THA.

- The term *anchor hospitalization* is revised to complement the addition of anchor procedure: the initial hospital stay upon admission for a lower extremity joint replacement (LEJR), for which the institutional claim is billed through the Inpatient Prospective Payment System (IPPS). Anchor hospitalization also includes an inpatient hospital admission within 3 days after an outpatient TKA or THA.
- The term *episode of care (or episode)* is revised to include the finalized anchor procedure and anchor hospitalization definitions, as well as finalized changes to the start date of CJR PY 6 to October 1, 2021.
- A technical change is made to add the surgeon's Part B claim to an inpatient CJR episode when the procedure was performed on an outpatient basis at the participating hospital but the patient subsequently requires an admission, resulting in an anchor hospitalization. This change applies to surgeons' claims dated within 3 days of an inpatient admission (see §510.200(b)(15)).
- Similar to policy previously established for inpatient CJR episodes, on or after July 4, 2021, an episode triggered by an anchor procedure will be canceled and a new episode initiated if the beneficiary is readmitted to any CJR participant hospital for another anchor hospitalization or receives an anchor procedure at any participant hospital.

CMS notes that the definition of anchor procedures effectively excludes operations performed in ambulatory surgical centers (ASCs) from the CJR model, although LEJRs completed in ASCs are eligible for Medicare reimbursement. CMS also notes having decided not to include a 3-day lookback period for outpatient CJR (as is done for inpatient admissions under the IPPS), but the technical change to §510.200(b)(15)) assures that the surgeon's Part B claim for the procedure will be included in the CJR episode's costs when an inpatient admission becomes necessary after an outpatient TKA or THA performed in the preceding 3 days. CMS confirms that CJR outpatient episodes will be identified by the presence of CPT code 27447 (TKA) or 27130 (THA) on a hospital institutional claim for an outpatient TKA or THA billed through the OPPS. CMS assures another questioner that outpatient cost data will be provided monthly to CJR participant hospitals.

2. Episode Categories for Setting Target Prices: Blended (Site-Neutral) Price

The CJR model sets target prices based on MS-DRG and the presence or absence of hip fracture. To incorporate outpatient TKA and THA episodes, CMS proposed to revise the framework of groups into which CJR episodes are aggregated for target price setting. CMS finalizes its proposal with modifications: 1) to reflect the adoption of new MS-DRGs 521 and 522 into the model's price setting structure effective with episodes having discharges on or after October 1, 2020, as provided for in the November 2020 IFC;[5] and 2) to adjust for the finalized start date of PY 6 (October 1, 2021).

[5] MS-DRG 521 Hip Replacement with Principal Diagnosis of Hip Fracture, with major complication or comorbidity (MCC) and MS-DRG 522 Hip Replacement with Principal Diagnosis of Hip Fracture, without MCC. Prior to the adoption of MS-DRGs 521 and 522, hip replacement procedures for treatment of hip fractures were identified by a combination of ICD-10 hip fracture diagnosis codes with either MS-DRG 469 or 470.

For target price setting, CJR episodes are now grouped into subsets and a target price assigned to each subset as listed below, starting with episodes that begin on or after July 4, 2021.[6]

- Outpatient TKA and THA without hip fracture, and Inpatient TKA and THA without MCC and without hip fracture;
    - Episodes group to a target price based on MS-DRG 470;
    - This is the "site-neutral" or "blended price" subset.[7]
- Inpatient TKA and THA with MCC and without hip fracture;
    - Episodes group to a target price based on MS-DRG 469.
- Outpatient THA with hip fracture, and Inpatient THA with hip fracture and without MCC;
    - Episodes group to a target price based on MS-DRG 522.
- Inpatient THA with hip fracture and with MCC;
    - Episodes group to a target price based on MS-DRG 521.

Concerns raised about the blended price framework included the risk of incenting providers to inappropriately recommend outpatient procedures be done in the lower-cost outpatient setting. CMS responds that the finalized risk-adjustment methodology discussed later in the rule (and in this summary) mitigates this risk, defers to surgeon judgment regarding safe site selection, and states its plan for ongoing monitoring for potentially inappropriate patterns of site selection. CMS again defers to clinical judgment in response to a request that CMS issue criteria for site selection and refers to publicly available guideline sources. The agency declines requests to develop separate cost categories for outpatient procedures, responding with excerpts from its cost data analyses and noting the precision of its risk-adjustment methodological approach. CMS ends by reporting that support was received for the blended price framework in comments from the Medicare Payment Advisory Commission (MedPAC).

3. Total Ankle Replacement

Total ankle replacement (TAR) is an LEJR procedure that satisfies the CJR model definition of an anchor hospitalization. CMS, however, chose to exclude outpatient TAR from the definition of anchor procedure related to 1) the very low frequency of TARs performed on Medicare beneficiaries – TARs comprised < 1 percent of all CJR episodes performed in 2020; and 2) the predominant performance of TAR in the inpatient setting because of greater operative complexity and higher costs than TKA or THA, acknowledged by Medicare through the automatic mapping of TAR procedures to MS-DRG 469 rather than 470 even when MCC are not present. CMS notes that while it became permissible and reimbursable to perform TAR in the hospital outpatient department beginning with CY 2021, only inpatient TAR cases are included in the CJR model test.

[6] MS-DRG 469 includes LEJR procedures with MCC; MS-DRG 470 includes LEJR procedures without MCC.
[7] CMS notes that a similar site-neutral joint replacement episode is available to hospital participants in the Bundled Payment for Care Improvement-Advanced model (BPCI-Advanced) ss of January 1, 2020. More information about BPCI-Advanced episodes is available at https://innovation.cms.gov/initiatives/bpci-advanced.

4. Implementation Timeline

CMS describes receiving multiple comments requesting the agency to delay the implementation date of the addition of outpatient episodes and the operational and financial methodological changes described in the February 2020 CJR proposed rule. Some commenters questioned the safety of THA and TKA in the Medicare patient population and stated that Medicare had insufficient experience with outpatient LEJRs to make valid judgments. CMS responds that outpatient THA and TKA have been reimbursable by Medicare since 2018 and 2020, respectively; data have been consistent during that time and have not generated safety concerns when reviewed by CMS. Commenters also argued for delay based on the ongoing COVID-19-PHE effects on clinicians, hospitals, and post-acute care providers caring for beneficiaries undergoing LEJRs. CMS responds with data showing the rising frequency of TKA and THA during 2020 towards pre-pandemic levels and cites the mitigation of provider effects that will result as COVID-19 vaccination rates increase among providers and beneficiaries. CMS declines to delay the finalized start date of October 1, 2021 for CJR PY 6.

5. Freezing Hip Fracture and Episode Exclusion Code Lists

CMS proposed to freeze the hip fracture diagnosis and episode exclusions lists, discontinuing an annual subregulatory process for their maintenance. CMS encountered no opposition and finalizes the proposal without modifications. CMS notes that the adoption of MS-DRGs 521 and 522 into the framework for identifying and aggregating CJR episodes (discussed above) renders the hip fracture list largely irrelevant as the new MS-DRGs specify admissions with principal diagnoses of hip fractures.

B. Target Price Calculation

1. Background/Overview of Changes to Target Price Calculation

CMS provides an overview of how the target price calculation has been determined for PYs 1 through 5. Currently, for example, participant hospitals are provided with prospective episode target prices for four MS-DRG/hip fracture combinations (MS-DRG 469 with hip fracture/MS-DRG 521, MS-DRG 469 without hip fracture, MS-DRG 470 with hip fracture/MS-DRG 522, and MS-DRG 470 without hip fracture), based on historical episode spending. Participant hospitals have the opportunity to achieve a reconciliation payment if their performance year spending is below the applicable target price, or they may owe a repayment if their spending is above the applicable target price. Episode target prices are based on 100 percent regional spending beginning in PY4; high episode spending is capped at 2 standard deviations above the mean regional episode payment and target prices are trended forward at reconciliation.

In this section, CMS discusses three policy changes to the target price methodology. This includes:

- Change to one year of baseline data to calculate initial target prices;
- Removal of anchor factors and weights and removal of the prospective payment system target pricing updates;

- Changes to the methodology for determining the high episode spending cap amount in initial target price calculation.

2. Change to One Year of Baseline Data

The CJR model currently uses 3 years of baseline data to calculate initial target prices with the 3-year baseline data updated every other year. CMS chose this policy because it wanted to ensure that it had sufficient historical episode volume to reliably calculate target prices. This was particularly important in PYs 1 through 3, as CMS incorporated hospital-specific data into target prices. These concerns, however, were mitigated beginning in PY 4 as target prices are now based entirely on aggregated regional episode spending data.

For performance years 6 through 8, CMS finalizes its proposal, with modifications to use 1 year of data rather than the 3 years of data currently available. CMS believes that this approach would result in a more appropriate baseline period on which to set target prices given the removal of TKA/THA from the IPO list, along with the national shift in LEJR spending. Because of the impact of COVID-19 PHE on 2020 data, CMS modified its approach for PYs 7 and 8 to use the recently available 1 year of data available prior to the start of the performance year to calculate target prices.

CMS lays out the following schedule to set target prices:

- PY 6 target prices: episode baseline data from 2019
- PY 7 target prices: episode baseline data from 2021
- PY 8 target prices: episode baseline data from 2022

Comments/Response: Many commenters expressed concern that due to the COVID-19 PHE, baseline data from 2020 and 2021 would be inappropriate to utilize for PY 7 and PY 8 target price calculations. Some expressed a concern that by using only 1-year of data that some regions could experience a surge in COVID-19 cases causing distortions in the regional pricing model CMS proposed. CMS agreed with commenters that baseline data from 2020 would likely not be as reflective of true market conditions as if the COVID-19 PHE had not occurred, and that modifications must be made to avoid using baseline data from 2020. It notes that given the new start and end dates of PYs 6 through 8, it will now have access to 2021 calendar year claims data prior to the start of PY 7. Thus, CMS will use 2021 data for the PY 7 and 2022 data for the PY 8 target price calculations.

Other commenters expressed concern about transitioning to just 1 year of data instead of 3 years as they believe this would result in target prices that would be too variable, unpredictable, or susceptible to unexpected disruptions in the markets. They cited shifts in the TKA procedures to the outpatient setting and related Recovery Audit Contractor (RAC) audits as examples of disruptions in the market. CMS notes in its response that the most recently available calendar year of baseline data is sufficient and in fact should be preferred given the shift of TKA and THA procedures to the outpatient setting and the continuing changes in the LEJR market environment.

3. Removal of Anchor Factors and Weights and Removal of the Prospective Payment System Target Pricing Updates

Also, for PYs 6 through 8, CMS finalizes its proposal to stop using the national anchor factor calculations and the subsequent regional and hospital weighting steps in the CJR target price calculation method. Anchor weights are no longer necessary because CMS will use regional episode spending data only (no hospital specific data) to calculate target prices and thus no longer has the concern that a lack of volume of data for certain participant hospitals may limit the predictability of the target price calculation. CMS also discontinues the at least twice annual updates to the target prices that account for changes in the Medicare prospective payments systems and fee schedule updates. CMS believes that this will no longer be necessary because it is finalizing its proposal (in section II.C. of the summary) to add a market trend adjustment to the target prices at the time of reconciliation.

Comments/Response: CMS received limited comments on this issue. Several stated that the existing update methodology appropriately accounts for target price changes using inpatient prospective payment system and OPPS updates and the CMS discount is sufficient for CMS to receive guaranteed savings. CMS, in response, believes that the use of a market trend factor will be simpler than the anchor factors and weights and less burdensome to monitor than the twice annual updates.

4. Changes to the Methodology for Determining the High Episode Spending Cap Amount in Initial Target Price Calculation

CMS incorporated a high episode spending cap policy as part of the CJR model to prevent participant hospitals from being held responsible for catastrophic episode spending amounts that they could not reasonably have been expected to prevent. The high cost episode cap is set at 2 standard deviations above the regional mean episode price for calculating the target price and for comparing actual episode payments during the performance year to the target prices. Episode costs exceeding the 2 standard deviation high episode spending cap are not included as actual episode payments in the calculation. For example, if the high episode cap was set at $30,000, and an actual episode cost was $50,000, the episode cost for purposes of the model would be reduced by $20,000 and thus the cost of that episode would be $30,000. When CMS established this policy it assumed that episode costs would be normally distributed, and with a normal statistical distribution, 95 percent of episodes would have costs that are within 2 standard deviations of the mean cost.

Based on its experience so far with the CJR model, CMS notes several challenges that have limited the ability of its current methodology to appropriately cap high episode spending. First, CMS observes that based on its data TKA and THA episode costs in the CJR model are not normally distributed, and more TKA and THA episodes exceed the 2 standard deviation amount than is observed with other clinical episode costs that are distributed normally. Second, given reliance on only regional data for target price calculations for PYs 4 and 5 and PYs 6 through 8, a participant hospital with higher cost episodes relative to its region would benefit more from this capping method. Third, CMS states that the lack of a normal distribution is exacerbated

during the reconciliation process, as episode costs at reconciliation are derived from only performance period episode costs from CJR participant hospitals.

To address these challenges, CMS finalizes it proposal to change its method of deriving the high episode amount applied to initial target prices by setting the high episode spending cap at the 99th percentile of historical costs. CMS will utilize the national summary of episode data to calculate the 99th percentile of each MS-DRG and hip fracture combination for each region. Total episode costs above the 99th percentile will be capped at the 99th percentile amount prior to calculating target prices for each MS-DRG and hip fracture combination for each region.

Comments/Response: CMS did not receive comments about this proposed policy and finalizes it without modification.

C. Reconciliation

1. Background

In the current CJR model, for each performance year, CMS reconciles payment twice: at 2 months and again at 14 months after the close of a performance period. At reconciliation, performance year episode costs are computed for each participant hospital for each MS-DRG and hip fracture combination and these costs are then capped at 2 standard deviations above the regional mean episode price. All participant hospitals in the CJR model are assigned a target price with a quality discount factor of 3 percent, which can be lowered to 2 percent if the hospital earns quality score of "good" or 1.5 percent if the hospital earns a quality score of "excellent". [8] CMS also applies "stop-gain limits" and "stop-loss limits", as applicable. For example, all participant hospitals that achieved LEJR actual spending below the target price and achieved a minimum quality score were eligible up to 5 percent of the difference in PYs 1 and 2; 10 percent of the different in PY 3, and 20 percent in PYs 4 and 5. CMS implemented a parallel approach for stop-loss limits and believes that such an approach was necessary to provide similar protections to CMS and to hospital participants.

2. Overview of Proposed Changes to Reconciliation Process

In this section, CMS discusses five policy changes to the reconciliation process. This includes:

- Change to the frequency and timing of reconciliation;
- Additional episode-level risk adjustment;
- Changes the methodology for determining the high episode spending cap amount at reconciliation;
- Changes to the trend factor calculation; and
- Changes to composite quality score adjustment.

[8] Based on results from the first 2 performance years of CJR, 18 percent of providers achieved quality scores of "Excellent", 60 percent achieved "Good", 12 percent "Acceptable", and less than 10 percent were deemed "Below Acceptable".

3. Changes to Frequency and Timing of Reconciliation

For each of performance years 6 through 8, CMS finalizes its proposal to conduct one reconciliation 6 months following the end of the performance year. For example, for PY 6 (all CJR episodes ending on or after October 1, 2021 and on or before December 31, 2022), CMS proposes to reconcile a participant hospital's CJR actual episode payments against the applicable target prices one time only, based on claims data available on July 1, 2022. CMS believes that reconciling payment twice at 2 and 14 months is not necessary and that, in particular, the 14 months reconciliation is not necessarily required to sufficiently capture claims run and overlap with other models. It also notes that this approach would reduce the administrative burden associated with an extra reconciliation calculation on CMS and participant hospitals.

CMS is not finalizing extending previous overlap calculations and post-episode spending calculations to PYs 6 through 8, since they were previously applied at the subsequent reconciliation. It adds §510.305(m)(1)(v) to account for any episode cancelations due to overlap between the CJR model and other CMS models and programs for PYS 6 through 8.
CMS also adds §510.305(m)(1)(vi) to specify that the post-episode spending calculation will be applied at the single reconciliation for PYs 6 through 8. This policy determines whether a hospital's 30-day post-episode spending is 3 standard deviations greater than the regional average. Any spending amount exceeding this threshold is subtracted from the hospital's net reconciliation. CMS notes the distribution of 30-day post-episode spending is more normally distributed and there have been few issues with the post-episode methodology to date.

CMS also modifies its proposed text at 510.301 to specify that episodes that are subject to a PY 5.2 target price but are reconciled in PY 6, will not be subject to the additional risk and market trend adjustments that will otherwise apply at the first reconciliation for PY 6. CMS determined this adjustment would not be appropriate because PY 5.2 target prices were designed to apply to inpatient episodes only, and incorporates a prospective update factor rather than a retrospective market trend adjustment.

Comments/Response: Commenters were generally supportive of CMS' proposal to move from 2 reconciliations to one reconciliation (conducted 6 months after the end of the performance year). They believed that 6 months was an adequate period of claims run-out to capture episode costs and that the change would reduce administrative burden on the hospitals. Other commenters requested that CMS considers strategies to mitigate cash flow issue from the transition and expressed their continued concern about the lack of timely feedback loop to the providers and the long-term between the beginning of the performance year and the reconciliation.

CMS agrees with commenters that 6 months is an adequate period of claims runout, that it reduce administrative burden, as well as eliminates the uncertainty of whether the second reconciliation would result in the participant owing a repayment. It does not believe that cash flow issues will be a significant issue given that participants in the CJR model continue to bill and be paid through normal Medicare FFS process throughout the model. With respect to timely feedback, CMS notes it continues to provide a monthly claims data feed including all claims for services included in a given episode; it believes that this information can be used by participants to identify cost drivers, opportunities for greater care coordination, and gauge model

performance. CMS also clarifies how it plans to apply certain overlap and post-episode spending calculations in PYs 6 through 8 (as described above).

4. Additional Episode-Level Risk Adjustment

Given its proposals to incorporate outpatient hip and knee procedures into the CJR model, CMS believes that additional risk adjustment is needed in order to account for variability within the four categories of target price: MS-DRG 469 and MS-DRG 470 with/without hip fracture. It is concerned that a single blended price within these four categories could potentially underestimate spending on some inpatient episodes and likewise, could potentially overestimate spending on some outpatient episodes.

CMS finalized its proposed risk adjustment methodology policy for performance years 6 through 8, with adjustments based on consideration of comments and additional analysis. After conducting a variety of analyses and regressions, CMS incorporate the following into its CJR pricing: dual eligibility status, CJR Hierarchical Condition Category (HCC) count risk adjustment variable, and beneficiary age.[9] It considered a number of factors that are not included in its proposed methodology because they were not strong predictors of cost, might result in unintended provider efficiency disincentives, were overly complex to calculate or administer, had limited credibility or quality of the underlying data sources, or conflicted with other bundled payment initiatives. The factors not chosen include joint region (i.e., hip, knee, or ankle), gender, CMS-HCC risk scores (community and institutional), rural/urban designation of the participant hospital, clinical setting (inpatient/outpatient), rehospitalization rate, and indices of social determination of health.

CMS discovered (when updating its estimates for the final rule) that dual eligibility status has a statistically significant effect on episode costs. It discovered an error in the original programming regarding the definition of a dual-eligible beneficiary for the regression that inadvertently included beneficiaries enrolled in Medicare Part A and/or Part B and receiving full or partial Medicaid benefits. The correction to only include beneficiaries fully eligible for the Medicaid benefits resulted in this variable being statistically significant in its statistical models.

CMS incorporates the total number of clinical conditions per beneficiary by assessing the count of CJR-HCC conditions. Specifically, CMS will use five CJR-HCC condition count variables, representing beneficiaries with zero, one, two, three, or four or more HCC conditions. These will be incorporated into a regression model to account for differences in the average anticipated episode costs by beneficiaries with a different number of clinical conditions.

CMS also will use four age variables for the risk adjustment methodology to represent beneficiaries aged less than 65 years, 65 to 74 years, 75 years to 84 years, and 85 years or more, based on the patient's age at the time the HCC files were created. CMS will select the age

[9] CMS proposed to name this risk adjustment factor the "CMS-HCC condition count" but is updating the term in this final rule to be the "CJR HCC count risk adjustment variable" to avoid confusion with other applications of the CMS-HCC data.

bracket coefficient based on the patients' age on the date of admission for the anchor hospitalization or the date of the anchor presentation.

The risk adjustment model for CJR will be prospective in that it will use the most recently available data to predict the average expected adjustment in target price relative to the two risk adjustment variables for future performance years. CMS will use the following CJR-HCC condition count and age baseline data for use in calculating the age and HCC coefficients for the risk adjustment variables:

- Baseline of January 1, 2019 to December 31, 2019 for PY 6 and PY 7
- Baseline of January 1, 2021 to December 31, 2021 for PY 8

To avoid potential distorting effects of the COVID-19 PHE on the 2020 data, CMS modified its proposed policy and will instead use the same regression analysis results and corresponding coefficients that were calculated for PY 6 for PY 7 (i.e., holds baseline 2019 data constant). CMS notes that for any beneficiaries with missing CJR-HCC condition count data, it will apply a CJR-HCC condition count risk adjustment coefficient of one, so that missing data will neither adjust risk up nor down based on this factor.

CMS will use a linear regression model approach to estimate the episode cost of an average beneficiary, based on typical spending patterns for a nationwide sample of beneficiaries based on dual-eligibility status, number of CJR-HCC conditions and age bracket. Specifically, CMS will use an exponential model, with the dependent variable equal to the ratio of the individual episode cost to the regional target price. It will transform the equation to logs through logarithmic transformation; this has the added benefit of allowing for easier interpretation of the coefficients and taking into account that costs for these episodes are not normally distributed, as discussed previously. In technical terms, in transforming its exponential model, the dependent variable becomes the difference in the logs of the individual episode costs and the applicable regional MS-DRG/fracture target prices and the proportional increases or decrease for each independent variable are obtained by exponentiating the regression coefficients of the log-transformed model.

CMS describes the steps it will take to develop its analytic dataset and the dependent variable that it uses to run its regression model. Specifically, it will subtract the log transformed episode target price for a given category from each log transformed standardized episode cost. There are 36 categories based on the 36 combinations of the 9 regions and the 4 MS-DRG/permitted OP/TKA/THA/hip fracture status categories, CMS notes that it applies the high spending cap before computing the log-values of the episode costs. In other words, it replaced the actual cost amount for each episode that exceeded the applicable 99th percentile amount with that 99th percentile amount.

CMS then regresses, or determines the strength of the relationship between each risk adjustment factor and episode costs. These coefficients are calculated at the national level; it runs one model and the coefficients are applied uniformly across all regions. An example of regression output from its model is provided in Table 3a in the final rule (reproduced below). This model was calculated using national episode data from January 1, 2018 to December 31, 2018, for MS-DRG

469, MS-DRG 470, and the permitted outpatient TKA/THA HCPCS code. This was prior to the implementation of MS-DRGs 521 and 522.

The dual eligibility status, age, and CJR-HCC count variables are all statistically significant (have p-values less than 0.05). The "e^x" column in the table represents the anticipated marginal cost associated with each specific risk adjustment factor. For example, the 1.3418 value in Table 3a for beneficiaries with four CJR-HCC clinical conditions indicates that these beneficiaries are expected to increase marginal episode costs by 13.4 percent. CMS will rerun this linear regression model on updated baseline data and post the coefficients on the CMS website prior to the start of PY 6 and 8. As discussed above, CMS will use the same PY 6 model coefficients for PY 7. Updating the model coefficients is intended to take into account spending patterns that disproportionately affects certain subgroups that may have changed.

Table 3a: Regression Output from Log Linear Regression Model

Parameters	Model Estimates	Standard Error	t Value	Pr > |t| (p values)	e^x
Intercept	-0.1648	0.0024	-67.98	<.0001	0.8480
Age 85+	0.4107	0.0028	148	<.0001	1.5079
Age 75 to 84	0.1191	0.0024	49.27	<.0001	1.1265
Age 65 to 74	0.0159	0.0024	66.72	<.0001	1.0160
Age Under 65	0				1
Dual Eligibility	0.1959	0.0021	93.69	<.0001	1.2164
CJR-HCC Count = 4	0.2940	0.0016	184.85	<.0001	1.3418
CJR-HCC Count = 3	0.1432	0.0018	77.83	<.0001	1.1540
CJR-HCC Count = 2	0.0903	0.0016	57.3	<.0001	1.0946
CJR-HCC Count = 1	0.0366	0.0014	25.58	<.0001	1.0373
CJR-HCC Count = 0	0				1

Table 4a in the final rule (reproduced below) illustrates the risk permutations for each age bracket and HCC count category that would be used by CMS to calculate an adjusted target price. These are derived from the regression coefficients displayed in Table 3a.

Table 4a: Risk Factor Multipliers for CJR for All Age Bracket and HCC Count Combinations

Dual Eligibility = No					
Age Bracket	**CJR HCC Count = 4**	**CJR HCC Count = 3**	**CJR HCC Count = 2**	**CJR HCC Count = 1**	**CJR HCC Count = 0**
Age 85+	2.0233	1.7400	1.6504	1.5641	1.5079
Age 75 to 85	1.5115	1.2999	1.2330	1.1685	1.1265
Age 65 to 74	1.3633	1.1725	1.1121	1.0539	1.0160
Age Under 65	1.3418	1.1540	1.0946	1.0373	1.0000

Dual Eligibility = Yes					
Age Bracket	**CJR HCC Count = 4**	**CJR HCC Count = 3**	**CJR HCC Count = 2**	**CJR HCC Count = 1**	**CJR HCC Count = 0**
Age 85+	2.4612	2.1166	2.0076	1.9026	1.8342
Age 75 to 85	1.8387	1.5813	1.4998	1.4214	1.3703
Age 65 to 74	1.6584	1.4262	1.3528	1.2820	1.2359
Age Under 65	1.6322	1.4037	1.3314	1.2618	1.2164

CMS provides an illustrative example to show how these factors would be used to calculate an adjusted target price: A 70-year-old beneficiary with a CJR HCC count of 4, not a dual eligible status beneficiary, located in the West North Central Division, region 4, has an MS-DRG 470 no fracture episode during PY 6. CMS assumes that the total actual cost for this episode was $21,900 and no high-cost episode cap approach was needed. In addition, CMS assumes that the beneficiary was treated at a CJR hospital with a composite quality score of 'Good' with a 1.5 percent withhold. In this example, CMS assumes the target price for region 4 DRG 470 no fracture is $17,097 (reflects a 3 percent quality withhold), the normalization factor in effect for performance year 6 is 0.95, and the market trend factor is 1.023. The computation would be as follows:

Step 1. Risk adjust the target price – Locate the appropriate risk adjustment co-efficient combination for an CJR HCC count of 4 and age of 70 (from Table 4a) which is listed as 1.3633 and multiply the target price of $17,097 by that value:

$17,097*1.3633 = $23,308.34

Step 2. Normalize the risk adjusted target price by multiplying it by the normalization factor (as discussed below):

$23,308.34*0.95 = $22,142.92

Step 3. Apply the market trend factor

$22,142.92*1.023 = $22,652.21

Step 4. Adjust the price to reflect the hospital's composite quality score category – in this example 'Good' (1.5% withhold rather than 3%) by restoring 3% and then adjusting to withhold 1.5%:

$22,652.21*100/97 = $23,352.79

$23,352.79*0.985 = $23,002.50

Once the applicable risk adjusted, normalized, trend adjusted and quality adjusted target price is computed, the actual episode costs of $21,900 would be compared to the target of $23,002.50 and this episode would therefore show a savings of $1,102.50.

CMS applies a normalization factor (as show in step 2 above) to remove the overall impact of adjusting for dual eligibility status, age, and CJR-HCC condition count on the national average target price. This normalization factor is the national mean of the target price for all episode types divided by the national mean of the risk-adjusted target price.

Comments/Response: Most commenters were generally supportive of CMS' overall risk adjustment approach. Commenters recommended certain adjustments to its approach.

Many favored adjusting the methodology to account for the severity, or weight, of certain HCC conditions instead of the count of conditions alone. In its response, CMS notes it did consider including specific adjustments for the weight and severity for certain HCC conditions, but their inclusion in the model did not contribute any material improvement in statistical predictability of the regression model compared to simply using HCC condition count alone.

Some suggested calculating the coefficients at the regional level instead of the proposed national level to capture unobserved socioeconomic characteristics or other factors that vary by region. CMS stated that it tested the model at the regional level and observed similar average effects compared to its nationally calculated coefficients. It also observed that its proposed approach is simpler and reduces the complexity of calculating and posting on the CMS website coefficients for each of the three risk adjustment variables for each of the 9 regions of the CJR model.

Commenters were in support of adding dual-eligibility or a similar risk adjustment variable that would effectively capture some of the cost variation related to a patient's socioeconomic determinants or status. CMS agrees, and as discussed above, CMS erred in its specification of the dual eligible status variable in the proposed rule and this variable will be included in the risk adjustment model for PYs 6 through 8. Similar to the other risk adjustment variables, the dual-eligible status variable will be a binary (yes or no) that indicates a beneficiary was enrolled in Medicare Part A and/or Part B and receiving full Medicaid benefits.

Some commenters suggested adding other risk adjustment variables, including functional status, disability status, joint location, urban/rural patient address, and other patient demographics, such as marital status, income, and education. In its reply, CMS anticipates that the inclusion of dual eligibility status may satisfy some of the recommendations of these commenters. It also notes that it must balance its objective to test innovative risk adjustment methodologies with the mandatory nature of the CJR model. It is also limited in its ability to capture certain risk adjustment factors, such as a patient's income or education.

There was also concern from some commenters about the impact of the COVID-19-PHE and suggestions that CMS reconsider the timing of baseline data used to calculate the coefficients, noting that adjustments would be needed for PY 7. These commenters were concerned that the 2020 volume of elective hip and knee surgeries would not reflect the typical spending pattern of a hospital or region. CMS agrees and as noted above, CMS is finalizing that PY 6 target prices will be based on episode baseline data from calendar year 2019, but PY7 target prices will be based on episode baseline data from calendar year 2021, and PY 8 target prices on episode baseline data from calendar year 2022.

5. Changes to the Methodology for Determining the High-Episode Spending Cap Amount at Reconciliation

As discussed above with respect to setting the target price, CMS notes that the current methodology for setting the high episode spending cap amount— capping costs for those episodes at 2 standard deviations above the regional mean episode price—has not been as successful when applied to actual performance period episode spending at reconciliation. CMS notes that this could be partly explained by the fact that TKA and THA procedure episode costs are not distributed normally.[10]

As a result, CMS finalizes its proposal to change its methodology of calculating the high episode spending cap amount applied during reconciliation by calculating high episode spending cap amounts based on the 99th percentile of costs. Total episode costs above this 99th percentile will be capped at the 99th percentile amount, and these capped episode amounts will be used when comparing performance year costs to target prices during reconciliation. CMS believes that this approach will more accurately represent the cost of infrequent and potential non-preventable complications for each category of episode.

Comments/Response: Commenters were generally supportive of this approach as this proposed cap is similar to spending cap policies for other CMS payment models. These commenters favored the consistent approach. Other commenters opposed the proposed methodology and suggested maintaining the current 2 standard deviation spending cap or setting the cap at a different level, such as at the 98th, 95th, 90th, or 80th percentile. CMS maintains in its response that the risk adjustment methodology described in the final rule will effectively adjust target prices to account for characteristics of certain LEJR patients that are associated with higher costs. It also notes that even at the 98th percentile, the high episode spending cap had the effect of capping more episodes than the previous method of capping episodes at 2 standard deviations. CMS adopts the 99th percentile.

6. Changes to the Trend Factor Calculation

CMS notes that the absence of a trend factor calculation at reconciliation is a limitation of the current target price methodology. It did not anticipate, for example, a nationwide downward trend in the use of post-acute care services that resulted in a decrease in LEJR episode prices in both CJR and non-CJR hospitals. This has led to artificially inflated target prices for CJR episodes. CMS also notes that another major change not accounted for in the CJR target price methodology is the recent restructuring of the SNF payment systems and change in case-mix classification methodology. CMS believes a trend factor calculation would help adjust target prices, more appropriately for such changes, going forward.

CMS finalizes its proposal to calculate a market trend factor at the time of reconciliation by calculating the ratio of performance period spending to baseline period spending and applying the resulting ratio to the target price. As a result, CMS will no longer apply the national update

[10] With a normal distribution of costs, 95 percent of episodes would have costs that are within 2 standard deviations of the mean cost.

factor and biannual Medicare prospective payment and fee schedule update methodology it currently applies to historical episode spending to trend prices forward prospectively. CMS will apply this trend factor after the beneficiary-level, risk adjusted target prices are normalized.

The market trend factor will be the regional/MS-DRG/fracture mean cost for episodes occurring during the performance year divided by the regional/MS-DRG/fracture mean cost for episodes occurring during the target price base year. CMS will calculate 36 market trend factors during reconciliation, one for each MS-DRG/fracture status and region combination. The resulting target prices will be the final target prices used when reconciling performance year episode costs.

For example, the performance year 6 market trend factor for MS-DRG 470 without hip fracture in Region 1 would be calculated as the Region 1 mean episode costs for MS- DRG 470 without hip fracture episodes ending between October 1, 2021 and December 31, 2022, divided by the Region 1 mean episode costs for MS-DRG 470 without hip fracture episode ending between January 1, 2019 and December 31, 2019.

Comments/Response: Most commenters were generally opposed to the proposed market trend factor citing reasons including that it was unnecessary, reduces financial predictability, increases target price volatility, leads to decreased target prices for well-performing CJR model participants, among other reasons. MedPAC expressed support for the market trend factor only when it reduces target prices and recommended that in years when the market trend factor would increase the target price, CMS should instead only update target prices to reflect updates to Medicare payment systems and fee schedules (consistent with the model's current approach).

Another commenter suggested CMS adopt a prospective trend factor, similar to BPCI Advanced. In response, CMS notes this update methodology is agnostic to a change in any one particular system, and more appropriately accounts for differences between baseline and performance period spending than the previous twice annual update. CMS also states that while it may have the effect of decreasing target prices the market trend factor could also have the effect of increasing target prices to reflect higher performance period average costs. This could be important for accounting for innovative new devices for LEJR patients or adjusting for significant changes in patient case mix. With respect to using a prospective trend factor, like BPCI Advanced, CMS believes that this approach is not appropriate for the mandatory CJR model participants given the potential burden of implementing a more complex approach and the administrative cost of calculating this factor each year. It also notes that adoption of this change is part of larger CJR model payment methodology approach (such as the risk adjustment methodology), and that all these changes combined should help alleviate many of the concerns cited by commenters, such as target price volatility.

7. Changes to the Composite Quality Score Adjustment

CMS currently applies a 3 percentage point discount to establish the episode target price that applies to the participant hospital's episodes during that performance year. This discount serves as Medicare's portion of reduced expenditures from the episode. For PYs 1 through 5, this 3 percentage point discount factor is reduced based on the participant hospital's quality performance: one percentage point for good quality performance (a composite quality score of

between 6.9 and 15) and 1.5 percentage points for excellent quality performance (a composite quality score greater than 15).

CMS finalizes its proposal to increase a participant hospital's ability to reduce the 3 percentage point discount factor as a result of the composite quality score. It believes that this is appropriate because the target prices will be more accurate and that all participant hospitals will be at financial risk during PYs 6 through 8.

Specifically, CMS finalizes its proposal that, for PYs 6 through 8, a 1.5 percentage point reduction be applied to the 3 percentage point discount factor for participant hospitals with good quality performance, defined as composite quality scores that are greater than or equal to 6.9 and less than or equal to 15.0. Additionally, CMS will apply a 3 percentage point reduction to the 3 percentage point discount factor for participant hospitals with excellent quality performance, defined as composite quality scores that are greater than 15.0. That is, for participant hospitals with excellent quality performance, the 3 percentage point discount factor would effectively be eliminated for the applicable performance year.

Comments/Response: Commenters were generally in favor of this approach. MedPAC suggested that CMS take various steps to increase the likelihood of savings being generated, such as increasing the episode target price discount factor from 3 percent to 5 percent. CMS disagrees and believes that 3 percent strikes the right balance to ensure that CJR participants make the investments necessary to be successful and can achieve a certain level of savings from the program.

D. CJR Model Three-Year Extension

1. Revised Performance Period

Prior Actions. In the February 2020 CJR proposed rule, CMS proposed to extend the CJR model for 3 additional years, performance years 6 through 8, each 12 months in length, that would run through December 31, 2023. Given the 90-day post-discharge period of the CJR episode, PY 6 would include episodes ending on or before January 1, 2021, so that PY 6 episodes would start October 4, 2020 or later based on the final rule's effective date.

Because of the COVID-19 PHE nationwide impacts on healthcare delivery including under the CJR model, CMS twice extended PY 5 via IFCs: through March 31, 2021 in the April IFC and through September 30, 2021 in a November 2020 IFC. The November 2020 IFC also sought comments on options for the durations of PYs 6 through 8 (start/end dates). The September end date for PY 5 was accompanied by a shift of the proposed PY 6 start date and the subsequent model timeline.

Final Actions. In this final rule, CMS finalizes the September 30, 2021 PY 5 end date and the October 1, 2021 PY 6 start date adopted in the November 2020 IFC. CMS also finalizes the proposed 3-year extension of the CJR model. (Modifications to specific model policies for PYs 6 through 8 are discussed in the relevant sections of this rule and this summary.) CMS further finalizes that PY 6 will be of 15-months duration, beginning with episodes ending on or after

October 1, 2021 and ending with episodes that end on or before December 31, 2022. PY 7 will be of 12-months duration, beginning with episodes ending on or after January 1, 2023 and ending with episodes that end on or before December 31, 2023. PY 8 also will be of 12-months duration, beginning with episodes ending on or after January 1, 2024 and ending with episodes that end on or before December 31, 2024.

Comments received urged delay of the start of PY 6, citing the COVID-19 PHE and continuing impacts thereof on CJR participant hospitals, including threats to their financial stability. Commenters also requested a range of exceptions and adjustments that would result in hospitals being held harmless from CJR penalties throughout PY 5. CMS declines, citing the exceptions granted to hospitals through application of the model's extraordinary circumstances exception policy via the IFCs. (The reader is referred to related discussion in section II.K of this rule and this summary).

2. Revised CJR Model Participants

CMS notes that the participant pool of the CJR model has been modified several times since the model's launch on April 1, 2016 that required mandatory participation by acute care hospitals from 67 MSAs. In the February 2020 CJR proposed rule, CMS proposed to further narrow the participant pool to include only hospitals in the always-mandatory 34 MSAs who are not rural or low-volume hospitals; hospitals who previously were not required but elected to opt in to CJR model participation would be excluded. CMS further proposed to use the notification date of its rural reclassification approval letter to determine which hospitals would be excluded as rural from the 3-year CJR extension and stated that date as October 4, 2020.

CMS finalizes the changes as proposed for PYs 6 through 8 (beginning October 1, 2021). CMS states that the narrowly-defined pool will enhance the generalizability of the model's results and increase the likelihood of significant cost reductions for the Medicare program. CMS notes that the rural classification status of hospitals used for inclusion decisions will now be July 4, 2021 to accommodate the revised start date of PY 6. CMS clarifies that LEJR episodes triggered at hospitals participating in both the CJR and BPCI-Advanced models will be included and reconciled only under CJR.

Objections were raised by participants who had opted in and will now be excluded as well as from some participants who are being required to remain in the model for an additional three years. Others asked that CMS create a pathway for CJR hospitals to transition to participation in the LEJR episode of the voluntary BPCI-Advanced model rather than requiring hospitals to continue in the CJR model for the additional three years.

CMS responds that the cost of evaluating the opt-in participants exceeds any added value of their performance data to generalizable results for the model. CMS notes that requiring hospitals from the 34 "always mandatory" MSAs to remain in the model is supported by the initial selection of those MSAs as typically having higher-than-average historical costs for LEJR episodes and thereby greater opportunities to generate Medicare program savings. The agency rejects the request to create a special BCI-Advanced pathway for former CJR hospitals and notes that 40 of

the 139 now-excluded, but formerly participating, hospitals are in fact enrolled in BPCI-Advanced and could have chosen to participate in the BPCI-Advanced LEJR episode. CMS also cites having received support from MedPAC recommending that the focus of the CJR model should now be on changes that could generate net savings to the Medicare program.

E. Participant Hospital Detailed Notification and Discharge Planning Notice

1. Participant Hospital Detailed Notification

With the addition of outpatient procedures to the CJR model, CMS proposed to require the hospital where an outpatient TKA or THA would occur to provide the beneficiary with a standardized CJR participant hospital beneficiary notification document at the time the procedure is scheduled. Further, for procedures not scheduled in advance, the hospital would be required to provide the notification on the date of the anchor procedure or the date of admission to the anchor hospitalization.

In response to comments, CMS finalizes its proposal with modification. Regardless of whether a case is scheduled in advance, the notification must be provided to the beneficiary prior to discharge from the anchor hospitalization or prior to discharge from the anchor procedure, as applicable.

CMS notes that the finalized policy will apply to episodes occurring in PYs 6 through 8 and aligns with the advance notification policy of the BPCI-Advanced model.

2. Discharge Planning Notice

CMS finalizes without modification its proposal that:

- A CJR model beneficiary must be notified via written notice about potential liability for non-covered post-acute care services that are recommended or presented as part of discharge planning after either an outpatient or inpatient CJR episode; and
- Provision of the written notice by the CJR participant hospital is required during the first discussion of the non-covered services or no later than beneficiary discharge from the anchor procedure or anchor hospitalization, as applicable.

The finalized requirements are applicable to episodes occurring in PYs 6 through 8.

Commenters were concerned that the discharge destination of a beneficiary undergoing outpatient TKA or THA may not be known before the procedure starts or, if known, may change after the procedure itself ends (e.g., a patient who was to be discharged with home health services unexpectedly requires skilled nursing facility care instead). They asked that the hospital only be required to make "best efforts" to provide the written discharge planning notice prior to discharge from the outpatient procedure. CMS denied this request as contrary to the agency's intention that beneficiaries be made fully aware of potential financial liability prior to the provision of non-covered services.

F. Quality Measures and Reporting

CJR participants are required to submit data on two measures, both of which are publicly reported: the THA/TKA Complications measure (NQF #1550) and the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure (NQF #0166). Hospitals also may voluntarily submit data on certain patient risk variables (e.g., body mass index) and from patient-reported outcome (PRO) surveys. Submitting PRO measure data may increase a hospital's composite quality score.

CMS proposed to update the performance periods for both the mandatory and voluntary measures for the proposed PYs 6 through 8 to align them with the performance periods established for PYs 1 through 5. CMS also proposed to increase the thresholds for successful submission of PRO data progressively from at least 80 percent to 100 percent during the 3-year extension. No changes were made to the measure set itself.

CMS finalizes its proposal with modification. The finalized performance periods have been updated to match the final timeline for PYs 6 through 8. The finalized PRO measure data submission threshold required to earn quality bonus points will range from 80 percent to 90 percent over the course of the 3-year extension. The finalized performance periods and PRO measure submission thresholds required to receive bonus points are found in Table 5a of the rule.

The changes in PRO measure submission thresholds were recommended by commenters who found the 100 percent submission requirement to be unrealistic and infeasible. Multiple other suggestions for changes to the quality measure set were made, several focusing on adding a measure related to procedures performed in the outpatient setting. Changes also were suggested to adjust the Composite Quality Score (CQS) calculation to reflect a participant's mix of inpatient and outpatient episodes. CMS notes that valid measures addressing outpatient orthopedic procedures are not readily available and declines to make any changes to the measure set. CMS further responds that no changes were proposed to the CQS calculations and declines to consider such at this time.

G. Financial Arrangements: Eliminating the 50 Percent Cap on Shared Payments

CMS proposed to eliminate the 50 percent cap on gainsharing, distribution, and downstream distribution payments made to physicians, non-physician practitioners, physician group practices, and non-physician practitioner group practices, for episodes beginning on or after January 2, 2021.[11]

CMS finalizes the proposal with modification to account for the delayed start of PY 6; the cap will be eliminated for episodes that end on or after October 1, 2021. Eliminating the cap reverses a policy that has been controversial and unpopular for hospitals and their episode partners since its inception, and commenters were strongly supportive of the proposal for its

[11] Under the cap, total payments of each type received in a single year by a practitioner or a group practice must not exceed 50 percent of the total Medicare approved amounts under the Physician Fee Schedule for items and services furnished during CJR episodes by the practitioner or group practice payment recipient during the same model performance year as that for which the payment is being made.

elimination. CMS notes that MedPAC, who previously supported the cap, also commented in support of the cap's removal, citing consistency with the BPCI-Advanced model, reduced administrative burden for hospitals and their partners, and encouragement of collaboration among providers as positive outcomes from cap elimination.

H. Waiver of Medicare Program Rules

The CJR model incorporates a waiver of the requirement for a 3-day inpatient admission prior to a covered SNF stay (SNF 3-day rule) and allows for up to 9 post-discharge visits after an anchor hospitalization by clinical staff to the beneficiary's home. CMS proposed to expand both waivers to apply after a beneficiary has been released following a permitted CJR outpatient procedure by revising §510.600(a) and (b) and 510.610.

1. SNF 3-day Rule Waiver

CMS believes that SNF admission will seldom be indicated after an anchor procedure but wants covered SNF care to be available for beneficiaries should the need arise. Therefore, CMS proposed to expand the SNF 3-day rule waiver to apply to outpatient CJR episodes.

CMS finalizes its proposal with modifications made in response to commenters; the changes specify that the waiver is:

- Available for use within 30 days from the date of service of the anchor procedure; and
- Limited to SNFs appearing on the applicable calendar quarter list of qualified SNFs at the time of the beneficiary's admission to the SNF.[12]

CMS clarifies that SNF stays meeting the above conditions are covered under the waiver and billable to Medicare by the SNF. CMS also states that the SNF stay is included in calculating the costs for the CJR episode. CMS emphasizes that beneficiary is protected from financial liability if admitted to a non-qualifying SNF without having previously received a discharge planning notice of potential liability (see §510.405(b)(3)) applies to outpatient CJR episodes (see section II.E of this summary above).

2. Post-discharge Home Visits Waiver

This waiver allows up to 9 visits after discharge from an inpatient CJR admission to a beneficiary's home by clinical staff under general rather than direct supervision of a physician or non-physician practitioner. CMS proposed to expand this waiver to permit similar visits provided after a beneficiary has been released following a permitted CJR outpatient procedure.

Following the publication of the CJR February 2020 proposed rule, CMS published a series of IFCs in response to the COVID-19 pandemic, each containing provisions related to a wide range of Medicare policies and regulations. In the IFC published on May 3, 2020 (86 FR 23575), CMS

[12] Qualifying SNFs are those with an overall rating of 3 stars or better for 7 of the preceding rolling 12-month period.

amended §510.310 to include visits provided after an anchor procedure.[13] In this final rule, CMS makes a technical change at §510.600(b)(1) to substitute *an anchor hospitalization or procedure* for *an anchor hospitalization* and to replace *qualifying inpatient stay* with *qualifying inpatient stay or anchor procedure* with regards to the SNF 3-day rule waiver.

I. Appeal Procedures

CMS proposed to revise and reorganize §510.310 to clarify that the following requirements apply to second-level appeals of certain payment calculations (e.g., reconciliation and repayment amounts):

- The reconsideration official must notify both CMS and the hospital of the issues in dispute, the review procedures, and the procedures for submission of briefs and evidence (via the Scheduling Notice).
- The parties may submit briefs and evidence in support of their positions.
- The second level appeal would remain an on-the-record review.

No concerns were raised by commenters and CMS finalizes the proposal without modifications.

J. Request for Comment: New LEJR-focused Models Including ASCs and Shared Accountability

Changes in Medicare regulations involving the Inpatient Only list, currently make Medicare payment possible for all LEJR procedures (TKA, THA, and TAR). When performed in ASCs, however, these procedures would not trigger CJR model episodes. In the CJR February 2020 proposed rule, CMS requested input on the design of a bundled payment model for LEJR procedures performed in the ASC setting and how financial accountability might be expanded beyond participant hospitals to the treating clinicians. In this final rule, CMS thanks commenters for their input and indicates ongoing consideration of incorporating ASCs into future models.

K. April 2020 IFC and November 2020 IFC

CMS finalizes the CJR related provisions in the April 2020 IFC. This IFC extended PY 5 through March 31, 2021 and adjusted the extreme and uncontrollable circumstances policy to account for the COVID-19 PHE. Comments on these policies were outlined in sections II.G.2 and II.G.5. of the November 2020 IFC.

In the November 2020 IFC, CMS implemented four changes to the CJR model, which CMS finalizes without modification in this final rule. First, CMS extended PY 5 an additional six months, so PY 5 ends on September 30, 2021. Second, CMS made changes to the reconciliation process for PY 5 to allow two subsets of PY 5 to be reconciled separately. Third, CMS made a technical change to include MS-DRGs 521 and 522 in the CJR episode definition, retroactive to

[13] As described in this final rule, commenters responding to the February 2020 CJR proposed rule were supportive of the home visit waiver expansion to outpatient CJR procedures. In this final rule, CMS provides no further discussion about finalizing this proposal nor refers to its related action taken in the May 3, 2020 IFC.

inpatient discharges beginning on or after October 1, 2020, to ensure that the model continues to include the same inpatient LEJR procedures, despite the adoption of new MS-DRGs 521 and 522 to describe those procedures. Lastly, CMS made changes to the extreme and uncontrollable circumstances policy for COVID-19 to adapt to an increase in CJR episode volume and renewal of the PHE, while providing protection against financial consequences of the COVID-19 PHE after the extreme and uncontrollable circumstances policy no longer applies.

Commenters were in support of extending PY 5 to September 30, 2021, agreeing with CMS that if PY 5 ended on March 31, 2021 it could be disruptive to hospitals and patient care, especially during the PHE. Most commenters also agreed with CMS to conduct two reconciliations for PY 5; otherwise, there would be a 21-month gap between reconciliation payments during the COVID-19 PHE. They also agreed with the addition of MS-DRGs 521 and 522 in the CJR episode definition and making it retroactive.

With respect to the extreme and uncontrollable circumstances policy for COVID-19 adopted in the November 2020 IFC, some commenters believed that CMS should revert to its policy in the April 2020 IFC and waive downside risk for all episodes until the PHE ends. Most commenters supported CMS' decision to hold participant hospitals harmless if a CJR beneficiary has a positive COVID-10 diagnosis during a CJR episode. In its reply, CMS stated that it understood commenters' concern about the PHE, but waiving downside risks for all episodes until the PHE ends could threaten the ability of the CJR model to generate any savings and noted that the agency's authority to conduct models is constrained to those anticipated to reduce program expenditures. It also notes that despite the COVID-19 PHE and the shift in LEJR procedures being performed in the outpatient and ambulatory surgery setting, the episode volume is experiencing an upward trend since June 2020 (about half of the 2019 volume).

III. Regulatory Impact Analysis

Overall Impact

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). CMS estimates that this rulemaking is "economically significant" as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, CMS prepared a Regulatory Impact Analysis to present the costs and benefits of the rulemaking.

A. Statement of Need

CMS states that this final rule is necessary for CMMI to continue to meet its goals to reduce expenditures while preserving or enhancing quality of care for CJR episodes, as policy changes since the CJR inception have shifted how these services are provided and paid for under Medicare. CMS highlights reasons for why it believes the final rule is necessary. Among other reasons, this includes changes to the inpatient only list that removed the TKA and THA

procedures thus allowing these services to be paid by Medicare when provided in a hospital outpatient department. Target prices require additional adjustments to ensure they better capture spending trends and changes, by using more recent historical spending data (one year instead of three). Because of more accurate target prices, CMS believes a more generous composite quality score adjustment to the discount factor is appropriate for hospitals ranked in the good and excellent CJR quality categories. It also believes that a 3-year extension is necessary to allow for enough time and information for it to reasonably evaluate the changes.

B. Anticipated Effects

CMS estimates that the changes in this final rule to the CJR model would result in a net Medicare program savings of about $217 million over the 3 additional performance years. Table 7a in the final rule (reproduced below) shows the estimated impact of these changes.

Table 7a: Financial Impact for the Final Changes and Three-Year Extension of CJR
[Figures are in $ millions, negative values represent savings]

Year	4th Quarter 2021	2022	2023	2024	Total
Episode Spending with Model	$316	$1,298	$1,356	$1,442	$4,392
Episode Spending without Model	323	1,327	1,409	1,472	4,531
Reconciliation	-6	-23	-24	-25	-78
Total Impact	-13	-52	-77	-75	-217

Note: Totals do not necessarily equal the sums of rounded components.

CMS estimates that the number of providers participating in the CJR model would decline from 470 providers (as of October 2019) to 330 for the 3-year extension, dependent on changes in rural reclassification status or mergers. By limiting participation to the non-rural, non-low-volume providers physically located in the 34 mandatory MSAs, CMS estimates this would remove about 139 voluntary, rural, and low volume hospitals. For purposes of modeling the impact for Table 7a, CMS used 2019 Medicare claims data, and limited the analysis to non-rural, non-low volume provider located in the 34 mandatory MSAs or about 330 eligible providers with CJR episode data. CMS also assumed that participants would reduce episode spending by 1 percent in 2021 compared to their respective regions and episode spending would grow at the same rate as their respective regions in 2022 and 2023. It believes that participant hospitals will have more difficulty producing additional savings over time. CMS also assumed that if the CJR model was not extended, participant hospitals would increase their episode spending by 2.65 percent as a response to the model ending, which represent about half of the savings shown by the evaluation. It did not make any assumptions about behavioral changes in the post-acute care space that may result from recent changes to Medicare skilled nursing facility payment and home health payment.

CMS also summarizes the anticipated qualitative impact on program costs or savings of each of the discrete provisions of this proposed rule (Table 6a in the final rule). The table below highlights the qualitative impact by final provision relative to original CJR model policies.

Annotated Extract of Table 6a: Anticipated Impacts by Final Provision

Provision	Direction of Transfers	Transfers	Notes
Changes to episode definition to include OP TKA/THA	Savings	79,000,000-178,000,000	Data trends on 3 years of episode data (2017-2019) shows that as the volume of OPPS episode increases, the target price for the blended inpatient and outpatient category (470/no fracture) decreases. Data from 2018 and 2019 show a material increase in the number of outpatient procedures and that these are lower cost.
Freezing hip fracture list and episode exclusions list	Zero Impact	N/A	List has not been updated to any significance in last 5 years, and no anticipated change in next 3 years, so CMS assumes this will have a zero impact.
Capping high episode spending at the 99th percentile (rather than two standard deviation methodology)	Savings	4,875,000	Using 2019 average standardized cost data, CMS observes a consistent increase by about 2% in target prices when applying 99th percentile regional high episode caps. CMS estimates this will contribute to about $1,500,000 in savings for each of the PYs 6 through 8.
Use of the most recently available one year of data to calculate target prices (rather than most recent three years of data), removal of regional and hospital anchor weighting factor(s) from target price calculation, and discontinuing twice annual updates to the target prices to account for changes in the Medicare prospective payment systems and fee schedule rates	Savings	N/A	Using historical data (2016-2018), CMS compared the percentage change in average target prices using 3 years of data versus using 1 year of data to calculate target prices. When using 3 years of data, it observed higher target prices for DRG 470 no fracture category episodes across all regions. CMS did not, however, include a specific transfer amount given the uncertainty in the market trend of outpatient procedures.
Applying a market trend factor (that is., the regional MS-DRG/fracture mean cost of episodes occurring during the performance year divided by the regional MS-DRG/fracture mean cost for episodes occurring during the target price base year)	Savings	201,000,000	Analyzing standardized payment data from 2016-2019, CMS observed a decreasing trend in CJR regional average episode prices. It observed regional average target prices for inpatient episodes that were about 1-3% higher than if it had included the market trend factor. It also notes that the market trend factor would have been larger if it had used 3 years of historical data rather than 1 year of data.

Provision	Direction of Transfers	Transfers	Notes
Incorporating a risk adjustment for beneficiary specific CMS- HCC condition count and age bracket	Zero Impact		This risk adjustment is designed to increase target prices somewhat for beneficiaries with increasing age and/or HCCs; it will lower targets somewhat for younger beneficiaries with fewer or no HCCs. The presumption is that episode costs for older, more complex beneficiaries should be higher than average and for younger, less complex beneficiaries they should be lower than average, so CMS anticipates a net impact of zero for this provision.
Increasing hospital quality incentive payments (that is, a 1.5 percentage point reduction for participant hospitals with "good" quality performance and a 3-percentage point for "excellent" quality performance)	Costs	27,000,000	CMS believes that offering a more generous quality score adjustment to the discount factor is appropriate, maintaining the policies applicable to PYs 1-5 would have contributed to $27,000,000 in savings over PYs 6 through 8.
Excluding opt-in low-volume and rural hospitals with a CCN primary address in a mandatory MSA and excluding opt-in hospitals with a CCN primary address in a voluntary MSA	Savings	172,250,000	For purposes of its estimate, CMS assumed that the opt-in low-volume, rural, and voluntary hospitals that participated in PY 4 of the model would participate in PYs 6-8. Assumes the cost per year would be $53,000,000 based on PY 4 data.

CMS believes that burden reductions should result from other policies it is making in this final rule. Its policy to move from two to one reconciliation should effectively half the level of effort participants and the agency need to expend on reconciliation. CMS estimates that moving to only one report for each performance year should reduce that cost to $240,958 from $481,916.

Likewise, CMS' policy to remove the 50 percent cap should result in a burden reduction on participants of $1.1 million as accounting hours necessary to ensure that no physician received more than 50 percent of his or her total billing for Medicare-approved amounts under the PFS will no longer be necessary. CMS' estimate is based on assumptions that each participant could have spent about $6,778 on the reviews for a total of $1.1 million across all 159 participants with CJR collaborators. CMS also believes that its policies to modify beneficiary notice requirements for model inclusion, discharge planning notices, and its extension of waivers of Medicare program rules will streamline the administrative procedures and reduce the effort needed for participants to comply with CJR requirements.

CMS does not believe that changes to the CJR model would materially affect the potential effect of the model on beneficiaries nor have an impact on small rural hospitals and other small entities.

C. Analysis of Regulatory Alternatives

CMS considered several alternatives to its proposals. These included:

- Broadening or modifying the types of entities that may convene an episode under the CJR model;
- Calculating coefficients separately for each region or applying risk-standardization to the regional target price prior to applying the beneficiary-specific risk score (as noted earlier in section II.C.3. of this summary "Additional Episode-Level Risk Adjustment"); and
- Utilizing the regional median episode costs as a basis for the market trend factor update calculation, rather than the regional mean episode costs for this calculation (as noted earlier in section II.C.5. of this summary "Changes to Trend Factor Calculation")

CMS notes that although it considered broadening and modifying the types of entities that could initiate an episode under the CJR model, this would have required more lead time, and complicated the evaluation and the generalizability of the results. It also decided, as discussed above, to calculate the risk adjustment coefficients at the national level. This approach resulted in similar results to the regional approach and was computationally less complex. CMS also determined that using the regional mean episode was preferred over the "median" as there was little difference between using the median and using the mean aligns the trend calculation with the methodology for deriving the target prices for the model.